FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS JANUARY 1, 2021, TO JUNE 30, 2021

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CONTENTS

TABLE OF CASES

VOLUME 171

D

E

F

G

H

I

J

K

L

M

P

R

S

T

U

V

W

Z

FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS
JANUARY 1, 2021, TO JUNE 30, 2021

IN THE MATTER OF

COSTAR GROUP, INC.,
AND
RENTPATH HOLDINGS, INC.

FINAL ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACTAND SECTION 7 OF THE CLAYTON ACT

Docket No. 9398; File No. 201 0061
Complaint, November 30, 2020 – Decision, January 4, 2021

This order addresses the $587.5 million acquisition by CoStar Group, Inc. of certain assets of RentPath Holdings, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by significantly reducing competition in the market for apartment internet listing services in the United States. Following RentPath's public announcement on December 29, 2020 that it had terminated the agreement to be acquired by CoStar; and the withdrawal of Respondents Hart-Scott-Rodino Notification and Report Forms filed for the proposed acquisition, Complaint Counsel and Respondents jointly moved to dismiss the complaint as moot. The order dismisses the complaint without prejudice.

Participants

For the *Commission*: *Helder Agostinho, Steven Couper, Derek Diaz, Kelly Fabian, Kurt Herrera-Heintz, Armando Irizarry, Steven Keely,* and *Nicolas Stebinger.*

For the *Respondents*: *Amanda Reeves, Latham & Watkins, LLP; Jonathan Klarfeld, Ropes & Gray LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents CoStar Group, Inc. ("CoStar") and RentPath Holdings, Inc. ("RentPath") have executed a merger agreement in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, which if consummated would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

I. NATURE OF THE CASE

1. CoStar proposes to acquire its chief competitor for apartment internet listing services ("ILSs"), RentPath. If consummated, the acquisition will eliminate price and quality competition that benefits renters and property managers today, resulting in higher prices for the internet listing services relied upon by managers of large apartment buildings. RentPath has summarized the effect of this transaction in simple terms: "Prices WILL NOT stay the same, it will almost be a monopoly."

2. Both Respondents operate ILSs, which are websites such as Apartments.com, ForRent.com, Rent.com, and ApartmentGuide.com that match prospective renters with available apartments. For prospective renters, ILSs provide zero price, user-friendly interfaces to search for a place to live from a database of available units. For apartment owners and managers, ILSs help to fill apartments by creating and targeting advertisements of vacant units to interested prospective renters. Millions of U.S. consumers rely on ILSs each year to gather information about rental properties, or to contact property managers about leasing an apartment. According to RentPath, "86% of renters use an ILS during their search."

3. A significant number of prospective renters use ILSs because they provide renters with a free and efficient apartment search experience. ILSs enable prospective renters to quickly search and filter a large quantity of rental listings to identify only listings that satisfy relevant criteria, such as number of bedrooms, monthly rent, available move-in date, and amenities like swimming pools or exercise rooms. Without leaving the ILS website, prospective renters can then obtain detailed information to compare the units they are considering, often including floor plans, real-time vacancy information, and high-quality photos or video tours. In the words of CoStar's Vice President of Product, ILSs thus allow prospective renters "to get a sense of [each] community without actually being there." According to a 2019 Confidential Information Presentation prepared by RentPath, renters plainly value this convenient and data-rich search experience: "Among recent renters, [redacted]% say an ILS was the most helpful resource—more than 3x the next best resource."

4. Respondents are able to provide free ILS search services to prospective renters because they charge fees to property managers to display rental properties on the ILS websites. CoStar and RentPath use a subscription-based business model, typically charging property managers a monthly, per-complex fee for ILS advertising and certain additional services. Property managers benefit from appearing on ILSs because ILSs attract significant numbers of prospective renters and provide a way for the prospective renters to contact a property directly to express interest in a rental unit. Such contacts are referred to as "leads," and allow the property manager to direct further marketing activity to prospective renters who are already known to be promising customer targets.

5. The primary source of ILS revenues is the fees paid by property management companies ("PMCs"). PMCs manage marketing activity for one or more apartment buildings, either as third-party contractors or as owner-operators.

6. For many PMCs, ILSs provide an attractive form of advertising because they generate a significant volume of quality leads. Leads generated by ILSs are particularly useful to PMCs because they come from prospective renters who have gained a significant amount of information about a unit from the ILS—including whether the unit meets their key criteria—and thus are more likely to want to rent the unit.

7. In addition to requiring a high volume of quality leads, PMCs that manage large apartment complexes have specific needs that Respondents' ILSs are uniquely well placed to satisfy. Respondents' ILSs employ a comparatively large and geographically dispersed sales force to maintain client relationships and promptly address PMC customers' needs and concerns. Respondents' ILS advertising subscription packages include various features beyond the simple posting of a property listing, such as HD video and 3D virtual tour production, generation of 2D or 3D floorplans, on-site photo shoots, display and social retargeting advertisements, and access to analytics to help customers better understand the efficacy of their marketing and refine their competitive strategies. These features of Respondents' ILS offerings help maximize the proportion of visitors to Respondents' ILSs who will contact a property for further information, or in other words, submit a "lead."

8. Reflecting these distinctive needs, PMCs managing large apartment complexes use Respondents' ILSs heavily. Nationally, approximately 70 percent of apartment complexes with 200 or more units, and approximately 50 percent of apartment buildings with 100 to 199 units, advertise on one or both of the Respondents' ILSs.

9. For years, CoStar and RentPath have competed fiercely with one another to sell ILS advertising to PMCs in metropolitan areas across the United States. For example, CoStar's internal documents reflect that in 2019, CoStar launched a sales campaign to "[c]ompet[e] directly and powerfully with RentPath for the business of our duplicative clients and those unique properties using RentPath but not Apartments.com." In preparing its sales staff for this campaign, CoStar informed them that RentPath itself had "severely cut [its] prices in an effort to compete." The Acquisition will eliminate this competition, leading to increased prices for the PMCs that advertise large apartment complexes on ILSs. Indeed, RentPath's CEO acknowledged in a 2019 e-mail to the company's Board of Directors that the Acquisition may lead to "more stable pricing and fewer promotions in the long term."

10. These higher prices will not be counterbalanced by benefits for PMCs or for prospective renters. To the contrary, the Acquisition will eliminate significant head-to-head competition to attract and engage prospective renters. By way of illustration, CoStar and RentPath monitor each other's consumer-facing websites, and may adjust their content if they see something they like on the other company's website. For example, in March 2020, RentPath created a set of best practices to help its PMC customers create high-quality, virtual apartment-tour videos to post on its ILS websites. RentPath emphasized in communications to the PMCs that "it is extremely important for communities to be able to show [prospective renters] impactful virtual tours of their propert[ies.]" Internal e-mails reflect that when CoStar learned of RentPath's effort to improve [redacted], CoStar quickly developed its own [redacted] to "counter" RentPath. The Acquisition would

eliminate this sort of competition in consumer-facing content and features, and thus reduce the quality of ILS search services.

11. New entry would not be timely, likely, or sufficient to counteract the anticompetitive effects of the Acquisition. Significant barriers exist for potential new entrants, due in part to the network effects that characterize ILS platforms. Network effects occur where the value of a product depends in part on the number of users. More specifically, indirect network effects arise in multi-sided platforms (like ILSs) when the value of the product to users on one side of the platform depends on the participation of users on another side. In the ILS context, indirect network effects give rise to a classic "chicken and egg" problem: an ILS cannot provide a significant number of leads to PMCs unless it can attract a large number of prospective renters to the ILS. However, an ILS cannot attract prospective renters unless it lists a sufficient number of properties. Such network effects and other barriers hinder both entry by new competitors and expansion by Respondents' existing rivals.

12. Respondents cannot show cognizable, merger-specific efficiencies that would offset the likely and substantial competitive harm resulting from the Acquisition.

II. JURISDICTION

13. Respondents are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

14. The Acquisition constitutes a merger subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

III. RESPONDENTS

15. CoStar is a publicly traded corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business located at 1331 L Street, N.W., Washington, D.C. 20005. CoStar is a top provider of data, analytics, and ILSs for the real estate industry in the United States. CoStar earned revenues of approximately $1.4 billion in 2019, with just over $490 million derived from its network of ILSs.

16. CoStar's ILS network includes Apartments.com, ApartmentFinder.com, and ForRent.com. The company assembled this network through a series of acquisitions, beginning with the purchase of Apartments.com in 2014 and more recently with the acquisition of ForRent.com in 2018.

17. RentPath is a privately held corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business located at 950 East Paces Ferry Rd N.E. #2600, Atlanta, Georgia 30326. RentPath's primary business is an ILS network that includes Rent.com and ApartmentGuide.com. RentPath generated approximately [redacted] in revenue in 2019, with about [redacted] derived from RentPath's ILSs.

IV. THE ACQUISITION

18. On February 12, 2020, CoStar agreed to acquire RentPath for $587.5 million (the "Merger Agreement"). As a condition of the acquisition offer, RentPath filed for bankruptcy protection and reorganization under Chapter 11 of the United States Bankruptcy Code the same day.

V. RELEVANT MARKETS

19. Respondents compete to provide residential rental ILSs, which are two-sided platforms that bring together (i) purchasers of ILS advertising (i.e., PMCs and rental properties), and (ii) consumers of ILS search services (i.e., prospective renters). The relevant line of commerce in which the Acquisition will lead to anticompetitive effects is ILS advertising for large apartment complexes. The relevant geographic markets in which the Acquisition will lead to anticompetitive effects are individual metropolitan areas within the United States.

A. Relevant Product Market: ILS Advertising for Large Apartment Complexes

20. Most PMCs that manage large apartment complexes rely on ILS advertising because it satisfies their distinctive requirements in ways that other methods of advertising do not. ILS advertising allows PMCs to market available units to an enormous number of prospective renters. Other methods of advertising are unable cost-effectively to scale up to provide the same volume and quality of leads as ILS advertising. Recognizing the unique value of ILS advertising, ILSs assign great weight to the pricing of other ILS advertising providers when they determine their own prices; no other form of advertising plays as significant a role.

21. Large apartment complexes, and the PMCs that manage them, are a distinct set of customers for ILS advertising. These customers' advertising requirements differ from the requirements of other purchasers of ILS advertising such that they are uniquely dependent on ILS advertising to meet their needs. The larger an apartment complex, the more likely it is to have a consistently high number of vacancies. To fill these vacancies, a substantial majority of large apartment complexes (and the PMCs that manage them) rely on ILSs as an efficient and high-volume source of quality leads.

22. Most large apartment complexes could not cost-effectively replace the volume of leads generated by ILS advertising through non-digital forms of advertising, such as on-site advertising, real estate brokers, or print advertising for two reasons. First, many other forms of advertising do not reach the same number of potential renters as ILS advertising. For example, real estate brokers and locator services—while generating high-quality leads—do not have as big of a footprint as ILSs and are cost-prohibitive to use on a large scale. Second, other types of advertising may reach a relatively large audience but do not generate sufficient volume of high-quality leads. For example, community signage, while relatively inexpensive, typically cannot deliver high-quality leads in the volumes needed to fill a large apartment complex's vacancies.

23. Nor could these customers economically replace ILS advertising with other forms of digital advertising, such as search engine marketing and search engine optimization, because

these forms of advertising cannot cost-effectively generate the high volume of quality leads that ILS advertising customers require for large apartment complexes. Search engine marketing involves bidding on keywords to appear in the sponsored results for relevant searches on search engines like Google and Bing. Search engine marketing offers the potential to reach a broader pool of prospective renters but is too expensive for most PMCs to use on a scale that could replace the leads obtained through ILS advertising. Moreover, property websites compete with ILSs for paid search traffic, bidding against Respondents on the most critical search engine marketing keywords. This competition with ILSs for paid traffic makes it prohibitively expensive for many large properties to turn to this advertising tool to replace the volume of leads they currently receive through ILS advertising. As a result, if the price of ILS advertising increased by a small but significant amount, customers would not substitute away from ILS advertising for large apartment complexes in sufficient volumes to render such a price increase unprofitable. The same is true for other forms of online marketing, including search engine optimization and social media advertising.

24. Search engine optimization is the process of designing website structure and content to increase the likelihood that the website will appear closer to the top of organic search results for relevant keywords. Although certain PMCs that manage large apartment complexes engage in some amount of search engine optimization in addition to search engine marketing, few could increase their reliance on these tools as a cost-effective substitute for ILS advertising. It is difficult for individual properties to compete with highly optimized, content-rich ILS websites to appear prominently in organic search results; at most, only a few property websites can secure the coveted but scarce front-page page ranking necessary to attract meaningful organic traffic. For this reason, and because of the high cost of search engine marketing, ILS advertising is the most cost-effective way for many large properties to gain large scale exposure to prospective renters who begin their apartment search on search engines.

25. Some ILSs offer access to unique benefits that differentiate their advertising services from other forms of digital advertising. For example, many ILSs offer optional ancillary services to improve their advertising customers' property listings, including data and analytics services, sending professional photographers to on-site photo shoots, generating floorplans, and creating 3D virtual tours. In addition, ILSs often simplify PMCs' use of other forms of online marketing, by coordinating and optimizing PMCs' advertising strategies across other channels including search engine marketing, social media advertising, and other online display advertising. These ancillary services enhance the performance of ILS advertising for PMCs and can improve both the quantity and quality of leads the PMCs receive.

26. Respondents recognize that PMCs' demand for ILS advertising for large apartment complexes is relatively inelastic. As CoStar CEO Andrew Florance remarked on a July 2019 earnings call, "[W]hen you think about what's at stake for them as they launch a $200 million community in the lease-up, they don't really care if our ad cost[] $1,000 or $10,000. They're in a nine-month lease-up period and we are the source for the majority of their communities."

27. Respondents know which of their customers' properties are large apartment complexes, because PMCs disclose the number of units in each apartment complex when advertising their properties through an ILS. This makes large apartment complexes readily identifiable for purposes of differential pricing.

28. Respondents can and do vary advertising pricing based on the number of units in an apartment complex, whether in their standard rate cards or in individually negotiated contracts with PMC customers. A hypothetical monopolist similarly could implement a targeted price increase on ILS advertising for large apartment complexes.

29. Customers of ILS advertising for large apartment complexes could not avoid a targeted price increase through arbitrage because ILS advertising is inherently property-specific. Many PMCs make decisions about whether to use ILS advertising, and which ILS to use, on a complex-by-complex basis. PMCs (and in some cases, individual properties) must engage directly with ILSs to opt in to advertising services and to update listings for each discrete property.

30. A hypothetical monopolist of ILS advertising profitably could impose a small but significant increase in price to customers seeking to fill vacancies for large apartment complexes. These customers would not switch to an alternative source of leads in sufficient volume to render the price increase unprofitable. Because the hypothetical monopolist test is satisfied, ILS advertising for large apartment complexes is a relevant product market.

B. Relevant Geographic Markets: Individual Metropolitan Areas

31. ILSs provide geographically-filtered listings to renters seeking apartments in specific metropolitan areas. A renter seeking an apartment in Tampa, Florida, for example, will only use an ILS that contains listings for apartments in Tampa to find an apartment. Such a renter would be unwilling to use an ILS that did not include a sufficient number of quality Tampa-area listings even if the ILS did maintain listings for other areas, like Los Angeles. Likewise, a PMC with properties in Tampa, Florida, must attract renters who have decided to live in or around Tampa. That PMC would have no use for an ILS that is successful at generating leads from renters interested in living in Los Angeles, but that fails to generate leads from renters interested in living in the Tampa area.

32. In the event of a small but significant price increase, a PMC with properties in one metropolitan area could not substitute away from its current ILS to an ILS that only operates effectively in a different metropolitan area. A PMC with properties in Tampa, Florida could not, for example, switch to an ILS that is only available or attractive to renters seeking apartments in Los Angeles.

33. ILSs compete to supply advertising services to PMCs within individual metropolitan areas. This competition includes competition on region-specific price, which varies based on the location of the customers' properties, and competition on region-specific quality, including an ILS's ability to provide internet traffic and leads.

34. ILSs also compete on the quality and breadth of their local sales forces in each metropolitan area. For example, Respondents maintain geographically dispersed sales organizations to compete locally by means of regular property visits and other relationship-building initiatives with customers and prospects. Respondents' ordinary-course documents demonstrate the competitive significance of their local sales staff: RentPath notes that its "[l]arge local sales force allows RentPath to tap into apartment inventory which competitors may not have access to." Similarly, CoStar's local sales representatives are able to "actually visit, in a reasonable amount of time and distance, [CoStar's] customers in person."

35. It is appropriate to analyze the proposed Acquisition's competitive effects in these local, metropolitan area markets. Because ILS advertising customers can only turn to ILSs with a local presence, a hypothetical monopolist of ILS advertising for large apartment complexes in a given metropolitan area profitably could impose a small but significant price increase. Individual metropolitan areas thus constitute the relevant geographic markets in which to analyze the Acquisition's impact on competition for ILS advertising for large apartment complexes.

36. Appendix A identifies 49 of the local markets in which the Acquisition would lead to anticompetitive effects with respect to ILS advertising for large apartment complexes. Most of these local geographic markets also include Zillow Group, Inc. ("Zillow") and a fringe of pay-for-performance ILSs that are active nationwide, including Apartment List, Inc. ("Apartment List"), and Zumper Inc. ("Zumper"). Some of the relevant local geographic markets may feature additional local competitors, but most of these local competitors are quite small, or participate in the market only tangentially (e.g., only as an add-on to other products).

37. Though Respondents compete within individual metropolitan areas across the United States, competitive conditions are substantially similar across many of these local markets. The proposed acquisition is likely to lead to anticompetitive effects in a large number of local metropolitan areas nationwide.

38. PMCs that manage large apartment complexes in more than one region of the country often negotiate master contracts to provide common terms for their full portfolios of managed properties, with the same ILSs and under similar competitive conditions for all of their complexes.

39. Accordingly, while the relevant geographic markets in which to analyze the Acquisition include at least the 49 metropolitan areas identified in Appendix A, national information is relevant and useful for analyzing the effect of the Acquisition.

VI. OTHER ILS ADVERTISING FIRMS

40. Zillow is a publicly traded company headquartered in Seattle, Washington. Zillow offers real estate platforms and products, including a network of rental listing sites under its own brand name, as well as the Trulia, HotPads, and Street Easy (which is focused on New York City) brands. Zillow's primary business is an advertising-supported search portal for homes for sale. [redacted] Zillow offers ILS advertising to PMCs at prices

based on the number of leads, leases, clicks, or listings provided. [redacted]

41. Apartment List is a privately held company headquartered in San Francisco, California. Apartment List operates using its brand name [redacted] Apartment List offers ILS advertising to PMCs on a pay-for-performance basis. [redacted]

42. Zumper is a privately held company headquartered in San Francisco, California. Zumper operates using its brand name and provides ILS advertising to properties of all sizes, **{with a focus on large properties.}** Zumper offers ILS advertising to PMCs on a pay-for-performance basis. [redacted]

43. In addition to Zillow, Apartment List, and Zumper, some metropolitan areas feature local competitors. Alone or in combination, local competitors generally operate on too small a scale to constrain a post-Acquisition price increase, even in their respective local markets.

VII. THE ACQUISITION IS PRESUMPTIVELY ILLEGAL

44. The Acquisition would lead to a significant increase in market concentration in already highly concentrated local markets for ILS advertising for large apartment complexes. The concentration levels in no fewer than 49 local markets, identified in Appendix A, exceed the thresholds for presumptive illegality.

45. The 2010 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines ("Merger Guidelines") employ a metric known as the Herfindahl-Hirschman Index ("HHI") to assess market concentration. The Merger Guidelines explain that an acquisition is presumptively unlawful if it leads to (i) a post-acquisition HHI above 2500 points and (ii) an HHI increase of more than 200 points.

46. Although the appropriate geographic markets are individual metropolitan areas, it is directionally informative to consider the Respondents' aggregate market shares across the nation. In 2019, CoStar and RentPath accounted for the vast majority of ILS revenues derived from advertising for large apartment complexes. On a nationwide basis, CoStar recognized approximately [redacted] in ILS advertising revenue from large apartment complexes; RentPath was a strong second with approximately [redacted] in revenue. [redacted]

1 For purposes of this Complaint, we estimate market shares based on ILS advertising revenues from properties with over 100 units, but this unit threshold is not dispositive. The Acquisition is also presumptively illegal when market shares are calculated using higher or lower unit counts.

[redacted]

47. In each of the 49 local markets identified in Appendix A, the Acquisition would similarly lead to sufficient concentration and change in concentration to give rise to a presumption of illegality. Both the post-Acquisition concentration and the increase in concentration would far exceed the presumptive thresholds for illegality identified by the Merger Guidelines.

VIII. THE ACQUISITION IS LIKELY TO RESULT IN ANTICOMPETITIVE EFFECTS

48. The Acquisition will eliminate significant head-to-head competition in the relevant markets. CoStar and RentPath are one another's closest competitors for ILS advertising for large apartment complexes, and the competition between them has benefited customers in metropolitan areas across the United States.

49. Respondents are easily the top two providers—whether measured by ILS revenue or by leads delivered—of ILS advertising to large apartment complexes. Respondents' ILSs closely resemble one another, and the similarity extends to their advertising business models; CoStar and RentPath are the only two major ILSs that charge monthly subscription fees to their customers, rather than relying primarily on pay-for-performance packages. Each Respondent on its own generates far more leads for large apartment complexes than the [redacted] largest pay-for-performance ILSs combined. For example, in 2019, CoStar and RentPath each generated approximately [redacted] leads for large apartment complexes, [redacted]

50. Respondents' own executives recognize that they are each other's closest competitors. CoStar's CEO has described RentPath as CoStar's "primary competitor" during public earnings calls with CoStar's investors. RentPath's Senior Vice President of Customer and Industry Relations put a finer point on the same sentiment, writing internally: "[O]ur only true ILS competitor is CoStar." Industry analysts likewise view Respondents as close competitors, and have observed that if CoStar's acquisition of RentPath is allowed to proceed, despite "antitrust issues," it would remove the "risk" that RentPath might improve "its competitive position against http://Apartments.com."

51. This close competition has benefited Respondents' customers, including in the form of lower advertising prices. In recent years, CoStar has aggressively targeted properties that advertise on RentPath, running sales campaigns referred to internally as [redacted] Through these initiatives, CoStar has offered significant discounts to RentPath's customers as well as financial incentives to spur its sales representatives to win more business from these customers.

52. Similarly, RentPath prices aggressively against CoStar. For example, in the summer of 2019, RentPath responded to CoStar's attempts to woo RentPath customers by brainstorming a [redacted] that would include [redacted] to protect its existing customer relationships from CoStar's advances. According to RentPath's [redacted]: "We want them to see this." RentPath ultimately decided to offer [redacted] RentPath expressly shaped this offer as a competitive response to the terms of CoStar's discounts: [redacted]

53. The harm that the Acquisition will cause on the ILS advertising side of the market is not outweighed by countervailing effects on consumers of ILS search services. To the contrary, the Acquisition will harm these consumers by eliminating close competition between Respondents to win their attention and engagement. Today, CoStar and RentPath compete fiercely to attract prospective renters through their marketing efforts and by improving their ILS websites' features, ease of use, and quality of information. These improvements make it faster and easier for consumers to find the most relevant and user-friendly information to aid in their apartment search. The Acquisition will eliminate this head-to-head rivalry and reduce competitive pressure on the ILSs to improve their offerings to renters, leading to lower quality and forgone innovation.

IX. LACK OF COUNTERVAILING FACTORS

54. Respondents cannot demonstrate that entry or repositioning would be timely, likely, or sufficient to offset the anticompetitive effects of the Acquisition in each relevant market.

55. Existing smaller ILSs will not reposition or expand to replace the ILS advertising competition lost should the Acquisition proceed. It is expensive and time-consuming to overcome the barriers to entry and expansion facing ILSs, particularly those associated with network effects. No existing player is poised quickly to muster the necessary scale to deliver significant numbers of leads while maintaining near-term hopes of profitability.

56. [redacted] Accordingly, Zillow would not be likely to provide sufficient competitive discipline on the merged firm to eliminate or substantially offset the harm from the Acquisition. Other, smaller ILSs lack the capital, scale, and ability to timely restore the competition that the Acquisition would destroy, whether nationally or in the relevant local markets.

57. New entry is unlikely for the same reasons. By way of illustration, the most recent entrant of significance, the mobile-based Zumper, was founded in 2012, but has failed to expand to become a meaningful competitive constraint on Respondents. [redacted] As acknowledged by RentPath in a 2019 draft Confidential Information Presentation: "RentPath's platform offers a wide moat providing protection against market entrants."

58. Google, LLC ("Google") does not, and will not, exert sufficient competitive discipline to eliminate or substantially offset the competitive harm associated with the Acquisition. Respondents cannot demonstrate that Google competes with Respondents in the relevant markets, let alone that it will prevent the Acquisition from resulting in competitive harm.

59. Respondents cannot demonstrate cognizable and merger-specific efficiencies that would be sufficient to rebut the presumption and evidence of the Acquisition's likely anticompetitive effects.

X. VIOLATION

Count I: Illegal Agreement

60. The allegations of Paragraphs 1 through 59 above are incorporated by reference as though fully set forth.

61. The Merger Agreement constitutes an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

Count II: Illegal Acquisition

62. The allegations of Paragraphs 1 through 61 above are incorporated by reference as though fully set forth.

63. The Acquisition, if consummated, may substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and is an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the first day of June 2021, at 10:00 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause

why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted. If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Acquisition challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and/or Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Acquisition is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant markets, with the ability to offer such products and services as CoStar and RentPath were offering and planning to offer prior to the Acquisition.

2. A prohibition against any transaction between CoStar and RentPath that combines their businesses in the relevant markets, except as may be approved by the Commission.

3. A requirement that, for a period of time, CoStar and RentPath provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant markets with any other company operating in the relevant markets.

4. A requirement to file periodic compliance reports with the Commission.

5. Any other relief appropriate to correct or remedy the anticompetitive effects of the Acquisition or to restore RentPath as a viable, independent competitor in the relevant markets.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this thirtieth day of November 2020.

By the Commission, Commissioner Wilson dissenting.

Appendix A

DMA	Post-Merger HHI[1]	Delta HHI[2]
Atlanta, GA	> 6500	> 2100
Austin, TX	> 6500	> 1800
Baltimore, MD	> 6500	> 3300
Boston, MA	> 6000	> 2400
Buffalo, NY	> 8500	> 3300

1 HHIs are calculated for buildings with over 100 units within particular DMAs for the purposes of the Complaint.

2 "Delta HHI" is the difference between the pre-merger HHI and the post-merger HHI.

Complaint

Charlotte, NC	> 6500	> 2400
Chicago, IL	> 6000	> 2300
Cincinnati, OH	> 7000	> 3500
Cleveland, OH	> 7500	> 3700
Columbus, OH	> 8000	> 3200
Dallas, TX	> 6500	> 2000
Denver, CO	> 5000	> 1400
Detroit, MI	> 8000	> 3700
Houston, TX	> 6500	> 1900
Indianapolis, IN	> 7000	> 3500
Jacksonville, FL	> 6000	> 2700
Kansas City, MO	> 7000	> 2200
Las Vegas, NV	> 6000	> 2100
Los Angeles, CA	> 5500	> 2100
Louisville, KY	> 7500	> 3300
Madison, WI	> 8000	> 2900
Memphis, TN	> 7500	> 3600
Miami, FL	> 6500	> 2400
Milwaukee, WI	> 8000	> 2800
Minneapolis-St. Paul, MN	> 6500	> 2800
Nashville, TN	> 6500	> 2800
New Haven, CT	> 7000	> 3200
Norfolk, VA	> 7500	> 3600
Oklahoma City, OK	> 7000	> 3100

Omaha, NE	> 7500	> 3500
Orlando, FL	> 6500	> 2400
Philadelphia, PA	> 6500	> 3000
Phoenix, AZ	> 6000	> 2200
Pittsburgh, PA	> 7000	> 3100
Portland, OR	> 5000	> 1100
Providence, RI	> 6500	> 2500
Raleigh, NC	> 6500	> 2700
Richmond, VA	> 7000	> 3300
Rochester, NY	> 8000	> 3000
Sacramento, CA	> 6500	> 2000
Salt Lake City, UT	> 7000	> 2800
San Antonio, TX	> 6500	> 1500
San Diego, CA	> 5500	> 1900
San Francisco, CA	> 5000	> 1400
Seattle, WA	> 5000	> 1400
St. Louis, MO	> 7000	> 2700
Tampa, FL	> 6500	> 2600
Tucson, AZ	> 7000	> 3300
Washington, DC	> 6000	> 2500

ORDER DISMISSING COMPLAINT

This matter comes before the Commission on Complaint Counsel and Respondents' Joint Motion to Dismiss Complaint. Having considered the motion, it is hereby **ORDERED**:

The Joint Motion to Dismiss Complaint, dated December 30, 2020, is **GRANTED;**

and the complaint is **DISMISSED** without prejudice.

By the Commission.

Complaint

IN THE MATTER OF

THE PROCTOR & GAMBLE COMPANY,
AND
BILLIE, INC.

FINAL ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

Docket No. 9400; File No. 201 0042
Complaint, December 8, 2020 – Decision, January 8, 2021

This order addresses the $295 million acquisition by The Procter & Gamble Company of certain assets of Billie, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by significantly reducing competition in the market for wet shave system razors and disposable razors in the United States. On January 5, 2021, Respondents publicly announced that they mutually terminated their agreement for P&G to acquire Billie and withdrew the Hart-Scott-Rodino Notification and Report Form filed for the proposed acquisition. Complaint Counsel and Respondents jointly moved to dismiss the complaint as moot. The order dismisses the complaint without prejudice.

Participants

For the *Commission*: *Greta Burkholder, Keitha Clopper, Clarke Edwards, Megan Henry,* and *Marc Schneider.*

For the *Respondents*: *Joseph Antel, Kate Brockmeyer, Aimee DeFilippo, Peter Julian,* and *Craig Waldman, Jones Day LLP; Dennis Carlton, Dan O'Brien,* and *Rajiv Gokhale, Compass Lexecon; Mark Ostrau, Fenwick & West LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents The Proctor & Gamble Company ("P&G") and Billie, Inc. ("Billie") have executed a merger agreement in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, which if consummated would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

I. NATURE OF THE CASE

1. In late 2017, Billie, Inc. launched an online only, direct-to-consumer challenge to P&G's women's razor dominance. Among other things, Billie charged a low price, employed savvy marketing designed to draw attention to the "pink tax"—that is, the practice of charging a

premium for razors marketed to women that are substantially similar to razors marketed to men—and positioned the Billie product as "anti-Venus."

2. Two years later, Billie had grown substantially and at P&G's expense. P&G now seeks to acquire Billie on the eve of Billie's expansion into brick-and-mortar retail. As P&G's CEO for Grooming observed, the "big" value from this acquisition to P&G is the "removal of the competitive threat." The removal of Billie as an independent competitor eliminates important and growing head-to-head competition between P&G and Billie, and is likely to harm consumers through higher prices, among other harms.

3. P&G is the market leader in the sale of women's and men's wet shave razors. Wet shave razors require the use of water and, typically, a shave prep product such as shaving cream, shave gel, or shave soap. Nearly all wet shave razors are system or disposable razors. System razors consist of a reusable handle and a detachable razor cartridge that a consumer can replace with refill cartridges. Disposable razors comprise a handle with permanently affixed blades that consumers throw away after use.

4. Launched in 2017, and backed by venture capital firms including Goldman Sachs and celebrity investors Venus and Serena Williams, Billie is a fast-growing online company that sells a mid-tier women's system razor. Billie built its brand by finding an underserved customer base of Generation Z and Millennial women. Billie won their business by, among other things, offering a low price and attacking the incumbents' perceived practice of charging a pink tax for women's razors. Billie also emphasized a "female-first" message. Billie challenged traditional portrayals of women's razors. Billie became the first brand to use advertisements that normalized female body hair, which many saw as a critique of P&G Venus's advertising. Billie targeted P&G from the start, with a vision to "[d]ethrone Gillette Venus to become the number one women's razor brand in the U.S." Billie's objective was to shake up the women's shaving category, and even P&G recognized Billie as "anti-Venus."

5. The Proposed Acquisition is likely to result in significant harm by eliminating competition between the market leader and an important and growing head-to-head competitor. The Proposed Acquisition arrests Billie's progress as it was on the cusp of expanding into brick-and-mortar retail stores, which would have greatly heightened the already fierce competition between P&G and Billie.

6. P&G's CEO of Grooming viewed the "big" value from this acquisition as the "removal of the competitive threat." P&G's Senior Vice President of Grooming in North America encouraged others to "think of" the value created by acquiring Billie in terms of the "reduction of the competitive threat."

7. The Proposed Acquisition would significantly increase concentration in relevant antitrust markets that are already highly concentrated today. As a result, the Proposed Acquisition is presumptively anticompetitive. Current market share statistics and concentration measures understate Billie's future competitive significance, however, because Billie is a fast-growing brand that would grow even faster after its expansion into brick-and-mortar retail.

8. Respondents cannot show that the Proposed Acquisition will induce new entry or repositioning by existing razor suppliers that would be timely, likely, or sufficient to counteract the anticompetitive effects of the Proposed Acquisition. Billie's first-mover advantage targeting Millennial and Gen Z women online, the high costs of and challenges inherent in establishing a razor brand, the rising costs of online advertising, and the now crowded space at brick-and-mortar retailers (due to P&G's launch of Joy, Harry's launch of Flamingo, and Billie's likely addition to Walmart or Target), among other things, combine to make entry or repositioning in response to the merger unlikely.

9. Respondents cannot show cognizable, merger-specific efficiencies that would offset the likely and substantial competitive harm resulting from the Proposed Acquisition.

II. JURISDICTION

10. Respondents are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

11. The Acquisition constitutes a merger subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

III. RESPONDENTS

12. P&G is a publicly held company, headquartered in Cincinnati, Ohio, that specializes in the manufacture and sale of consumer goods. P&G generated net sales across all business units of approximately $71 billion for the fiscal year ending June 30, 2020. P&G manufactures, produces, and sells a variety of razors and shave products online and in brick-and-mortar retail, under brands that include Gillette, Venus, Joy, Braun, Bevel, and The Art of Shaving. P&G generated approximately $6 billion in FY 2020 net sales from its Global Grooming business unit, which encompasses most of its razors and ancillary products. From January 2020 to March 2020, P&G generated approximately $407 million in revenue in wet shave products, $121 million of which was attributable to women's wet shave razors.

13. Billie, Inc. ("Billie") is a privately held company based in New York, New York, that sells a five-blade wet shave systems razor through its DTC platform under the Billie brand. Billie purchases the cartridges for this razor from Edgewell and other third parties provide the handles and final assembly for the product. Billie also sells shave cream, body wash, lotion, lip balm, dry shampoo, and facial wipes. Billie's 2019 sales of women's system razors accounted for the bulk of its $31.5 million in net sales. By the end of June 2020, Billie had already exceeded its net sales for all of 2019.

IV. THE ACQUISITION

14. On December 31, 2019, P&G and Billie signed an Agreement and Plan of Merger, pursuant to which P&G will acquire 100 percent of the voting securities of Billie for approximately $295 million.

V. RELEVANT MARKETS

15. A relevant market in which to evaluate the effects of the Proposed Acquisition is no broader than production and sale of wet shave system razors and disposable razors ("wet shave razors") sold in the United States.

16. It is also appropriate to analyze the effects of the Proposed Acquisition in at least two narrower relevant markets within the wet shave razor market: (1) the market for the production and sale of women's wet shave razors in the United States and (2) the market for the production and sale of wet shave system razors in the United States.

A. Relevant Product Markets

17. The relevant product market is no broader than the production and sale of wet shave razors, which includes system and disposable razors. One internal P&G presentation notes that in "Reality: The Shave Care Customer is an Omnichannel Shopper"—that is, customers purchase razors both online and in brick and mortar retail stores.

18. System razors consist of a reusable handle and a detachable razor cartridge. Consumers typically replace the razor cartridge with refill cartridges sold by the same manufacturer without the need to replace the handle.

19. Disposable razors comprise a single assembly of handle with permanently affixed blade(s). Consumers discard disposable razors after they finish using them.

20. Other forms of hair removal, such as electric (or "dry") shaving razors and alternative hair removal products (*e.g.*, hair removal creams or waxes) are not close substitutes for wet shave razors. Industry participants and Respondents recognize that wet shave razors are distinct from dry shave razors and alternative hair removal products and sell these products at distinct price points to distinct consumers.

21. Customers would not switch from wet shave razors to dry shave razors or alternative hair removal products in sufficient numbers to defeat a small but significant non-transitory increase in price ("SSNIP") by a hypothetical monopolist of wet shave razors.

22. The Proposed Acquisition would produce anticompetitive effects within at least two narrower relevant markets, in addition to producing anticompetitive effects in the broader wet shave razor market. The Proposed Acquisition would harm competition in narrower relevant markets for the production and sale of: (i) women's wet shave razors and (ii) system razors (including both women's and men's).

23. Industry participants recognize narrower product markets divided along gender lines (women's or men's) and by product type (system or disposable). Industry participants recognize each segment as distinct from others and conduct their business accordingly.

24. In each of these narrower relevant markets, a hypothetical monopolist could profitably impose a SSNIP on purchasers of the relevant product.

B. Relevant Geographic Market

25. The relevant geographic market in which to analyze the Proposed Acquisition is no broader than the United States. Razor suppliers negotiate distinct terms of sale with customers for different countries and, in some cases, offer distinct product assortments in different countries. Respondents and other industry participants generally do not make granular or distinctive purchasing or sale decisions for smaller regions within the United States.

26. A hypothetical monopolist of wet shave razors in the United States profitably could impose a SSNIP on U.S. customers. Customers based in the United States cannot defeat a price increase in the United States via arbitrage or substitution.

VI. MARKET PARTICIPANTS

27. P&G is the leading manufacturer of branded systems razors globally and in the United States. P&G is also a major producer of disposable razors. P&G's razor brands include the Gillette family (including the Joy and Venus women's razor brands), Braun, Bevel, and The Art of Shaving. P&G holds a dominant market position in the sale of wet shave razors, accounting for more than [redacted] of sales by revenue in some relevant markets. P&G manufactures its own blades and cartridges for its wet shave razor brands.

28. Billie is a fast-growing, digitally-native company that began selling a five-blade women's system razor in November 2017. Billie purchases the components of its razors from other manufacturers and assembles them into a finished razor. It does not manufacture the blade cartridge itself.

29. Edgewell is a consumer products company that sells a full line of system and disposable razors marketed separately to men and women. Edgewell owns over 25 established brand names, including razor brands Schick and Personna/American Safety Razor. Edgewell also sells private label wet shave products and components in North America through its Private Brands Group to retailers and non-integrated razor companies, including Billie.

30. Société BiC ("BiC") manufactures and sells consumer products including disposable lighters, pens, and razors. [redacted] of BiC's wet shave razor sales in the United States are men's and women's disposable razors, although BiC also sells a system razor. [redacted]

31. Harry's Inc. ("Harry's") manufactures and sells five-blade men's and women's system razors. Harry's sells its men's system razor under the Harry's brand and its women's system razor under the Flamingo brand. The vast majority of Harry's branded razor sales are made under the Harry's brand. [redacted]. Harry's does not manufacture or sell disposable razors.

32. Dollar Shave Club, Inc. ("Dollar Shave Club"), now owned by Unilever plc/Unilever N.V. ("Unilever"), sells system razors purchased predominantly by men. Dollar Shave Club does not manufacture or sell disposable razors.

VII. THE PROPOSED ACQUISITION IS PRESUMPTIVELY ILLEGAL

33. Under the 2010 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines ("Merger Guidelines"), a post-acquisition market concentration level above 2500 points, as measured by the Herfindahl-Hirschman Index ("HHI"), and an increase in HHI of more than 200 points renders an acquisition presumptively unlawful. Transactions resulting in highly concentrated markets—markets with an HHI above 2500 points—with an HHI increase of more than 100 points potentially raise significant competitive concerns and warrant scrutiny. The HHI is calculated by totaling the squares of the market shares of every firm in the relevant market.

34. The market for the production and sale of wet shave razors in the United States is already highly concentrated, with an HHI of over 3000. The Proposed Acquisition increases the concentration by more than 125 points and therefore potentially raises significant competitive concerns and warrants scrutiny.

35. The market for the production and sale of women's wet shave razors in the United States is already highly concentrated, with an HHI of more than 2500. The Proposed Acquisition increases the concentration in this market by more than 300 points and is therefore presumptively illegal.

36. The market for the production and sale of women's and men's wet shave system razors in the United States is already highly concentrated, with an HHI of over 4000. The Proposed Acquisition increases the concentration in this market by more than 200 points and is therefore presumptively illegal.

37. Changes in HHI based on current market shares understate the competitive significance of the Proposed Acquisition because Billie is rapidly growing. Billie was about to expand its sales into additional channels, particularly brick-and-mortar retail, before the Proposed Acquisition arrested its progress.

VIII. ANTICOMPETITIVE EFFECTS

38. In each of the relevant markets, the Proposed Acquisition would eliminate substantial and growing head-to-head competition between P&G and Billie, likely leading to higher prices and other harm for consumers.

39. P&G has long been the market leader in sales of women's and men's wet shave system razors. Billie saw an opportunity to attack P&G's position and shake up the category by entering the market positioned as an "anti-Venus" razor fighting the practice of charging women a "pink tax."

A. Billie Competes Aggressively Against P&G Today

40. In November 2017, Billie began selling a $9 woman's system razor through an online direct-to-consumer ("DTC") platform. Billie targeted Generation Z and Millennial women as customers, with "female first" messaging that challenged traditional marketing approaches to women's razors.

41. Billie successfully built its brand through marketing campaigns focused on fighting the pink tax and normalizing body hair on women. As Billie's website explains, "[w]e noticed that women were overpaying for razors and shamed for having body hair. Kind of a double whammy, when you think about it. So, we did away with the Pink Tax and put body hair on the big screen."

42. Billie grew from $55,000 in net sales in 2017 to $7,100,000 in net sales in 2018. Billie's growth caught P&G's attention, especially after Harry's and Dollar Shave Club's recent disruption of P&G's stable market leadership in men's wet shave razors.[1] A mid-2018 draft memorandum discussing a potential acquisition or partnership with Billie explained: "The male grooming business has seen the disruption caused by Dollar Shave Club and Harry's where P&G did not act early enough. The female business is ripe for similar disruption. By partnering with Billie we can avoid learning the same lessons twice."

43. By August 2018, P&G set up a women's system razor DTC business, called Venus Direct, as a competitive response to Billie. Venus Direct offered customers a subscription service featuring the same line-up of Venus razors available in brick-and-mortar stores.

44. P&G's new DTC business did not stop Billie's growth. By April 2019, P&G was losing share online and in the "total female world." P&G believed this loss was primarily due to Billie. P&G's market analysis revealed that Billie was sourcing its customers primarily from non-online sources. Billie only "sourced minimally from other DTC brands."

45. From the start, Billie positioned its product to attack P&G's Gillette Venus product. Billie told its initial investors that its goal was to "Dethrone Gillette Venus." P&G noted the attack: "Billie has positioned itself as notably 'anti-Venus,' with negative references to portraying women as 'a goddess just for shaving.'"

46. P&G, for its part, was "being proactively paranoid," according to its CEO of Grooming. In addition to its DTC offering, in March 2019, P&G launched its Joy razor exclusively with Walmart. Joy became part of P&G's plan to offer a youthful-oriented mid-tier female razor, much like Billie. In certain countries where Billie is not available, P&G launched Joy quickly as an online DTC brand to pre-empt Billie.

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1 *See In the Matter of Edgewell Personal Care Company and Harry's, Inc.*, FTC Docket No. 9390, Complaint (Filed Feb. 3, 2020) (describing disruption by Harry's and Dollar Shave Club in men's razors).

47. Joy and Billie target a similar age group. P&G hoped that they could get Generation Z and Millennial women to join the Joy family before Billie (or Flamingo) could sign them up.

48. Joy's branding has a number of resemblances to the Billie product. Upon seeing the Joy razor, Billie's cofounder wrote that Joy "just ripped off a bunch of our stuff," even "the tile choice of the bathroom." Industry observers likewise recognize that Joy and Billie are close competitors.

49. P&G considered Billie's vocal stance on the "pink tax" and Billie's pricing before setting Joy's suggested retail price, among other factors. In response to Joy's launch, Billie's cofounder guessed that Joy "intended to match [Billie's] pricing."

50. Joy was priced at $8.97 at Walmart (Joy prices at other locations vary). Billie prices its razor at $9.

B. The Proposed Acquisition Halted Billie's Expansion Into Brick-And-Mortar Retail, Which Would Have Increased Competition Between P&G And Billie

51. Billie was poised to expand into brick-and-mortar in the months immediately prior to the P&G deal.

52. Billie and [redacted] understood that Billie needed to transition from a DTC-only brand to one that is available at brick-and-mortar retailers as well. [redacted] believed that expanding into brick-and-mortar stores would help Billie achieve profitability. Billie's cofounder believed that Billie was leaving more profitable sales on the table, recognizing that the costs of acquiring customers online are higher than those of acquiring customers in store.

53. [redacted]

54. P&G worried about Billie's expansion into retail and took steps with retailers with the hope of delaying or blocking Billie's expansion. In April 2019, after a round of negotiations with Walmart, a P&G employee cited keeping Billie out of Walmart as "Win #1" in the women's system razor segment.

55. Nevertheless, Billie was close to completing negotiations to expand into retail before the Proposed Acquisition abruptly halted its talks. Throughout the spring and summer of 2019, Billie negotiated with Target and Walmart for a 2021 brick-and-mortar launch. Both retailers were excited about the prospect of launching Billie at their stores. Both offered favorable terms for an exclusive initial launch.

56. Billie believed that those negotiations were likely to conclude favorably. In seeking additional funding during the fall of 2019, Billie represented to potential investors that brick-and-mortar expansion was feasible. As late as November 2019, Billie's management presented financials to the company's Board of Directors assuming that Billie would launch in brick-and-mortar in 2021, the brick-and-mortar segment would be profitable, and this expansion would lead to positive earnings by early 2022.

57. Billie put its negotiations to expand retail distribution on hold when P&G and Billie announced the Proposed Acquisition. If Billie were to resume those negotiations, there is no reason to doubt that Billie would successfully conclude its negotiations to expand into brick-and-mortar retail stores. [redacted]. Regardless of the Proposed Acquisition, Billie will successfully expand into brick and mortar retail.

58. If Billie expands into brick-and-mortar retail, it will do so at P&G's (and others') expense. Regardless of which retailer or retailers agree to carry Billie, Billie is likely to take significant sales and shelf space from P&G. Analyzing the Proposed Acquisition, executives presented deal analyses to the P&G Board that predicted significant cannibalization of P&G's brick-and-mortar sales by Billie, using figures based on P&G's "fair share" of the total market.

59. P&G's senior grooming executives recognize the heightened competition that would follow Billie's expansion into brick-and-mortar retail. They viewed preventing Billie's retail expansion—in a posture where Billie was a competitor to P&G—as a primary motivation for pursuing the Proposed Acquisition.

60. In mid-2019, P&G Senior Vice President of Grooming provided a list of ways in which P&G would "create value from this [the purchase of Billie]." He included on his list the "reduction of the competitive threat." P&G's CEO of Grooming responded to the list: "The big one is removal of the competitive threat." A P&G analyst observed that the proposed transaction would "remove [a] significant disruptor from the market: This is big news!"

61. When valuing Billie, P&G assumed that if Billie expanded into brick-and-mortar retail, the business it gained would come in significant part from P&G's sales.

IX. LACK OF COUNTERVAILING FACTORS

62. Respondents cannot demonstrate that new entry or expansion by existing firms would be timely, likely, or sufficient to offset the anticompetitive effects of the Acquisition.

63. Operating a successful DTC business requires a product or service that is delivering an unmet need in a category. Among other things, Billie enjoyed a first-mover advantage that led to success in the DTC channel, which, in turn, led to interest from brick-and-mortar retailers that a new entrant could not easily replicate. Billie identified and exploited a previously unsatisfied consumer need for a mid-tier women's system razor appealing to Generation Z and Millennial women. Billie earned its loyal customer base and reputation

through its marketing campaigns against P&G and other incumbents' practice of charging a pink tax, among other things.

64. In the words of one of Billie's co-founders: "it's harder to enter into the market as a second mover." Any new entrant will find it difficult to secure a sufficient return on investment because Billie already secured the most readily available DTC online customers. Attracting new online customers will now require higher advertising spend. A new entrant is unlikely to be able to enter through retailers because retailers are typically not interested in carrying a razor supplier that has not previously shown an ability to secure sales online. A new entrant is also unlikely to be able to enter as an online DTC brand to pave a path to retailers as did Harry's and Billie because of the high cost of online advertising and Billie's first-mover advantage.

65. In addition, the costs of online advertising are increasing significantly year over year. Any new DTC entrant would face higher costs than Billie did. These growing costs are a stronger entry barrier than Billie faced.

66. The failure of current "second movers" to replicate Billie's significance in the woman's razor space confirms that successful new entry or repositioning is unlikely. No DTC company has been able to replicate Billie's online success to date. Established razor manufacturers Harry's and P&G followed Billie's successful online launch with launches of women's system razors at similar price points (Flamingo and Joy, respectively). Despite backing from established razor companies and access to mass retailers, these products have lagged behind Billie in market share and sales. The space is now crowded, further impeding entry or repositioning in response to the anticompetitive effect of the acquisition.

67. Respondents cannot demonstrate cognizable and merger-specific efficiencies that would be sufficient to rebut the presumption and evidence of the Proposed Acquisition's likely anticompetitive effects.

68. Respondents also cannot demonstrate that Billie's business will fail and that its assets will exit the market absent the proposed acquisition.

X. VIOLATION

Count I – Illegal Agreement

69. The allegations of Paragraphs 1 through 68 above are incorporated by reference as though fully set forth.

70. The Merger Agreement constitutes an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

Count II – Illegal Acquisition

71. The allegations of Paragraphs 1 through 70 above are incorporated by reference as though fully set forth.

72. The Merger, if consummated, may substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and is an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the twenty-second day of June, 2021, at 10:00 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted. If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.2l(a) requires a meeting of the parties' counsel as early as practicable before the

pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.3l(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Merger challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and/or Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Merger is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant markets, with the ability to offer such products and services as P&G and Billie were offering and planning to offer prior to the Merger.

2. A prohibition against any transaction between P&G and Billie that combines their businesses in the relevant markets, except as may be approved by the Commission.

3. A requirement that, for a period of time, P&G and Billie provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant markets with any other company operating in the relevant markets

4. A requirement to file periodic compliance reports with the Commission.

5. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to restore Billie as a viable, independent competitor in the relevant markets.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this eighth day of December, 2020.

By the Commission, Commissioner Wilson dissenting.

ORDER DISMISSING COMPLAINT

This matter comes before the Commission on Complaint Counsel and Respondents' Joint Motion to Dismiss Complaint. Having considered the motion, it is hereby ORDERED:

The Joint Motion to Dismiss Complaint, dated Januaiy 6, 2021, is **GRANTED;**

and the complaint is **DISMISSED** without prejudice.

By the Commission.

Complaint

IN THE MATTER OF

ZOOM VIDEO COMMUNICATIONS, INC.
D/B/A
ZOOM

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4731; File No. 192 3167
Complaint, January 19, 2021 – Decision, January 19, 2021

This consent order addresses Zoom Video Communications, Inc.'s representations regarding their videoconferencing services and various add-on services, such as cloud storage. The complaint alleges that Zoom violated Section 5(a) of the Federal Trade Commission Act by representing that consumers could secure all Meetings with end-to-end encryption using, in part, Advanced Encryption Standard (AES) and a 256-bit encryption key; and that recorded meetings would be stored in their secure cloud storage "once the meeting has ended." The complaint further alleges that Zoom represented that it was updating its Mac application in order to resolve minor bug fixes, but failed to disclose, or failed to disclose adequately, the material information that the update would deploy the ZoomOpener web server, which would circumvent a Safari browser privacy and security safeguard, and would remain on users' computers even after they had uninstalled Zoom's Mac application. The consent order prohibits Zoom from misrepresenting its privacy and security practices in the future.

Participants

For the *Commission*: *Linda Holleran Kopp, Ryan Mehm,* and *Caroline Schmitz.*

For the *Respondents*: *Dee Bansal, Scott Dailard, David Houska, Jina John, Travis LeBlanc, Kaitland Kennelly, David Mills,* and *David Navetta, Cooley LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Zoom Video Communications, Inc., a corporation ("Respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Zoom Video Communications, Inc. ("Zoom") is a Delaware corporation with its principal office or place of business at 55 Almaden Boulevard, 6th Floor, San Jose, California, 95113.

2. The acts and practices of Respondent Zoom alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Respondent's Business Practices

3. Founded in 2011, Zoom is a videoconferencing platform provider that provides customers with videoconferencing services and various add-on services, such as cloud storage. Zoom's 2019 annual revenue was $622.7 million; its Q1 2020 revenue was $328.2 million. Zoom has over 2,000 employees.

4. Zoom's core product is the Zoom "Meeting," which is a platform for one-on-one and group videoconferences. Zoom Meetings also have the capability, among other things, for accompanying chat messages, screen sharing, and the recording of videoconferences. Zoom offers certain customers the option to host Zoom's videoconferencing services on the customer's internal network through its "Connecter" product.

5. A Zoom Meeting is comprised of a host who organizes the Meeting and the individual attendees who participate in those video meetings. To schedule and host a Zoom Meeting, a user must create a Zoom account and download Zoom's software application ("Zoom App") for desktop or laptop (e.g., Windows or Mac) or mobile (e.g., iOS or Android).

6. By creating a Zoom account, a user can create and host a videoconference and invite others to attend by providing them with a hyperlink, conference identifier, or telephone dial-in instructions. To join a Meeting, individual attendees typically download the Zoom App, but do not need to create a Zoom account. Rather than download the Zoom App, attendees can also join a Meeting through their browser or by telephone. Attendees who join a Meeting through their browser or by telephone do not have access to all of the same features that are available through the Zoom App.

7. Zoom offers its videoconferencing services through a number of monthly and annual subscription plans. Zoom offers a free basic videoconferencing plan that includes unlimited one-on-one and group videoconferencing for up to 40 minutes and 100 participants. It also offers three tiers of paid plans based on the number of features and host licenses provided, with minimum monthly subscription fees of $14.99 (Pro), $199.90 (Business), and $999.50 (Enterprise).

8. Zoom routinely collects certain information about users, including: first and last name; email address; user name and password; approximate location; date of birth; technical information about users' devices, network, and internet connection; and in the case of a paid subscription, billing address and payment card information of the account holder. Zoom also collects and stores event details for all Zoom Meetings, including the date, time, and length of Meetings; the Meeting participants' user names; and each participant's answers to any polling questions asked during a Meeting. Finally, Zoom also collects and stores information shared while using the service, such as recorded Meetings that users store on Zoom's cloud storage, voice mails, chat and instant messages, files, and whiteboards.

9. As of July 2019, Zoom had approximately 600,000 paid customers of its videoconferencing services. Approximately 88% of those customers were small businesses with ten or fewer employees.

10. In December 2019, approximately 10 million people worldwide participated in a Zoom Meeting each day. By April 2020, that number had skyrocketed to 300 million daily meeting participants worldwide, in large part due to an increased demand for videoconferencing services as a result of social distancing recommendations and local government stay-at-home orders related to the novel coronavirus pandemic. In addition to Zoom's traditional business customers, individuals, doctors, mental health professionals, schools, and others began to use Zoom's videoconferencing services in greater numbers.

11. Users share sensitive information during Zoom meetings. This can include financial information, health information, proprietary business information, and trade secrets. For example, Zoom has been used for therapy sessions, Alcoholics Anonymous meetings, and telehealth appointments.

12. As reflected in Zoom's Security Guide, the security of users' Zoom communications relies not only on its Meeting encryption or similar features, but also on its internal network security. Malicious actors who infiltrate Zoom's internal network could gain access to Zoom's administrative controls and compromise Zoom users' personal information. Despite this, Zoom, among other things, has:

a. Failed to implement a training program on secure software development principles;

b. Failed to test, audit, assess, or review its applications for security vulnerabilities at certain key points, such as prior to releasing software updates, including failing to ensure that its software is free from commonly known or reasonably foreseeable attacks, such as "Structured Query Language" (SQL) injection attacks and "Cross-Site Scripting" (XSS) attacks;

c. Failed to monitor service providers or other contractors who have access to Zoom's network;

d. Failed to secure remote access to its networks and systems through multi-factor authentication or similar technology;

e. Failed to use readily available measures to safeguard against anomalous activity and/or cybersecurity events across all of Zoom's systems, networks, and assets within those networks, including monitoring all of Zoom's networks and systems at discrete intervals, properly configuring firewalls, and segmenting its networks;

f. Failed to implement a systematic process for incident response;

g. Failed to implement a systematic process for inventorying, classifying, and deleting user data stored on Zoom's network; and

h. Been a year or more behind in patching software in its commercial environment.

Respondent's Deceptive and Unfair Privacy and Security Practices

13. Zoom has made numerous, prominent representations touting the strength of the privacy and security measures it employs to protect users' personal information. For example, Zoom has claimed on its website, in Security Guides, and in its privacy policy, that it takes "security seriously," that it "places privacy and security as the highest priority," and that it "is committed to protecting your privacy."

14. The privacy and security of video communications, including the level of encryption used to secure those communications, is important to users and their decisions about which videoconferencing platform to use, the price to pay for such services, and/or how they use those services. In numerous blog posts, Zoom has pointed to its security as a reason for potential customers to use Zoom's videoconferencing services. In a January 2017 blog post, "Zoom: The Fastest Growing App on Okta," Zoom specifically cited, based on customer feedback, its security feature of "end-to-end AES 256 bit encryption" as important to businesses and one of the reasons for Zoom's growth.

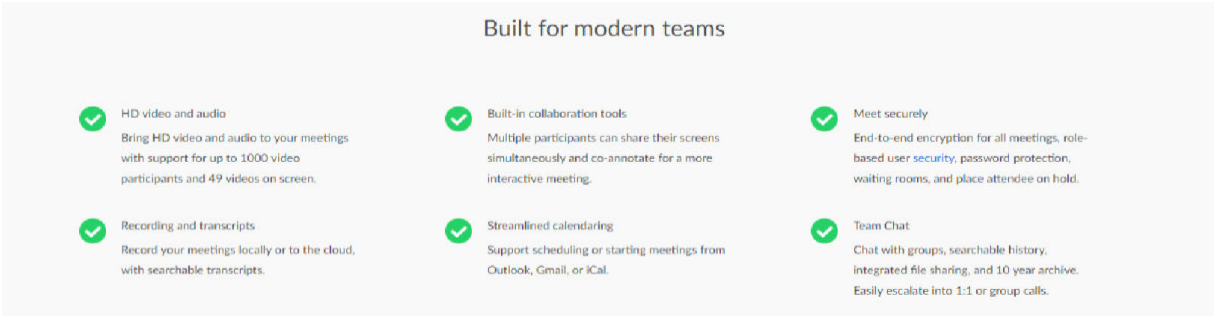
Zoom's Deceptive End-to-End Encryption Claims

15. End-to-end encryption is a method of securing communications where an encrypted communication can only be deciphered by the communicating parties. No other persons can decrypt the communications because they do not possess the necessary cryptographic keys to do so. End-to-end encryption is intended to prevent communications from being read or modified by anyone other than the true sender and recipient(s).

16. Since at least June 2016, Zoom has represented in its App, on its website, in its Security Guides, in its HIPAA Compliance Guide, in blog posts, and in direct communications with customers, that it offered end-to-end encryption to secure videoconference communications between hosts and attendees during Zoom Meetings.

17. For example, Zoom has represented that it provided end-to-end encryption in the Zoom App. When a user hovered over a green padlock in the top left corner of a Meeting, the user would see a popup stating, "Zoom is using an end to end encrypted connection."

18. Zoom also has represented that it employed end-to-end encryption for Zoom Meetings on the "meetings" and "security" pages of its public website, available at zoom.us/meetings and zoom.us/security. For example, on its "meetings" webpage, Zoom claimed that it offered end-to-end encryption for "all meetings":



19. Zoom has made similar representations in its Security Guides, which are available through its public website at www.zoom.us/security. In its June 2019 Security Guide, Zoom explained that Meeting hosts could "Enable an end-to-end (E2E) encrypted meeting." Zoom likewise claimed in its June 2016 Security Guide that Meeting hosts could "Secure a meeting with end-to-end encryption (E2E)." Zoom also claimed that it used "industry-standard end-to-end" encryption with AES 256-bit encryption as a way for its healthcare customers to comply with the Health Insurance Portability and Accountability Act (HIPAA)'s Security Rule. The HIPAA Security Rule applies to certain healthcare entities and contains federally mandated standards for protecting individuals' electronic personal health information.

20. For example, on the "healthcare" webpage of Zoom's website, available at zoom.us/healthcare, Zoom claimed that its customers could "Achieve HIPAA (signed BAA) and PIPEDA/PHIPA compliance with complete end-to-end 256-bit AES encryption." Zoom similarly explained in its June 2016 and July 2017 HIPAA Compliance Guides, available through its public website at zoom.us/healthcare, that its end-to-end encryption, among other security features, supported its healthcare customers' compliance with the HIPAA Security Rule:

> **Security and Encryption**
> Only members invited by account administrators can host Zoom meetings in accounts with multiple members. The host controls meeting attendance through the use of meeting IDs and passwords. Each meeting can only have one host. The host can screen share or lock screen sharing. The host has complete control of the meeting and meeting attendees, with features such as lock meeting, expel attendees, mute/unmute all, lock screen sharing, and end meeting.
>
> Zoom employs industry-standard end-to-end Advanced Encryption Standard (AES) encryption using 256-bit keys to protect meetings. Zoom encryption fully complies with HIPAA Security Standards to ensure the security and privacy of patient data.

21. In a January 2019 white paper entitled "End to End Encryption," Zoom represented that it offered end-to-end encryption for Zoom Meetings as an "added layer of application security for Zoom meetings, webinars, and chat (instant messaging) sessions." Zoom explained that end-to-end encryption meant that Zoom Meetings, webinars, and chat sessions could only be decrypted by "authenticated participant(s) who have the key required for decryption." The white paper also explained that video, audio, and screen sharing were all "protected with the Advanced Encryption Standard (AES) 256-bit algorithm."

22. Zoom specifically touted its level of encryption as a reason for customers and potential customers to use Zoom's videoconferencing services in numerous blog posts on its website. For example, in an April 24, 2017 blog post, "Zoom Reporting Live from American Telemedicine Association 2017," Zoom promoted its "End-to-end AES 256-bit encryption of all meeting data and instant messages" as a reason for healthcare providers to use Zoom as their telehealth videoconferencing solution.

23. Additionally, in response to inquiries from customers or potential customers who contacted Zoom directly to ask about Zoom's security practices and the level of encryption it employed for Zoom Meetings, Zoom informed them that it offers AES 256-bit, end-to-end encryption and directed them to its Security Guide that, as described above, made similar representations.

24. In fact, Zoom did not provide end-to-end encryption for any Zoom Meeting that was conducted outside of Zoom's "Connecter" product (which are hosted on a customer's own servers), because Zoom's servers—including some located in China—maintain the cryptographic keys that would allow Zoom to access the content of its customers' Zoom Meetings. Zoom has acknowledged that its Meetings were generally incapable of end-to-end encryption in an April 2020 blog post by its Chief Product Officer:

> In light of recent interest in our encryption practices, we want to start by apologizing for the confusion we have caused by incorrectly suggesting that Zoom meetings were capable of using end-to-end encryption. Zoom has always strived to use encryption to protect content in as many scenarios as possible, and in that spirit, we used the term end-to-end encryption. While we never intended to deceive any of our customers, we recognize that there is a discrepancy between the commonly accepted definition of end-to-end encryption and how we were using it. This blog is intended to rectify that discrepancy and clarify exactly how we encrypt the content that moves across our network.

https://blog.zoom.us/wordpress/wpcontent/uploads/2020/04/zoom-servers-news.jpg.

Zoom's Deceptive Claims Regarding Level of Encryption

25. Encrypting communications with the Advanced Encryption Standard (AES) and a 256-bit encryption key can be an effective way to secure communications and prevent eavesdropping. The 256-bit encryption key refers to the length of the key needed to decrypt the communications. Generally speaking, a longer encryption key provides more confidentiality protection than shorter keys because there are more possible key combinations, thereby making it harder to find the correct key and crack the encryption.

26. Since at least June 2015, Zoom has made numerous and prominent claims that it encrypted Zoom Meetings, in part, by using AES, with a 256-bit encryption key ("AES 256-bit Encryption" or "256-bit Encryption").

27. For example, in a June 2015 blog post entitled "Why Zoom's Security Features Matter for your Business," available at https://blog.zoom.us/wordpress/2015/06/17/why-zooms-

security-matter-for-business/, Zoom explained that encryption was important for video communications because people "discuss sensitive things in unplanned moments," and touted "**Zoom's use of AES 256 encryption**" as making it "**it impossible for a hacker to grab anything outside of a hopelessly garbled transmission**…" (emphasis in original).

28. On the "security" page of Zoom's website, available at zoom.us/security, Zoom also has claimed that it used 256-bit Encryption to protect user data:

29. Zoom likewise claimed that it uses 256-bit Encryption in its Security Guide and in its online Help Center. For example, Zoom's June 2019 Security Guide stated, "Webinar contents and screen sharing are secured using AES 256 and communicate over secured network using 256-bit encryption standard." In Zoom's online Help Center, available at https://support.zoom.us/hc/en-us/articles/201362723-Encryption-for-Meetings, Zoom answered a "Frequently Asked Question[]" about its Meeting encryption by explaining, in part, that its Meetings were encrypted "by default" with AES 256-bit Encryption:

30. In fact, Zoom used a lower level of encryption for securing Zoom Meetings, AES 128-bit encryption in Electronic Code Book ("ECB") mode. AES 128-bit encryption uses a shorter encryption key than AES 256-bit Encryption, and therefore provides less confidentiality protection because there are fewer possible values for the 128-bit key than for a 256-bit key. Reflecting the comparative strength of AES 256-bit Encryption and AES 128-bit Encryption, the National Security Agency has reported that AES 256-bit Encryption may be used for securing "TOP SECRET" materials, whereas AES 128-bit encryption may only be used for securing "SECRET" communications.

Zoom's Deceptive Claims Regarding
Secure Storage for Zoom Meeting Recordings

31. Zoom offers customers the ability to record their Zoom Meetings and store such recordings on either the host's local device or, for paying customers, in Zoom's secure cloud storage ("Cloud Recordings").

32. In Zoom's June 2019 Security Guide, Zoom claims that Cloud Recordings are processed and stored in Zoom's cloud "after the meeting has ended," where they "are stored encrypted as well." Zoom's June 2016 Security Guide similarly claimed that Cloud Recordings "are processed and securely stored in Zoom's cloud once the meeting has ended."

33. In fact, recorded Meetings are kept on Zoom's servers for up to 60 days, unencrypted, before Zoom transfers the recordings to its secure cloud storage, where they are then stored encrypted.

Zoom's Unfair Circumvention of a
Third-Party Privacy and Security Safeguard

34. In July 2018, Zoom updated its App for Mac computers by deploying a web server onto users' computers—without adequate user notice or consent—in order to circumvent a security and privacy safeguard in Apple's Safari browser. Specifically, Apple had updated its Safari browser to help defend its users from malicious actors and popular malware by requiring interaction with a dialogue box when a website or link attempts to launch an outside App.

35. As a result of the new browser safeguard, users who clicked on a link to join a Zoom Meeting would receive an additional prompt that read, "Do you want to allow this page to open 'zoom.us'?" If the user selected "Allow," the browser would connect the user to the Meeting, while clicking "Cancel" would end the interaction and prevent the Zoom App from launching.

36. To avoid this dialogue box, Zoom issued a manual update in July 2018 for its Zoom App for Mac desktop computers that secretly deployed a web server, called the "ZoomOpener," as a means to bypass the new privacy and security safeguard.

37. The ZoomOpener web server was installed on users' Mac computers and operated in the computer's background. When it detected a request to join a Zoom Meeting, the web server bypassed the new Safari browser safeguard to directly launch the Zoom App. It would then automatically join the user to the Zoom Meeting and, if the user had not changed her default video settings, automatically activate the user's webcam. Zoom automatically activated users' webcams immediately upon their joining a Meeting unless users changed their default video settings by logging into their Zoom account, going to their "preferences," clicking on "video," and then finding and clicking on the box, "Turn off my video when joining a meeting."

38. The ZoomOpener web server harmed consumers by limiting the intended benefit of a privacy and security safeguard provided by their Safari browser. Zoom did not implement

any compensating measures to replace the privacy and security protections that it had circumvented, nor did Zoom take any steps to address the risks that malicious actors could exploit the ZoomOpener web server and harm users. Without the circumvented Safari safeguard, one wrong click could expose consumers to remote video surveillance by strangers through their computers' webcams.

39. For example, malicious actors could exploit this vulnerability by using a phishing attack, a common form of cyberattack that typically entails a criminal sending out thousands of emails that pretend to be from a legitimate source in order to direct recipients to a bogus website where the criminal can capture personal information or engage in other malicious activity. Here, the phishing email could trick consumers into clicking on an innocuous-looking link that does not appear to be a Zoom Meeting invite. This link could then direct the consumer to an otherwise benign-looking website that has a Zoom Meeting embedded in it. Zoom Meetings can be embedded in websites through the use of the iframe HTML tool, which allows a segment of a website to display content from another source without leaving the original website (such as a YouTube video playing on a host's website).

40. Without the consumer taking any additional steps, the ZoomOpener web server would automatically join the consumer to the Zoom Meeting and activate her webcam—without the user's consent and perhaps without even realizing it. Merely leaving the website would not exit the Meeting or disable the webcam. Had Zoom not circumvented the Safari safeguard, users would have been alerted to the Zoom Meeting and would have had to give their permission before being joined to the Meeting.

41. In addition to bypassing the Safari browser safeguard, the ZoomOpener web server also harmed users by introducing two additional security vulnerabilities. First, the web server exposed some users to a potential Remote Control Execution (RCE) attack because the ZoomOpener web server would download and install software updates, including potentially malicious code, without properly validating that it was downloading the software from a trusted source. This code could then allow the malicious actor to execute code on the user's computer. On July 9, 2019, Zoom posted information about this vulnerability on its website, available at https://support.zoom.us/hc/en-us/articles/360031245072-Security-CVE-2019-13567, where it characterized the vulnerability as having "High Severity." Second, the ZoomOpener web server exposed users to a local denial of service ("DoS") attack where a hacker could potentially target a Zoom user with an endless loop of invalid Meeting join requests that would effectively cause the targeted machine to lock up.

42. As discussed in further detail in Paragraphs 49-52 below, Zoom did not notify users that its manual software update would install the ZoomOpener web server on their Mac computers. Nor did Zoom provide users with any information about the web server's operation, including the fact that it would bypass a Safari privacy and security safeguard.

43. In addition to bypassing the Safari privacy and security safeguard to launch Zoom Meetings, the ZoomOpener web server had a second function: to reinstall the Zoom App. Specifically, if a Mac user deleted the Zoom App in accord with Apple's instructions for deleting

apps, the ZoomOpener web server would nevertheless remain on users' computers. If the user later clicked on a Zoom Meeting invite or visited a website with an embedded Zoom Meeting, the web server would secretly reinstall the Zoom App—without any user interaction—and automatically join the user to the Meeting.

44. Because the ZoomOpener web server remained and continued to function on users' computers even after the Zoom App was deleted, the vulnerabilities described in Paragraphs 39-41 persisted after users deleted the Zoom App.

45. Zoom's deployment of the ZoomOpener web server—without adequate notice or consent—to circumvent a browser privacy and security safeguard, while also exposing users to additional security vulnerabilities as described in Paragraph 41, reflects Zoom's poor privacy and security practices. As described more fully in Paragraph 12, Zoom's security policies and practices have been inconsistently applied across its systems, and it has lacked an effective training program on secure software development principles.

46. The ZoomOpener web server's vulnerabilities impacted over 3.8 million U.S. consumers who had the ZoomOpener web server secretly installed on their Mac computers.

47. After a security researcher published information about the web server in early July 2019, Zoom issued a patch to remove the ZoomOpener web server from users' computers. A day later, Apple, Inc. issued a silent operating system update to protect Mac users from the ZoomOpener web server and automatically removed the web server from their computers. Although Zoom still allows customers to embed Meetings on their own websites, Zoom introduced a new video preview screen so that users would be able to see their own webcam stream before joining a Meeting.

48. Consumers could not reasonably have avoided the harms resulting from the secret deployment of the ZoomOpener web server. Zoom did not inform users that it was installing the ZoomOpener web server on their computer or otherwise provide any information about its operation, and it did not inform users that the web server would remain on their computers after they uninstalled the Zoom App. Consumers also had no way of independently knowing about the web server's security vulnerabilities. This substantial injury is not offset by countervailing benefits to consumers or competition.

Zoom's Deceptive Deployment of the ZoomOpener Web Server

49. The ZoomOpener web server was deployed as part of a manual software update for Zoom's Mac App on July 1, 2018 ("Web Server Update"). Within the Zoom App, Zoom notifies users of software updates in several ways: a pop up window; a blue bar that informs users that new updates are available; and through a "check for updates" feature available through a drop down menu under the user's profile icon.

50. The pop-up notification and "check for updates" feature both provide users with "Release Notes" that give information about the update, such as a listing of new and enhanced

features included in the update as well as any resolved issues, such as bug fixes. They also include an "Update" button for users to click and manually update their software.

51. As reflected in the Release Notes shown below, Zoom told users that the Web Server Update would fix minor bugs. Zoom failed to disclose, or disclose adequately, that the update would install a local hosted web server, that the web server would circumvent a Safari browser privacy and security safeguard, or that it would remain on users' computers even after they had deleted the App:

> July 1, 2018 Version **4.1.27695.0702**
> Download Type: Manual
>
> **Resolved issues**
>
> - **Minor bug fixes**

52. The omitted information was not available to users from any other source, and would have been material to their decision on whether or not to install the update. Indeed, when Zoom announced in early July 2019 that it would update its software to remove the ZoomOpener web server, it reported that it was doing so in response to customer feedback.

53. For example, some consumers made the following public comments about Zoom's secret deployment of the ZoomOpener web server:

- "I think they [Zoom] need to be made aware that this isn't acceptable…I do not believe this is a fair trade-off - allowing any arbitrary web site local control of privileged software installed on my machine - because Safari offers a security prompt (specifically so that any arbitrary web site does not gain control of privileged software on my machine). I will be switching ~/.zoomus/ZoomOpener.app off, and considering other options until it has been fixed."

- "I liked Zoom when I used it a couple of times, but the reinstall 'feature' [of the ZoomOpener web server] is a huge violation of my trust. Software from the company behind it will not touch my system anymore."

- "I cancelled my subscription because of [Zoom's installation of the ZoomOpener web server]… This should not be considered OK."

VIOLATIONS OF THE FTC ACT

Count I
Deceptive Representation Regarding End-to-End Encryption

54. As alleged in Paragraphs 14-23, Zoom has represented, directly or indirectly, expressly or by implication, that it employed end-to-end encryption to secure the content of communications between participants using Zoom's video conferencing service.

55. In fact, as described in Paragraph 24, Zoom did not employ end-to-end encryption to secure the content of communications between participants using Zoom's video conferencing service. Therefore, the representation set forth in Paragraph 54 is false or misleading.

Count II
Deceptive Representation Regarding Level of Encryption

56. As alleged in Paragraphs 25-29, Zoom has represented, directly or indirectly, expressly or by implication, that it employed 256-bit Encryption to secure the content of communications between participants using Zoom's video conferencing service.

57. In fact, as described in Paragraph 30, Zoom did not employ 256-bit Encryption to secure the content of communications between participants using Zoom's video conferencing service. Therefore, the representation set forth in Paragraph 56 is false or misleading.

Count III
Deceptive Representation Regarding Secured Cloud Storage for Recorded Meetings

58. As alleged in Paragraphs 31-32, Zoom has represented, directly or indirectly, expressly or by implication, that recorded Meetings are stored encrypted in Zoom's cloud storage immediately after a Meeting has ended.

59. In fact, as set forth in Paragraph 33, recorded Meetings are not stored encrypted in Zoom's cloud storage immediately after a Meeting has ended. Therefore, the representation set forth in Paragraph 58 is false or misleading.

Count IV
Unfair Circumvention of Third-Party Privacy and Security Safeguard

60. As alleged in Paragraphs 34-48, Zoom installed the ZoomOpener web server, without adequate notice or consent, to circumvent a browser privacy and security safeguard and did not implement measures to replace the circumvented privacy and security protections.

61. Respondent's actions caused or are likely to cause substantial injury to consumers that consumers cannot reasonably avoid and that is not outweighed by countervailing benefits to

consumers or competition. Therefore, the practice set forth in Paragraph 60 is an unfair act or practice.

Count V
Deceptive Failure to Disclose

62. As alleged in Paragraph 51, in connection with the advertising, marketing, promotion, offering for sale, or sale of its video conferencing products, Respondent represented, directly or indirectly, expressly or by implication, that Zoom was updating its Mac App in order to resolve minor bug fixes.

63. In numerous instances in which Respondent made the representation set forth in Paragraph 62, Respondent failed to disclose or disclose adequately that the update would deploy a local hosted web server, that the web server would circumvent a Safari browser privacy and security safeguard, or that the web server would remain on users' computers even after they had uninstalled the Zoom App.

64. In light of the representation described in Paragraph 62, Respondent's failure to disclose or disclose adequately the material information as set forth in Paragraph 63 constitutes a deceptive act or practice in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Violations of the FTC Act

65. The acts and practices of Zoom as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

THEREFORE, the Federal Trade Commission this nineteenth day of January 2021, has issued this Complaint against Respondent.

By the Commission, Commissioners Chopra and Slaughter dissenting.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondent named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violations of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: (1) statements by Respondent that it neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, it admits the facts necessary to establish jurisdiction; and (2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondent is Zoom Video Communications, Inc., a Delaware corporation, with its principal office or place of business at 55 Almaden Boulevard, 6th Floor, San Jose, California 95113.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "**Covered Incident**" means any instance in which any United States federal, state, or local law or regulation ("Breach Notification Law") requires, or would require if recorded or livestream video or audio content from a Meeting were included as a type of personal information covered by such Breach Notification Law, Respondent to notify any U.S. federal, state, or local government entity that information collected or received, directly or indirectly, by Respondent from or about an individual consumer was, or is reasonably believed to have been, accessed or acquired without authorization. For purposes of this definition, "Covered Incident" does not include any instance of unauthorized access or acquisition of video or audio content if Respondent determines that such instance: (a) affected fewer than 500 Users; (b) resulted from a User accessing the video or audio content by using a link, password, or other access information, obtained directly or indirectly, as a result of its distribution by a Meeting host or organizer; or (c) resulted from a Meeting that is offered or made publicly accessible by the Meeting host or organizer; or (d) the video or audio content was encrypted and the

encryption key was not also accessed or acquired from Respondent by an unauthorized person.

B. "**Covered Information**" means information from or about an individual, including: (a) a first and last name; (b) a physical address; (c) an email address or other online contact information, such as an instant messaging user identifier or a screen name; (d) a telephone number; (e) a Social Security number; (f) a driver's license or other government-issued identification number; (g) a financial institution account number; (h) credit or debit card information; (i) recorded or livestream video or audio content, chat transcripts, documents, or any other multimedia content shared by Users during a Meeting; (j) a persistent identifier, such as a customer number held in a "cookie," a static Internet Protocol ("IP") address, a mobile device ID, or processor serial number; or (k) any information combined with any of (a) through (j) above.

C. "**Credential**" or "**Credentials**" means the user name and password that a User utilizes for logging in or otherwise accessing Respondent's products or services.

D. "**Meeting**" means a one-on-one or group videoconference on Respondent's platform, including but not limited to, webinars and conference room videoconference connectors.

E. "**Meeting Service**" **or** "**Meeting Services**" means all features and ancillary services developed by or on behalf of Respondent and used in the context of a Meeting (*e.g.*, video, audio, chat, content-sharing, recording, and storage of recordings). "Meeting Service" or "Meeting Services" does not include any plugin, cookie, or application that is offered or provided by a third party, including but not limited to, applications offered by third parties through the Zoom app store.

F. "**Respondent**" or "**Zoom**" means Zoom Video Communications, Inc., and its successors and assigns.

G. "**Third-Party Security Feature**" means any feature or tool built into an internet browser or operating system that: (a) has been specified as a security feature in the developer's official release notes; or that (b) has been identified by Zoom Security Personnel designated by Respondent for this purpose, based on their experience and expertise in secure software development principles, as a feature that protects the security of a User against the risk of unauthorized access, collection, disclosure, use, misuse, loss, theft, alteration, destruction, or other compromise of the User's Covered Information. "Third-Party Security Feature" does not include any software, system, feature, or tool, including without limitation, any plugin, cookie, or application, that is not developed by or for the browser or operating system developer.

H. "**User**" means any entity or individual that uses Zoom's Meeting Services.

I. "**Zoom Security Personnel**" means any person(s) working by or on behalf of Respondent who has been trained in secure software development principles, including secure engineering and defensive programming concepts, such as Respondent's Chief Information Security Officer.

Provisions

I. Prohibited Misrepresentations

IT IS ORDERED that Respondent, and Respondent's officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with any product or service, must not misrepresent in any manner, expressly or by implication:

A. Respondent's collection, maintenance, use, deletion, or disclosure of any Covered Information;

B. The security features, or any feature that impacts a Third-Party Security Feature, included in any Meeting Service, or the material changes included in any updates thereof;

C. The extent to which Respondent protects any Covered Information from unauthorized access;

D. The extent to which a User can control the privacy or security of any Covered Information collected and maintained by Respondent, and the steps the User must take to implement such controls;

E. The categories of third parties to which Respondent makes Covered Information accessible; or

F. The extent to which Respondent otherwise maintains the privacy, security, confidentiality, or integrity of Covered Information.

II. Mandated Information Security Program

IT IS FURTHER ORDERED that Respondent, and any business that Respondent controls directly or indirectly, in connection with the collection, maintenance, use, or disclosure of, or provision of access to, Covered Information, must, within sixty (60) days of issuance of this order, establish and implement, and thereafter maintain, a comprehensive information security program ("Program" or "Information Security Program") that protects the security, confidentiality, and integrity of such Covered Information. To satisfy this requirement, Respondent must, at a minimum:

A. Document in writing the content, implementation, and maintenance of the Program, including all processes and procedures that will be used to implement all Program policies and safeguards;

B. Provide the written Program and any material evaluations thereof or material updates thereto to Respondent's board of directors or governing body or, if no such board or equivalent governing body exists, to a senior officer of Respondent responsible for Respondent's Program at least once every twelve (12) months and promptly (not to exceed thirty (30) days) after a Covered Incident;

C. Designate a qualified employee or employees to coordinate and be responsible for the Program;

D. Assess and document, at least once every twelve (12) months and promptly (not to exceed thirty (30) days) following a Covered Incident, internal and external risks to the security, confidentiality, or integrity of Covered Information that could result in the (1) unauthorized collection, maintenance, use, or disclosure of, or provision of access to, Covered Information; or the (2) misuse, loss, theft, alteration, destruction, or other compromise of such information;

E. Design, implement, maintain, and document safeguards that control for the internal and external risks Respondent identifies to the security, confidentiality, and integrity of Covered Information identified in response to sub-Provision II.D. Each safeguard must be based on the volume and sensitivity of Covered Information that is at risk, and the likelihood that the risk could be realized and result in the (1) unauthorized collection, maintenance, use, or disclosure of, or provision of access to, Covered Information; or the (2) misuse, loss, theft, alteration, destruction, or other compromise of such information. Such safeguards must also include:

1. Implementing a security review by Zoom Security Personnel designated by Respondent of all new Meeting Services software or software updates, prior to release that, at a minimum, includes:

   a. Policies, procedures, and any applicable technical measures for reviewing all new Meeting Service software or software updates for commonly known vulnerabilities, including those identified by the Open Web Application Security Project (OWASP) and critical or high severity vulnerabilities in the National Vulnerability Database (NVD), and remediating or otherwise mitigating any such vulnerabilities;

   b. Policies, procedures, and any applicable technical measures to: (i) determine whether any new Meeting Services software or software update is designed to circumvent or bypass, in whole or in part, any Third-Party Security Feature such that the Third-Party Security

Feature no longer provides the same protection(s) for Users against the risk of unauthorized access, collection, disclosure, use, misuse, loss, theft, alteration, destruction, or other compromise of Users' Covered Information; and (ii) assess the risk of unauthorized access, collection, disclosure, use, misuse, loss, theft, alteration, destruction, or other compromise of the User's Covered Information that will result from such circumvention or bypass, based on the volume and sensitivity of Covered Information that is at risk, and the likelihood that the risk could be realized; and

c. Policies, procedures, and any applicable technical measures so that Respondent will not implement any new Meeting Services software or software update that has been identified under Part II.E.1.b(i) of this Order as designed to circumvent or bypass a Third-Party Security Feature, unless: (i) Zoom Security Personnel determine that the bypass or circumvention does not create a material risk of unauthorized access, collection, disclosure, use, misuse, loss, theft, alteration, destruction, or other compromise of Users' Covered Information; or (ii) Respondent implements security measure(s) that offset or otherwise mitigate the risk(s) of unauthorized access, collection, disclosure, use, misuse, loss, theft, alteration, destruction, or other compromise of Users' Covered Information that were identified under Part II.E.1.b(ii) of this Order;

2. Implementing a vulnerability management program that includes:

a. Conducting vulnerability scans of Respondent's networks and systems on at least a quarterly basis; and

b. Policies, procedures, and any applicable technical measures for remediating or otherwise mitigating any critical or high severity vulnerabilities promptly (but in no event later than thirty (30) days after the vulnerability is detected), unless Respondent documents its rationale for not doing so;

3. Implementing a default, randomized naming convention for recorded Meetings that are to be stored on Users' local devices, and instructing Users to employ a unique file name when saving such recorded Meetings;

4. Policies, procedures, and any applicable technical measures to: (a) systematically classify and inventory Covered Information in Respondent's control; (b) log and monitor access to repositories of Covered Information in Respondent's control; and (c) limit access to Covered Information by, at a minimum, limiting employee and service

provider access to Covered Information to what is needed to perform that employee or service provider's job function;

5. Data deletion policies, procedures, and any applicable technical measures, including validating that all copies of Covered Information identified for deletion are deleted within thirty-one (31) days;

6. Policies, procedures, and any applicable technical measures designed to reduce the risk of online attacks resulting from the misuse of valid Credentials by unauthorized third parties, including: (a) requiring Users to secure their accounts with strong, unique passwords; (b) using automated tools to identify non-human login attempts; (c) rate-limiting login attempts to minimize the risk of a brute force attack; and (d) implementing password resets for known compromised Credentials;

7. Regular security training programs, on at least an annual basis, that are updated, as applicable, to address internal or external risks identified by Respondent under sub-Provision II.D of this Order, and that include, at a minimum:

    a. Security awareness training for all employees on Respondent's security policies and procedures, including the requirements of this Order and the process for submitting complaints and concerns; and

    b. Training in secure software development principles, including secure engineering and defensive programming concepts, for developers, engineers, and other employees that design Respondent's products or services or that are otherwise responsible for the security of Covered Information;

8. Technical measures to monitor all of Respondent's networks, systems, and assets within those networks to identify anomalous activity and/or data security events on Respondent's network, including unauthorized attempts to exfiltrate Covered Information from Respondent's networks;

9. Incident response policies, procedures, and any applicable technical measures, including centralized log management and documenting remedial security actions;

10. Technical measures designed to safeguard against unauthorized access to any network or system that stores, collects, maintains, or processes Covered Information, such as properly configured firewalls; properly configured physical or logical segmentation of networks, systems, and databases; and securing of remote access to Respondent's networks through multi-factor authentication or similar technology except for when accessing such networks is for the purpose of using Meeting Services; and

11. Protections, such as encryption, tokenization, or other same or greater protections, for Covered Information collected, maintained, processed, or stored by Respondent, including in transit and at rest;

F. Assess, at least once every twelve (12) months and promptly (not to exceed thirty (30) days) following a Covered Incident, the sufficiency of any safeguards in place to address the internal and external risks to the security, confidentiality, and integrity of Covered Information, and modify the Program based on the results;

G. Test and monitor the effectiveness of the safeguards at least once every twelve (12) months and promptly (not to exceed thirty (30) days) following a Covered Incident, and modify the Program based on the results. Such testing and monitoring must include penetration testing of Respondent's network at least once every twelve (12) months and promptly (not to exceed thirty (30) days) after a Covered Incident;

H. Select and retain service providers capable of safeguarding Covered Information they access through or receive from Respondent, and contractually require service providers to implement and maintain safeguards for Covered Information sufficient to address the internal and external risks to the security, confidentiality, or integrity of Covered Information;

I. Consult with, and seek appropriate guidance from, independent, third-party experts on data protection in the course of establishing, implementing, maintaining, and updating the Program; and

J. Evaluate and adjust the Program in light of any changes to Respondent's operations or business arrangements, a Covered Incident, new or more efficient technological or operational methods to control for the risks identified in sub-Provision II.D of this Order, or any other circumstances that Respondent knows or has reason to know may have a material impact on the effectiveness of the Program or any of its individual safeguards. At a minimum, Respondent must evaluate the Program at least once every twelve (12) months and modify the Program as necessary based on the results.

III. Independent Program Assessments by a Third Party

IT IS FURTHER ORDERED that, in connection with compliance with Provision II of this Order, titled Mandated Information Security Program, Respondent must obtain initial and biennial assessments ("Assessments"):

A. The Assessments must be obtained from one or more qualified, objective, independent third-party professionals ("Assessor"), who: (1) uses procedures and standards generally accepted in the profession; (2) conducts an independent review of the Program; and (3) retains all documents relevant to each Assessment for five (5) years after completion of such Assessment and (4) will provide such

documents to the Commission within ten (10) days of receipt of a written request from a representative of the Commission. No documents may be withheld by the Assessor on the basis of a claim of confidentiality, proprietary or trade secrets, work product protection, attorney-client privilege, statutory exemption, or any similar claim;

B. For each Assessment, Respondent must provide the Associate Director for Enforcement for the Bureau of Consumer Protection at the Federal Trade Commission with the name(s), affiliation, and qualifications of the proposed Assessor, whom the Associate Director shall have the authority to approve in her or his sole discretion;

C. The reporting period for the Assessments must cover: (1) the first one hundred eighty (180) days after the Information Security Program has been put in place for the initial Assessment; and (2) each two-year period thereafter for twenty (20) years after issuance of the Order for the biennial Assessments;

D. Each Assessment must, for the entire assessment period:

1. Determine whether Respondent has implemented and maintained the Information Security Program required by Provision II of this Order, titled Mandated Information Security Program;

2. Assess the effectiveness of Respondent's implementation and maintenance of sub-Provisions II.A-J;

3. Identify any gaps or weaknesses in, or instances of material noncompliance with, the Information Security Program;

4. Address the status of gaps or weaknesses in, or instances of material non-compliance with, the Information Security Program that were identified in any prior Assessment required by this Order; and

5. Identify specific evidence (including documents reviewed, sampling and testing performed, and interviews conducted) examined to make such determinations, assessments, and identifications, and explain why the evidence that the Assessor examined is (a) appropriate for assessing an enterprise of Respondent's size, complexity, and risk profile; and (b) sufficient to justify the Assessor's findings. No finding of any Assessment shall rely primarily on assertions or attestations by Respondent's management. The Assessment must be signed by the Assessor, state that the Assessor conducted an independent review of the Information Security Program and did not rely primarily on assertions or attestations by Respondent's management, and state the number of hours that each member of the assessment team worked on the Assessment. To the extent that Respondent revises, updates, or adds one or more safeguards required

under Provision II of this Order during an Assessment period, the Assessment must assess the effectiveness of the revised, updated, or added safeguard(s) for the time period in which it was in effect, and provide a separate statement detailing the basis for each revised, updated, or additional safeguard; and

E. Each Assessment must be completed within sixty (60) days after the end of the reporting period to which the Assessment applies. Unless otherwise directed by a Commission representative in writing, Respondent must submit the initial Assessment to the Commission within ten (10) days after the Assessment has been completed via email to DEbrief@ftc.gov or by overnight courier (not the U.S. Postal Service) to Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin, "In re Zoom Video Communications, Inc., FTC File No. 192 3167, Docket No. C-4731." All subsequent biennial Assessments must be retained by Respondent until the order is terminated and provided to the Associate Director for Enforcement within ten (10) days of request.

IV. Cooperation with Third Party Assessor(s)

IT IS FURTHER ORDERED that Respondent, whether acting directly or indirectly, in connection with any Assessment required by Provision III of this Order, titled Independent Program Assessments by a Third Party, must:

A. Provide or otherwise make available to the Assessor all information and material in its possession, custody, or control that is relevant to the Assessment for which there is no reasonable claim of privilege;

B. Provide or otherwise make available to the Assessor information about Respondent's networks and all of Respondent's IT assets so that the Assessor can determine the scope of the Assessment, and visibility to those portions of the networks and IT assets deemed in scope; and

C. Disclose all material facts to the Assessor, and not misrepresent in any manner, expressly or by implication, any fact material to the Assessor's: (1) determination of whether Respondent has implemented and maintained the Information Security Program required by Provision II of this Order, titled Mandated Information Security Program; (2) assessment of the effectiveness of the implementation and maintenance of sub-Provisions II.A-J; or (3) identification of any gaps or weaknesses in, or instances of material noncompliance with, the Information Security Program.

V. Annual Certification

IT IS FURTHER ORDERED that Respondent must:

A. One (1) year after the issuance date of this Order, and each year thereafter, provide the Commission with a certification from a senior corporate manager, or, if no such senior corporate manager exists, a senior officer of Respondent responsible for Respondent's Information Security Program that: (1) Respondent has established, implemented, and maintained the requirements of this Order; and (2) Respondent is not aware of any material noncompliance that has not been (a) corrected or (b) disclosed to the Commission. The certification must be based on the personal knowledge of the senior corporate manager, senior officer, or subject matter experts upon whom the senior corporate manager or senior officer reasonably relies in making the certification.

B. Unless otherwise directed by a Commission representative in writing, submit all annual certifications to the Commission pursuant to this Order via email to DEbrief@ftc.gov or by overnight courier (not the U.S. Postal Service) to Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "In re Zoom Video Communications, Inc., FTC File No. 192 3167, Docket No. C-4731."

VI. Covered Incident Reports

IT IS FURTHER ORDERED that Respondent, within thirty (30) days after the date of Respondent's discovery of a Covered Incident, but in any event no later than ten (10) days after the date Respondent first notifies any U.S. federal, state, or local government entity of the Covered Incident, must submit a report to the Commission. The report must include, to the extent possible:

A. The date, estimated date, or estimated date range when the Covered Incident occurred;

B. A description of the facts relating to the Covered Incident, including the causes of the Covered Incident, if known;

C. A description of each type of Covered Information that was affected or triggered any notification obligation to the U.S. federal, state, or local government entity;

D. The number of consumers whose information was affected or that triggered the notification obligation to the U.S. federal, state, or local government entity;

E. The acts that Respondent has taken to date to remediate the Covered Incident and protect Covered Information from further exposure or access, and protect affected

individuals from identity theft or other harm that may result from the Covered Incident; and

F. A representative copy of any materially different notice sent by Respondent to consumers or to any U.S. federal, state, or local government entity.

Unless otherwise directed by a Commission representative in writing, all Covered Incident reports to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "In re Zoom Video Communications, Inc., FTC File No. 192 3167, Docket No. C-4731."

VII. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondent obtain acknowledgments of receipt of this Order:

A. Respondent, within ten (10) days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order, sworn under penalty of perjury;

B. For five (5) years after the issuance date of this Order, Respondent must deliver a copy of this Order to: (a) all principals, officers, directors, and LLC managers and members; (b) all employees, agents, and representatives with managerial responsibilities related to the subject matter of the Order; and (c) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within ten (10) days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities; and

C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within thirty (30) days, a signed and dated acknowledgment of receipt of this Order.

VIII. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondent make timely submissions to the Commission:

A. One (1) year after the issuance date of this Order, Respondent must submit a compliance report, sworn under penalty of perjury, in which Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet

addresses; (c) describe the activities of each business, including the goods and services offered, and the means of collection, maintenance, use, deletion, or disclosure of information; (d) describe in detail whether and how Respondent is in compliance with each Provision of this Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission;

B. Respondent must submit a compliance notice, sworn under penalty of perjury, within fourteen (14) days of any change in the following: (a) any designated point of contact; or (b) the structure of the Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order;

C. Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within fourteen (14) days of its filing;

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature; and

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "In re Zoom Video Communications, Inc., FTC File No. 192 3167, Docket No. C-4731."

IX. Recordkeeping

IT IS FURTHER ORDERED that Respondent must create certain records for five (5) years after the issuance date of the Order, and retain each such record for five (5) years. Specifically, Respondent must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold;

B. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. Copies of all U.S. consumer complaints that were submitted to Respondent and relate to the subject matter of the Order, and any response(s) to such complaints;

D. All records necessary to demonstrate full compliance with each Provision of this Order, including all submissions to the Commission;

E. A copy of each widely disseminated and materially different representation by Respondent that describes (a) Respondent's collection, maintenance, use, deletion, or disclosure of any Covered Information; (b) the security features, or any features that impact a Third-Party Security Feature, included in any Meeting Service, or the changes included in any updates thereof; (c) the extent to which Respondent protects Covered Information from unauthorized access, including any representation on any website or other service controlled by Respondent that relates to the privacy, security, confidentiality, and integrity of Covered Information; (d) the extent to which a User can control the privacy or security of Covered Information and the steps the User must take to implement such controls; and (e) the categories of third parties to which Respondent makes Covered Information accessible; and

F. For five (5) years after the date of preparation of each Assessment required by this Order, all materials relied upon to prepare the Assessment, whether prepared by or on behalf of Respondent, including all plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, and any other materials concerning Respondent's compliance with related Provisions of this Order, for the compliance period covered by such Assessment.

X. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondent's compliance with this Order:

A. Within fourteen (14) days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, appear for depositions, and produce records for inspection and copying;

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit representatives of the Commission to interview anyone affiliated with Respondent who has agreed to such an interview. The interviewee may have counsel present; and

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, without the necessity of identification or prior notice. Nothing in this Order limits the

Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

XI. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate January 19, 2041, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than twenty (20) years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioners Chopra and Slaughter dissenting.

MAJORITY STATEMENT OF CHAIRMAN JOSEPH J. SIMONS, COMMISSIONER NOAH JOSHUA PHILLIPS, AND COMMISSIONER CHRISTINE S. WILSON

At a time when millions of Americans are using videoconferencing services on a daily basis, the settlement that the Commission announces today ensures that Zoom will prioritize consumers' privacy and security. The Commission's complaint alleges that Zoom made misrepresentations regarding the strength of its security features and implemented a software update that circumvented a browser security feature. The proposed order provides immediate and important relief to consumers, addressing this conduct. The order requires that Zoom establish and implement a comprehensive security program that includes detailed and specific security measures. These obligations include reviews of all new software for common security

vulnerabilities; quarterly scans of its internal network and prompt remediation of critical or severe vulnerabilities; and prohibitions against privacy and security misrepresentations.[1] This order will enable the Commission to seek significant penalties for noncompliance. This settlement provides critical, and timely, relief.

We are confident that the proposed relief appropriately addresses the conduct alleged in the complaint and is an effective, efficient resolution of this investigation. Our dissenting colleagues suggest additional areas for relief that likely would require protracted litigation to obtain. Given the effective relief this settlement provides, we see no need for that. Hundreds of millions of people use Zoom on a daily basis, often for free or through month-to-month contracts. We feel it is important to put in place measures to protect those users' privacy and security now, rather than expend scarce staff resources on speculative, potential relief that a Court would not likely grant, given the facts here.[2] Our goal is a safe and secure Zoom that can continue to provide essential services to enable Americans to conduct business, engage in learning, participate in religious services, and stay connected. We applaud the FTC Staff for their professional and expeditious work to achieve this settlement in the midst of the pandemic. This case reflects the Commission's ongoing commitment to work on behalf of consumers to respond to the panoply of new challenges presented by COVID-19.

DISSENTING STATEMENT OF COMMISSIONER ROHIT CHOPRA

Summary

- When companies deploy deception, this harms customers and honest competitors, and it distorts the marketplace. This is particularly problematic when it comes to the digital economy.

- Zoom's alleged security failures warrant serious action. But the FTC's proposed settlement includes no help for affected parties, no money, and no other meaningful accountability.

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1 Although the complaint does not allege privacy violations, the order includes targeted fencing in relief providing privacy protections to consumers. For example, it prohibits Zoom from misrepresenting its privacy practices, and requires Zoom to implement changes to its naming procedures for saving or storing recorded videoconference meetings, and to develop data deletion policies and procedures. These and other requirements serve to protect consumers' privacy as well as the security of their information and communications.

2 Our dissenting colleagues also argue that the settlement is insufficient because it does not require Zoom to notify consumers of its past misconduct. The conduct at issue was broadly publicized and we believe the Commission's press release and business and consumer education provide ample information for consumers to learn more.

- The FTC's status quo approach to privacy, security, and other data protection law violations is ineffective. However, Commissioners can take a series of concrete steps to change this.

Introduction

Sometimes a new product becomes inextricably linked to the brand that made it popular. Kleenex, Band-Aids, and Frisbees are examples where the company became synonymous with the product.[1] This is particularly true in the digital economy where products can improve the use and capability of technology to the point of transforming its role in everyday life. We use "Google" as a verb when referring to use of a search engine. We "Uber" when we need a ride across town. And now, we "Zoom" when referring to videoconferencing. If becoming a verb threatens a trademark, firms fight against it. If it means becoming the default product in a market, they fight for it. But, profiting through unlawful means must come with real consequences.

Zoom (NASDAQ: ZM) did not invent web-based video conferencing. Indeed, there are many other players in the market. But Zoom succeeded in becoming the "default" for many businesses, both large and small, capturing a significant market share despite a crowded field. However, the allegations in the FTC's complaint raise questions whether Zoom's success – and the tens of billions of dollars of wealth created for its shareholders and executives in a short period of time – was advanced through fair play.[2] In my view, the evidence suggests that deception helped to create this windfall.

With businesses, families, schools, and even governments using Zoom to share extremely sensitive information, the alleged security vulnerabilities of this video conferencing platform raise major concerns, including threats to our privacy[3] and national security.[4]

Today, the Federal Trade Commission has voted to propose a settlement with Zoom that follows an unfortunate FTC formula. The settlement provides no help for affected users. It does nothing for small businesses that relied on Zoom's data protection claims. And it does not require Zoom to pay a dime. The Commission must change course.

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1 Mark Abadi, *Taser, Xerox, Popsicle, and 31 more brands-turned-household names*, BUSINESS INSIDER (June 3, 2018), https://www.businessinsider.com/google-taser-xerox-brand-names-generic-words-2018-5.

2 Richard Waters, *Zoom to cash in on pandemic success with apps and events*, FINANCIAL TIMES (Oct. 14, 2020), https://www.ft.com/content/f1731672-e965-48a1-9362-bab122fc9bf4.

3 In her voting statement, Commissioner Rebecca Kelly Slaughter details some of the key intersections between privacy and security.

4 Sonam Sheth, *Foreign intelligence operatives are reportedly using online platforms and video-conferencing apps like Zoom to spy on Americans*, BUSINESS INSIDER (Apr. 9, 2020), https://www.businessinsider.com/foreign-intelligence-agents-china-spying-on-americans-zoom-2020-4.

Deception Distorts Competition

When companies need to act quickly to exploit an opportunity, deploying deception to steal users or sales from competing players is tantalizing. When video conferencing became a necessity for many businesses and families, existing players saw a potential gold mine. Even though we can all technically use multiple videoconferencing platforms as participants, a videoconferencing provider's monetization will largely be driven by how many businesses adopt its offering as their enterprise videoconferencing solution.[5] FTC prohibitions on unfair or deceptive practices are supposed to temper the temptation to deceive customers.

Before the pandemic, Zoom primarily focused on business customers. Small and large businesses alike were looking for ways to connect with clients and business partners through video conferencing. Zoom competed with Microsoft's Skype, Microsoft's Teams, Cisco's WebEx, BlueJeans, and many other products. Comparison guides point out the different strong points of each service – from encryption to price.[6] In the summer of 2019, Zoom had over 600,000 customers that paid fees to use Zoom's services.[7] These customers were overwhelmingly small businesses.[8]

Small businesses often don't have employees dedicated to information security or even to information technology more broadly. That's why they rely on representations made by those they purchase software and services from. Many businesses want to ensure that any software application they use, including any video conferencing solution, comes with meaningful security standards. Zoom had to respond to this critical customer need if it was going to compete. Once the pandemic shut down workplaces across the country, businesses needed to find a reliable solution that was also secure. Many chose Zoom.[9]

Zoom sold its customers on the idea that it was an easy-to-use service that took "security seriously." However, when examining the company's engineering and product decisions, a different reality emerges. For example, as the complaint alleges, Zoom installed a web server onto users' computers, without permission, as an end-run that would circumvent a browser security feature – all to avoid an extra dialogue box.[10] Zoom went further: even if you managed

5 Zoom Video Communications, Inc., Oct. 2019 Quarterly Report (Form 10-Q) (Dec. 9, 2019), https://www.sec.gov/ix?doc=/Archives/edgar/data/1585521/000158552119000059/zm-20191031 htm.

6 Kari Paul, *Worried about Zoom's privacy problems? A guide to your video-conferencing options*, THE GUARDIAN (Apr. 9, 2020), https://www.theguardian.com/technology/2020/apr/08/zoom-privacy-video-chat-alternatives.

7 Compl., *In the Matter of Zoom Video Communications, Inc.*, Comm'n File No. 1923167 (Nov. 9, 2020).

8 *Id*.

9 Matt Torman, *5 Reasons Why Zoom Will Benefit Your Small Business*, ZOOM (Jan. 24, 2020), https://blog.zoom.us/zoom-video-communications-small-business-benefits/.

10 Compl., *supra* note 7.

to uninstall Zoom, it would not remove the web server.[11] And that web server could secretly re-install Zoom, even without your permission.[12] This is not just troubling conduct – this is what some have called "malware-like" behavior.[13]

This fervent attention to detail – going to great lengths to avoid a single dialogue box – did not extend to the security features it touted in sales materials.[14] The FTC's complaint details a litany of serious security allegations, from not using what is "the commonly accepted definition" of end-to-end encryption to being a year or more behind in patching software in its commercial environment.[15]

Zoom's Windfall

Zoom has "cashed in" on the pandemic.[16] While Zoom doesn't publicly share its total number of users, the company has confirmed that it has nearly four times the number of customers with 10 or more employees than they had at this time a year ago.[17] Their stock value has soared.[18] Zoom's CEO, Eric Yuan, has increased his net worth by almost $16 billion *since March*, and is now one of the wealthiest individuals in America.[19]

Zoom can now use this new market penetration to increase monetization for users who currently do not pay any fees. With the pandemic-driven expansion, Zoom has announced that they're going to make a platform pivot and begin to offer an app marketplace and a paid events

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11 David Murphy, *Remove Zoom From Your Mac Right Now*, LIFEHACKER (July 9, 2020), https://lifehacker.com/remove-zoom-from-your-mac-right-now-1836209383.

12 *Id.*

13 Jacob Kastrenakes, *Zoom saw a huge increase in subscribers — and revenue — thanks to the pandemic*, THE VERGE (June 2, 2020), https://www.theverge.com/2020/6/2/21277006/zoom-q1-2021-earnings-coronavirus-pandemic-work-from-home.

14 Compl., *supra* note 7.

15 Michael Lee & Yael Grauer, *Zoom Meetings Aren't End-to-End Encrypted, Despite Misleading Marketing*, THE INTERCEPT (Mar. 31, 2020), https://theintercept.com/2020/03/31/zoom-meeting-encryption/; Compl., *supra* note 7; Oded Gal, *The Facts Around Zoom and Encryption for Meetings/Webinars*, ZOOM (Apr. 1, 2020), https://blog.zoom.us/facts-around-zoom-encryption-for-meetings-webinars/.

16 Richard Waters, *Zoom to cash in on pandemic success with apps and events*, FINANCIAL TIMES (Oct. 14, 2020), https://www.ft.com/content/f1731672-e965-48a1-9362-bab122fc9bf4.

17 *Id.*

18 *Id.*

19 Taylor Nicole Rogers, *Meet Eric Yuan, the founder and CEO of Zoom, who has made over $12 billion since March and now ranks among the 400 richest people in America*, BUSINESS INSIDER (Sep. 9, 2020), https://www.businessinsider.com/meet-zoom-billionaire-eric-yuan-career-net-worth-life; Kerry A. Dolan et al., *The Forbes 400: The Definitive Ranking of the Wealthiest Americans in 2020*, FORBES (Sep. 8, 2020), https://www.forbes.com/profile/eric-yuan/?list=forbes-400&sh=474b78c761bf.

platform.[20] Zoom disclosed to its investors how a shift to a "platform and sales model allow[s] us to turn a single non-paying user into a full enterprise deployment."[21]

Zoom stands ready to emerge as a tech titan. But we should all be questioning whether Zoom and other tech titans expanded their empires through deception.[22] Zoom could have taken the time to ensure that its security was up to the right standards. But, in my view, Zoom saw the opportunity for massive growth by quickly leaping into the consumer market, allowing it to rapidly emerge as the new way to virtually celebrate birthdays and weddings and further solidify itself into our lives. But had Zoom followed the law, it might all be different.

Status Quo Approach to Privacy and Security Settlements

In matters like these, investigations should seek to uncover how customers were baited by any deception, how a company gained from any misconduct, and the motivations for this behavior. This approach can help shape an effective remedy. While deciding to resolve a matter through a settlement, regulators and enforcers must seek to help victims, take away gains, and fix underlying business incentives.

Of course, all settlements involve tradeoffs, but like other FTC data protection settlements, the FTC's proposed settlement with Zoom accomplishes none of these objectives. This is particularly troubling given the nature of the alleged deception. Key features of the FTC's proposed settlement include:

No help. Small businesses that purchased Zoom services or signed long-term contracts based on false representations are not even addressed in the Commission's order. They will not have the ability to be released from any contracts, seek refunds, or get credit toward future service. Similarly, Zoom's law-abiding competitors and other consumers affected by the alleged misconduct will not get anything to address how they were harmed.

No notice. The targets of deception deserve the dignity of knowing that the product they were using did not use the security features that were advertised. Notice also provides information on whether or not users need to take any specific further actions to protect themselves or their place of business. This is especially critical in cases where individuals may not know if they are affected. In this matter, Zoom's technology was integrated into white label products that may not use Zoom's brand. Notice is also helpful when victims receive no restitution.

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20 *Supra* note 16.

21 Zoom Video Communications, Inc., Quarterly Report (Form S-1) (Dec. 21, 2018), https://www.sec.gov/Archives/edgar/data/1585521/000095012318012479/filename1 htm.

22 Decision and Order, *In the Matter of Google Inc.*, Comm'n File No. 1023136 (Oct. 24, 2011), https://www.ftc.gov/sites/default/files/documents/cases/2011/03/110330googlebuzzagreeorder.pdf; Decision and Order, *In the Matter of Facebook, Inc.*, Comm'n File No. 0923184 (July 27, 2012), https://www.ftc.gov/sites/default/files/documents/cases/2012/08/120810facebookdo.pdf.

No money. In my view, the evidence is clear that Zoom obtained substantial benefits through its alleged conduct. However, the resolution includes no monetary relief at all, despite existing FTC authority to seek it in settlements when conduct is dishonest or fraudulent. If the FTC was concerned about its ability to seek adequate monetary relief, it could have partnered with state law enforcers, many of whom can seek civil penalties for this same conduct.

No fault. The Commission's order includes no findings of fact or liability. In other words, Zoom admits nothing and the Commission's investigation makes no significant conclusions. This will make it more difficult for affected parties to exercise any contractual rights or seek help through private actions.

Earlier this year, after a number of security concerns emerged, the Attorney General of New York quickly took action, and Zoom signed a voluntary compliance agreement, which requires certain third-party reports and compliance with additional standards.[23] The FTC's proposed settlement terms add some requirements to what Zoom has already agreed to with New York, largely involving additional independent monitoring and paperwork submissions. It is not clear to me that these new obligations are actually changing the way Zoom does business. In fact, Zoom may already be retaining third parties to assist with compliance as part of its contractual obligations with its largest customers.

Recommendations to Restore Credibility

To protect the public and promote fair markets, the FTC must be a credible law enforcement agency, especially when it comes to large players in digital markets. Our recent law enforcement actions raise questions that warrant careful attention if we aspire to be an effective enforcer. Below are some of the tangible steps the Commission should pursue:

1. *Strengthen orders to emphasize more help for individual consumers and small businesses, rather than more paperwork.*

When consumers and small businesses are the targets of unlawful data protection practices, the FTC's status quo approach often involves requiring the company engaged in misconduct to follow the law in the future and submit periodic paperwork. In certain orders, the Commission requires the retention of a third-party assessor, which the company might already be doing.

The FTC should focus its efforts on ensuring resolutions lead to meaningful help and assistance to affected consumers and small businesses. For example, the Commission could seek requirements that defendants respond to formal complaints and inquiries. This assists consumers while also allowing the Commission to track emerging harms and how the company is remediating them.

23 Press Release, N.Y. Att'y Gen., Attorney General James Secures New Protections, Security Safeguards for All Zoom Users (May 7, 2020), https://ag.ny.gov/press-release/2020/attorney-general-james-secures-new-protections-security-safeguards-all-zoom-users.

Another way to help affected consumers and businesses is to order releases from any long-term contractual arrangements. When customers are baited with deceptive claims, it would be appropriate to allow them to be released from any contract lock-in or otherwise amend contractual terms to make customers whole. This would also help honest competitors regain some of the market share improperly diverted by deceptive conduct.

The Commission should seek notices to affected parties, so that these individuals and businesses can determine whether they need to take any action and whether they want to continue to do business with a company that engaged in any wrongdoing.

2. Investigate firms comprehensively across the FTC's mission.

The FTC is a unique institution with legal authorities related to data protection, consumer protection, and competition, all under one roof, rather than divided up across multiple agencies. It is critical that the agency use its authority to deter unfair or deceptive conduct in conjunction with our authority to deter unfair methods of competition. The agency can do more to comprehensively use its authorities across its mission, particularly when unfair or deceptive practices can advance dominance in digital markets. When we do not, investigations may result in ineffective resolutions that fail to fix the underlying problems and may increase the likelihood of recidivism. The Commission may need to reorganize its offices and divisions to ensure investigations are comprehensive.

3. Diversify the FTC's investigative teams to increase technical rigor.

Engineers, designers, and other technical experts can offer major contributions to our investigative teams. Many of the cases previously pursued by the FTC were the result of press coverage from technical experts, especially security researchers. In fact, an independent researcher working in his private capacity was one of the first to discover a serious vulnerability in Zoom's product.[24]

Many of our peer agencies around the world approach investigations with diverse, interdisciplinary teams. Unfortunately, the Commission has deprived our litigators and enforcement attorneys of this needed expertise. The Commission should restore the role of the Chief Technologist and make a concerted effort to increase the proportion of technologists and others with technical knowledge in our investigative teams. If these individuals play meaningful leadership roles in our investigations, the agency can be much more effective.

With these technical skills and leadership in place, the Commission could proactively review the dominant digital products and services rather than primarily following up on concerning media reports after sensitive information or access has been at risk.

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24 The independent research solicited readers for contributions to assist with his work and pay off his student loans. Jonathan Leitschuh, *Zoom Zero Day: 4+ Million Webcams & maybe an RCE? Just get them to visit your website!*, INFOSEC WRITE-UPS (July 8, 2019), https://medium.com/bugbountywriteup/zoom-zero-day-4-million-webcams-maybe-an-rce-just-get-them-to-visit-your-website-ac75c83f4ef5.

4. Restate existing legal precedent into clear rules of the road and trigger monetary remedies for violations.

Markets benefit when there are simple, clear rules of the road. This allows honest businesses to know what is and is not permissible. This especially helps small businesses and startups. On the other hand, ambiguity helps large incumbents who can hire lawyers and lobbyists to sidestep their obligations. The FTC can promote fair markets by restating accepted legal precedent and past Commission experience through an agency rulemaking. These would create no new substantive obligations on market participants. But once restated and enforced, violations trigger significant monetary relief.

Under the FTC Act, the Commission has a number of authorities to seek monetary relief. While one of these authorities, Section 13(b), is under considerable scrutiny in the courts, the Commission can also seek money by restating existing legal precedent through a rulemaking. When the Commission has issued prior orders for past misconduct in the market or there is other information indicating a widespread pattern of unfair or deceptive conduct, Section 18 of the FTC Act authorizes the Commission to define what constitutes an unfair or deceptive practice by rule. Violations of these rules can trigger liability for redress, damages, penalties, and more.

Over the years, the Commission has finalized a substantial number of orders related to data protection, including privacy and data security. There have also been developments in case law in the courts. The Commission should consider restating this past precedent into a rule under Section 18 or other appropriate statutes to provide clear guidance and systematically deter unlawful data protection practices.[25]

5. Demonstrate greater willingness to pursue administrative and federal court litigation.

Congress intended for the FTC to serve as an expert agency that analyzes emerging business practices and determines whether they might be unfair or deceptive. Administrative litigation and final Commission orders can provide important guidance to the marketplace on the agency's analytical approach. It can also serve as the basis for triggering financial liability for other market actors, pursuant to the Commission's Penalty Offense Authority.[26]

Federal court litigation pursued by our staff has contributed to strong outcomes and important development of the law. For example, in 2012, the FTC took action against Wyndham Hotels, a major hospitality chain the Commission charged with employing unfair data practices.

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25 Statement of Commissioner Rohit Chopra Regarding the Report to Congress on Protecting Older Consumers, Comm'n File No. P144400 (Oct. 19, 2020), https://www.ftc.gov/system/files/documents/public_statements/1581862/p144400choprastatementolderamericansrpt.pdf.

26 *See* Rohit Chopra & Samuel A.A. Levine, *The Case for Resurrecting the FTC Act's Penalty Offense Authority* (Oct. 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256.

Wyndham Hotels waged an aggressive defense, challenging the FTC's theories before the District Court and the Third Circuit Court of Appeals. The court's ruling cemented the Commission's ability to target lax data security practices under existing law.

The public benefits from the work of the FTC's talented investigators and litigators across the agency, and as Commissioners, we should have confidence that they can hold accountable even the largest players in the economy. But recently, when it comes to data protection, FTC Commissioners have rarely voted to authorize agency staff to sue national players for misconduct. We must do more to safeguard against any perception about the agency's unwillingness to litigate.

6. Increase cooperation with international, federal, and state partners.

When it comes to data protection abuses and other harmful practices by large technology firms, these concerns are increasingly global. The FTC can use its resources more effectively and obtain superior outcomes when it cooperates with other law enforcement partners.

In the Ashley Madison matter, the FTC partnered with the Office of the Privacy Commissioner of Canada, Office of the Australian Information Commissioner, and many state attorneys general. This action was the result of significant cooperation and ultimately led to a joint resolution.[27] Unfortunately, this is too rare.

The FTC can rely on key provisions of the U.S. SAFE WEB Act that allow the FTC to share information with foreign counterparts to combat deceptive or unfair practices that cross national borders. Domestically, agencies can form multistate working groups to combine resources and leverage a diverse set of legal authorities.

In the matter before the Commission today, the conduct at issue might have also violated state laws. Additional liability triggered by these laws could have led to a resolution with a far superior outcome. Instead, other law enforcement agencies both at home and abroad will likely need to continue to scrutinize Zoom's practices, given the FTC's proposed resolution.

In addition, the Commission needs to rethink its approach to enforcing privacy promises by large technology firms related to their participation in international agreements, such as the EU-U.S. Privacy Shield Framework. Zoom's conduct may have violated key aspects of the framework, and I believe the Commission should have taken action accordingly. The Commission should now fully cooperate with our international partners to ensure that they can proceed with appropriate sanctions.

27 Press Release, Fed. Trade Comm'n, Operators of AshleyMadison.com Settle FTC, State Charges Resulting From 2015 Data Breach that Exposed 36 Million Users' Profile Information (Dec. 14, 2016), https://www ftc.gov/news-events/press-releases/2016/12/operators-ashleymadisoncom-settle-ftc-state-charges-resulting.

7. Determine whether third-party assessments are effective.

A common provision in FTC orders requires the defendant to retain a third party to monitor compliance and the company's data protection protocols. However, it is unclear whether those assessments are truly effective when it comes to deterring or uncovering misconduct. For example, in the FTC's investigation of Facebook for compliance with its privacy obligations under a 2012 Commission order, the FTC alleged major violations of the order even though an independent third party, PriceWaterhouseCoopers (PwC), was supposedly watching over the company's compliance.[28]

Additionally, the Commission's decision to not proactively make certain information about these third party reports public limits our ability to determine their effectiveness.[29] If independent researchers and journalists – often the ones who originally discovered data protection failures in the first place – had access to these reports, companies and third-party monitors might take them more seriously, which would help to fulfill the intended purpose of their efforts.

Conclusion

This year families have said their final goodbyes to loved ones over Zoom.[30] Desperate parents have propped their children in front of screens for school and hoped that they won't fall too far behind.[31] Small businesses have been turned upside down by our new way of life and have fought for a chance at survival by switching to doing business virtually.[32] But when tech companies cheat, rather than compete, and then face no meaningful accountability, all of us suffer.

I am concerned that Zoom simply thought that the FTC's law enforcement inquiry wasn't serious. That's probably why the company didn't even bother to disclose the agency's inquiry to

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28 *See* Nitasha Tiku, *Facebook's 2017 Privacy Audit Didn't Catch Cambridge Analytica*, WIRED (Apr. 19, 2018), https://www.wired.com/story/facebooks-2017-privacy-audit-didnt-catch-cambridge-analytica/; S*ee also* Dissenting Statement of Commissioner Rohit Chopra In re Facebook, Inc., Comm'n File No. 1823109 (July 24, 2019), https://www.ftc.gov/system/files/documents/public_statements/1536911/chopra_dissenting_statement_on_facebook_7-24-19.pdf.

29 Statement of Commissioner Rohit Chopra In the Matter of Uber Technologies, Inc., Comm'n File No. 1523054 (Oct. 26, 2018), https://www ftc.gov/system/files/documents/public_statements/1418195/152_3054_c-4662_uber_technologies_chopra_statement.pdf.

30 Sarah Zhang, *The Pandemic Broke End-of-Life Care*, THE ATLANTIC (June 16, 2020), https://www.theatlantic.com/health/archive/2020/06/palliative-care-covid-19-icu/613072/.

31 Heather Kelly, *Kids used to love screen time. Then schools made Zoom mandatory all day long.*, WASH. POST (Sep. 4, 2020), https://www.washingtonpost.com/technology/2020/09/04/screentime-school-distance/.

32 Justin Lahart, *Covid Is Crushing Small Businesses. That's Bad News for American Innovation.*, WALL STREET J. https://www.wsj.com/articles/covid-is-crushing-small-businesses-thats-bad-news-for-american-innovation-11602235804.

its investors.[33] The company seemed to guess that the FTC wouldn't do anything to materially impact their business. Sadly, for the public, they guessed right. Given the company's approach, efforts to hold Zoom accountable by regulators and enforcers in the U.S. and abroad will clearly need to continue.

Finally, the Federal Trade Commission has requested greater authority from Congress to protect Americans from abuse and misuse of personal data. But, actions like today's proposed settlement undermine these efforts. The agency must demonstrate that it is willing to use all of its existing tools to protect consumers and the market. Only then will the Commission be entrusted to take on more responsibilities.

It is critical that we restore the agency's credibility deficit when it comes to oversight of the digital economy. This does not stem from a lack of authority or resources or capabilities from our staff – it stems from the policy and enforcement approach of the Commission, and this needs to change.

For these reasons, I respectfully dissent.

DISSENTING STATEMENT OF COMMISSIONER REBECCA KELLY SLAUGHTER

Most weekday mornings, my two elementary-age children log on to school through Zoom. Their faces, voices, and occasional silliness are all captured in the Zoom classroom. I try not to dwell on what might occasionally float through in the background of their camera or microphone, but, like many families, we've had moments in our home where we are very much live. After my older kids settle in for class, my own workday begins in earnest and typically involves a series of confidential discussions often made possible through a Zoom meeting. My experience is not unique: Zoom expanded from 10 million daily users last December to over 300 million daily participants this spring. Zoom's overnight expansion from a modest video conferencing company to a company providing critical infrastructure for business, government, education, and social connection raises important questions for the Commission's obligations to protect consumer security and privacy.

33 Zoom Video Communications, Inc., July 2020 Quarterly Report (Form 10-Q) (Sep. 3, 2020), https://www.sec.gov/ix?doc=/Archives/edgar/data/1585521/000158552120000238/zm-20200731 htm. When publicly traded firms do not disclose to their investors that they are facing a federal law enforcement inquiry, this suggests that they do not believe the inquiry is material to their financial or operational performance.

Dissenting Statement

Years before the global pandemic would make Zoom a household name, the company made decisions that threatened the security and privacy of its longstanding core business customers. Yet the Commission's proposed settlement provides no recourse for these paying customers. When Zoom's user base rapidly expanded, its failure to prioritize privacy and security suddenly posed a much more serious risk in terms of scope and scale. This proposed settlement, however, requires Zoom only to establish procedures designed to protect user *security* and fails to impose any requirements directly protecting user *privacy*. For a company offering services such as Zoom's, users must be able to trust that the company is committed to ensuring security and privacy alike.

Because the proposed resolution fails to require Zoom to address privacy as well as security, and because it fails to require Zoom to take any steps to correct the deception we charge it perpetrated on its paying clients, I respectfully dissent.

1. Zoom's Practices

As set forth in the Commission's complaint, Zoom engaged in a series of practices that undermined the security and privacy of its users. First, we allege Zoom made multiple misrepresentations about its use of encryption. As charged in the complaint, Zoom made false statements about its encryption being "end-to-end," the level of encryption that it offered, and the time it took to store recorded meetings in an encrypted server.[1]

Zoom's problematic conduct was not limited to deception. The complaint charges that beginning in July 2018, Zoom secretly *and unfairly* deployed a web server, called the

"ZoomOpener," to circumvent certain Apple privacy and security safeguards enjoyed by Safari browser users. Because of these safeguards, Safari users who clicked on a link to join a Zoom meeting would receive an additional prompt that read, "Do you want to allow this page to open 'zoom.us'?"[2] That is until, we allege, Zoom overrode this feature through its secret ZoomOpener, which bypassed the Safari safeguard to directly launch the Zoom App.[3] The user was then automatically placed in the Zoom meeting, and, if the user had not changed her default video settings, her webcam was activated.[4]

In addition to these unfair and deceptive practices, which the Commission charged as law violations, there has been extensive public reporting on several other Zoom practices that raised serious privacy concerns. For example, Zoom business customers who subscribed to a service

1 *See* Complaint ¶¶ 16–33.

2 Complaint ¶ 35. If the user selected "Allow," the browser would connect the user to the Zoom meeting. *Id.* This safeguard was not specific to Zoom; Apple had designed its Safari browser to help defend its users from malicious actors and popular malware by requiring interaction with a dialogue box whenever any website or link attempted to launch an outside app. *Id.* at ¶ 34.

3 *Id.* at ¶ 36.

4 *Id.* at ¶ 37.

called "LinkedIn Sales Navigator" had access to LinkedIn profile data about other users in a meeting—even when the other user wished to remain anonymous.[5] Additionally, Security researchers found that Zoom-meeting video recordings saved on Zoom's cloud servers had a predictable URL structure and were thus easy to find and view.[6] And of course there was widespread coverage of "Zoom-bombing," in which uninvited users crashed Zoom meetings.[7] Zoom took steps to address these vulnerabilities after they surfaced by changing naming conventions, permanently removing the LinkedIn Sales Navigator app,[8] and requiring meeting passwords as the default setting for more Zoom users,[9] but these problems suggest Zoom's approach to user privacy was fundamentally reactive rather than proactive.

2. Lack of Privacy Protections

Too often we treat data security and privacy as distinct concerns that can be separately preserved. In reality, protecting a consumer's privacy and providing strong data security are closely intertwined, and when we solve only for one we fail to secure either. The Commission's proposed order resolving its allegations against Zoom requires the company to establish an information-security program and submit to related independent third-party assessments. These provisions strive to improve data-security practices at the company and to send a signal to others regarding the baseline for adequate data-security considerations. Nowhere, however, is consumer privacy even mentioned in these provisions. This omission reflects a failure by the majority to understand that the reason customers care about security measures in products like Zoom is that they value their privacy.

Some might argue that sound data security practices should naturally guarantee consumer privacy. I disagree. Strong security is necessary for consumer privacy, but it does not guarantee its achievement. Zoom's launch of its "ZoomOpener" to undermine the Apple Safari browser protections is an instructive example. Zoom prioritized maintaining its one-click functionality for users over privacy and security protections offered by Apple. The Commission's proposed order tries to solve for this problem solely as a security issue and makes it difficult for Zoom to bypass third-party security features in the future. But the order does not address the core problem:

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5 *See* Aaron Krolik and Natasha Singer, *A Feature on Zoom Secretly Displayed Data From People's LinkedIn Profiles*, N.Y. Times (Apr. 2, 2020), https://www.nytimes.com/2020/04/02/technology/zoom-linkedin-data html. Zoom subsequently stated that it had disabled the feature.

6 *See* Paul Wagenseil, *Zoom security issues: Here's everything that's gone wrong (so far)*, Tom's Guide (Nov. 3, 2020), https://www.tomsguide.com/news/zoom-security-privacy-woes.

7 *See* Jay Peters, *Zoom adds new security and privacy measures to prevent Zoombombing*, The Verge (Apr. 3, 2020), https://www.theverge.com/2020/4/3/21207643/zoom-security-privacy-zoombombing-passwords-waiting-rooms-default.

8 *See* Eric S. Yuan, *A Message To Our Users*, Zoom Blog (Apr. 1, 2020), https://blog.zoom.us/a-message-to-our-users/.

9 *See* Deepthi Jayarajan, *Enhanced Password Capabilities for Zoom Meetings, Webinars & Cloud Recordings*, Zoom Blog (Apr. 14, 2020), https://blog.zoom.us/enhanced-password-capabilities-for-zoom-meetings-webinars-cloud-recordings/.

Zoom's demonstrated inclination to prioritize some features, particularly ease of use, over privacy protections. Dumping Safari users automatically into a Zoom meeting, with their camera on, the first time they clicked on a link was not only a data-security failing—it was a privacy failing.

Similarly, we often discuss data encryption as a security issue, which of course it is, but we should simultaneously be recognizing it as a privacy issue. When customers choose encrypted communications, it is because they value their privacy in the content of their conversations. Treating encryption failures as a security-only issue fails to recognize the important privacy implications.

The FTC has approached privacy and security issues with related but distinct remedies: by imposing a comprehensive privacy program (as we did in *FTC v. Uber*) or by imposing a comprehensive information security program (as we did in *FTC v. Equifax*). This case provides a perfect example of a place where we ought to have required elements of both privacy and security programs. A more effective order would require Zoom to engage in a review of the risks to consumer *privacy* presented by its products and services, to implement procedures to routinely review such risks, and to build in privacy-risk mitigation before implementing any new or modified product, service, or practice. The Commission required this type of privacy-focused inquiry in the "Privacy Review Statement" provisions of its order in the *FTC v. Facebook* matter.[10] Privacy-focused provisions such as these should either be added to relevant data-privacy orders as a separate privacy program or review, or the Commission's information security programs should be modified to better integrate privacy and security.

When companies offer services with serious security and privacy implications for their users, the Commission must make sure that its orders address not only security but also privacy.

3. No Recourse for Customers

As of July 2019, Zoom had approximately 600,000 paying customers, and approximately 88% of those customers were small businesses with ten or fewer employees.[11] In securing these customers, the Commission charges that Zoom made express representations regarding its encryption offerings that were false. Yet, the proposed order does not require Zoom to take any steps to mitigate the impact of these statements we contend are false. Zoom is not required to offer redress, refunds, or even notice to its customers that material claims regarding the security of its services were false. This failure of the proposed settlement does a disservice to Zoom's customers, and substantially limits the deterrence value of the case.

10 To be clear, I am not suggesting that Zoom's conduct giving rise to this matter and Facebook's order violations are equivalents. Nor do the companies share similar business models. But in terms of the importance of consumer privacy, hundreds of millions of users are entrusting Zoom with some of their most sensitive interactions, and they are doing so from their homes.

11 Complaint ¶ 9.

Finally, I join Commissioner Chopra's call for the Commission to engage in critical reflection to strengthen our enforcement efforts regarding technology across the board—from investigation to resolution.[12]

12 Commissioner Chopra's dissenting statement sets forth an excellent list of *Recommendations and Corrective Actions* for the Commission to consider to improve the effectiveness of our enforcement efforts.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order from Zoom Video Communications, Inc. ("Zoom").

The proposed consent order ("proposed order") has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves Zoom, a videoconferencing platform provider that provides customers with videoconferencing services and various add-on services, such as cloud storage. Zoom's core product is the Zoom "Meeting," which is a platform for one-on-one and group videoconferences. Users can also, among other things, chat with others in the Meeting, share their screen, and record videoconferences.

In its proposed five-count complaint, the Commission alleges that Zoom violated Section 5(a) of the Federal Trade Commission Act. First, the proposed complaint alleges that Zoom misrepresented to users since at least June 2016 that they could secure all Meetings with end-to-end encryption. End-to-end encryption is a method of securing communications where an encrypted communication can only be deciphered by the communicating parties. No other person—not even the platform provider—can decrypt the communication because they do not possess the necessary cryptographic keys to do so. Contrary to its representations to users, Zoom did not provide end-to-end encryption for all Meetings because Zoom's servers maintained the cryptographic keys that could allow Zoom to access the content of its customers' Meetings.

Second, the proposed complaint alleges that Zoom misrepresented the level of encryption it used to secure communications between participants using Zoom's video conferencing service. Specifically, Zoom had claimed since at least June 2016 that it secured Meetings, in part, with Advanced Encryption Standard (AES) and using a 256-bit encryption key ("AES 256-bit encryption"). The 256-bit encryption key refers to the length of the key needed to decrypt the communication. Generally speaking, a longer encryption key provides more confidentiality protection than shorter keys because there are more possible key combinations, thereby making it harder to find the correct key and crack the encryption. Contrary to its representation to users, Zoom in fact secured its Meetings with AES with a 128-bit encryption key.

Third, the proposed complaint alleges that Zoom misrepresented that, for users who opted to store recordings of their Zoom Meetings in Zoom's secure cloud storage ("Cloud Recordings"), Zoom would process and store such recordings in Zoom's cloud "once the meeting has ended." Contrary to its representations to users, Zoom kept Cloud Recordings on Zoom's servers for up to 60 days, unencrypted, before transferring them to Zoom's secure cloud storage, where they are then stored encrypted.

Fourth, the proposed complaint alleges that Zoom violated Section 5 when it installed a local hosted web server (called "ZoomOpener") on 3.8 million users' Mac computers. In July

2018, Zoom updated its application for Mac desktop computers by secretly deploying a web server onto users' computers. The ZoomOpener web server was designed to circumvent a security and privacy safeguard in Apple's Safari browser. Apple had updated its Safari browser to help defend its users from malicious actors and popular malware by requiring interaction with a dialogue box when a website or link attempts to launch an outside App. As a result of the new browser safeguard, users who clicked on a link to join a Zoom Meeting would receive an additional prompt that read, "Do you want to allow this page to open 'zoom.us'?" If the user selected "Allow," the browser would connect the user to the Meeting, while clicking "Cancel" would end the interaction and prevent the Zoom application from launching. The ZoomOpener web server was designed to avoid this extra prompt. It also remained on users' computers even after users deleted the Zoom application, and would automatically reinstall the Zoom app—without any user interaction—if the user clicked on a link to join a Zoom Meeting or visited a website that had a Zoom Meeting embedded in it.

The proposed complaint alleges that it was an unfair act or practice for Zoom, without adequate notice or consent, to circumvent the Safari browser safeguard without implementing any measures to compensate for the circumvented privacy and security protections. The proposed complaint alleges that doing so caused or was likely to cause substantial injury to consumers, that consumers could not reasonably avoid themselves, and that was not outweighed by countervailing benefits to consumers or competition. Apple removed the ZoomOpener web server from users' computers through an automatic update in July 2019.

And finally, the proposed complaint alleges that Zoom violated Section 5 when it represented that it was updating its Mac application in order to resolve minor bug fixes, but failed to disclose, or failed to disclose adequately, the material information that the update would deploy the ZoomOpener web server, that the web server would circumvent a Safari browser privacy and security safeguard, or that the web server would remain on users' computers even after they had uninstalled Zoom's Mac application.

Part I of the proposed order prohibits Zoom from misrepresenting its privacy and security practices in the future. It prohibits, for example, misrepresentations about Zoom's collection, maintenance, use, deletion, or disclosure of Covered Information; the security features, or any feature that impacts a third-party security feature, included in any Meeting Service; or the extent to which Respondent otherwise maintains the privacy, security, confidentiality, or integrity of Covered Information. "Covered Information" means information from or about an individual.

Part II of the proposed order requires Zoom to establish, implement, and maintain a comprehensive information security program that protects the security, confidentiality, and integrity of Covered Information. Among other things, Zoom must implement specific security safeguards, such as a security review for all new software, a vulnerability management program for its internal networks, security training for its employees, inventorying personal information stored in its systems and implementing data deletion policies, and other specific security measures, such as proper network segmentation and remote access authentication.

Part III of the proposed order requires Zoom to obtain initial and biennial data security assessments for twenty years.

Analysis to Aid Public Comment

Part IV of the agreement requires Zoom to disclose all material facts to the assessor and prohibits Respondent from misrepresenting any fact material to the assessments required by Part III.

Part V requires Zoom to submit an annual certification from a senior corporate manager (or senior officer responsible for its information security program) that it has implemented the requirements of the Order, and is not aware of any material noncompliance that has not been corrected or disclosed to the Commission.

Part VI requires Zoom to submit a report to the Commission of its discovery of any Covered Incident. A "Covered Incident" is when any federal, state, or local law or regulation requires Zoom to notify any federal, state, or local government entity that information collected or received by Zoom from or about an individual consumer was, or is reasonably believed to have been, accessed or acquired without authorization. Video and audio content are specifically included as a type of personal information that would trigger notification.

Parts VII through X of the proposed order are reporting and compliance provisions. Part VII requires acknowledgement of the order and dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part VIII ensures notification to the FTC of changes in corporate status and mandates that the company submit an initial compliance report to the FTC. Part IX requires the company to create and retain certain documents relating to its compliance with the order. Part X mandates that the company make available to the FTC information or subsequent compliance reports, as requested.

Part XI states that the proposed order will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

Complaint

IN THE MATTER OF

PFIZER INC.,
UPJOHN INC.,
VIATRIS INC.,
MYLAN N.V.,
AND
UTAH ACQUISITION SUB INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

Docket No. C-4727; File No. 191 0182
Complaint, October 30, 2020 – Decision, January 25, 2021

This consent order addresses the combination of certain assets of Pfizer Inc. and Mylan N.V. to form Viatris Inc. The complaint alleges that the Combination, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current competition in the markets for: (1) amlodipine besylate/atorvastatin calcium tablets, (2) eplerenone tablets, (3) gatifloxacin ophthalmic solution, (4) medroxyprogesterone acetate injectable solution, (5) phenytoin chewable tablets, (6) prazosin hydrochloride ("HCl") capsules, and (7) spironolactone hydrochlorothiazide ("HCTZ") tablets in the United States. The complaint also alleges that the Combination would violate the aforementioned statutes by lessening future competition in the markets for: (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets. The consent order requires the parties to divest Upjohn's generic drug rights and assets related to six products and Mylan's rights and assets related to eplerenone tablets to Prasco, LLC. The consent order also requires prior Commission approval before Upjohn, Mylan, or Viatris may gain an interest in or exercise control over any third party's rights to (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets.

Participants

For the *Commission*: *Jasmine Y. Rosner, Danielle Sims* and *David von Nirschl.*

For the *Respondents*: *Harry T. Robins* and *Scott Stempel, Morgan, Lewis & Bockius LLP; Maggie D'Amico, Yonatan Even,* and *Christine Varney, Cravath, Swain & Moore LLP; Logan Breed, Chuck Loughlin,* and *Edith Ramirez, Hogan Lovells U.S. LLP.*

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Pfizer Inc. proposes to combine certain of its assets and liabilities, including Respondent Upjohn Inc. and Respondent Utah Acquisition Sub Inc., with Respondent Mylan N.V. to form Respondent Viatris Inc., all Respondents being corporations subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such combination, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it

appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Pfizer Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017.

2. Respondent Upjohn Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upjohn houses Pfizer's authorized generic distributor, Greenstone LLC. After the proposed transaction, Upjohn Inc. is to be renamed Viatris Inc.

3. Respondent Viatris Inc. is or will be a successor corporation of Upjohn Inc. Viatris is or will be a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

4. Respondent Mylan N.V. is a public limited liability company organized, existing, and doing business under and by virtue of the laws of the Kingdom of the Netherlands with its executive offices and principal place of business located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Mylan N.V. includes Mylan I B.V. and Mylan II B.V (collectively, "Respondent Mylan"). Mylan N.V.'s United States address for service of process is Mylan Inc., 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

5. Respondent Utah Acquisition Sub Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017.

6. Each Respondent is, and at all times relevant herein has been or will be, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and engages in business that is in or affects commerce, as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED COMBINATION

7. Pursuant to a Separation and Distribution Agreement by and between Pfizer Inc. and Upjohn Inc., dated July 29, 2019, and the Business Combination Agreement by and among Pfizer Inc., Upjohn Inc., Utah Acquisition Sub Inc., Mylan N.V., Mylan I B.V., and Mylan II B.V., dated July 29, 2019 (collectively, the "Agreements"), Respondent Pfizer will combine certain of its assets and liabilities with Respondent Mylan to form Respondent Viatris (the "Combination"). Respondent Pfizer will receive $12 billion in cash from Viatris as partial consideration in connection with the Combination, and Respondent Pfizer's shareholders will

gain an interest in Respondent Viatris. The Combination is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

8. The relevant lines of commerce in which to analyze the effects of the Combination are the development, license, manufacture, marketing, distribution, and sale of the following generic pharmaceutical products:

a. Amlodipine besylate/atorvastatin calcium tablets;

b. Eplerenone tablets;

c. Gatifloxacin ophthalmic solution;

d. Levothyroxine sodium tablets;

e. Medroxyprogesterone acetate injectable solution;

f. Phenytoin chewable tablets;

g. Prazosin hydrochloride capsules;

h. Spironolactone hydrochlorothiazide tablets;

i. Sucralfate tablets; and

j. Varenicline tartrate tablets.

9. The United States is the relevant geographic area in which to assess the competitive effects of the Combination in the relevant lines of commerce.

IV. THE STRUCTURE OF THE MARKETS

10. Amlodipine besylate/atorvastatin calcium tablets combine a calcium channel blocker to treat hypertension with a lipid-lowering agent to treat high cholesterol. Only four companies sell generic amlodipine besylate/atorvastatin calcium tablets: Greenstone, Mylan, Dr. Reddy's Laboratories Ltd., and Apotex Inc. The Combination will reduce the number of current suppliers from four to three. In all eleven strengths of amlodipine besylate/atorvastatin calcium tablets, Greenstone and Mylan account for greater than 30 percent of the market combined.

11. Eplerenone is a diuretic that is prescribed as an adjunctive therapy when treating hypertension or congestive heart failure after a heart attack. Significant sellers of eplerenone include Greenstone, Mylan, Breckenridge Pharmaceutical, Inc., and Accord Healthcare Inc. In both the 25mg and 50mg strengths, the Combination would reduce the number of significant suppliers and result in the combined entity accounting for approximately 50 percent of eplerenone tablets sold.

12. Gatifloxacin ophthalmic solution is an eye drop that treats bacterial conjunctivitis caused by susceptible strains of certain bacteria. The market for gatifloxacin has faced historical supply disruptions. Five companies supply this product today: Greenstone, Mylan, Sandoz International GmbH, Akorn, Inc., and Lupin Ltd. Together, Greenstone and Mylan account for more than 60 percent of gatifloxacin sales.

13. Levothyroxine sodium tablets are offered in a host of strengths and are prescribed to treat hypothyroidism or as an adjunct therapy for patients undergoing treatment for thyroid cancer. Suppliers for levothyroxine sodium tablets vary by strength. Should Upjohn or Greenstone launch an authorized generic of Pfizer's levothyroxine sodium branded product (Levoxyl®), the Combination would likely allow the combined entity to reduce the number of independent suppliers of some strengths of generic levothyroxine sodium tablets from three to two.

14. Medroxyprogesterone acetate is an injectable solution used to treat certain types of dysfunctional uterine bleeding. Injectable products, such as medroxyprogesterone acetate, often experience shortages and supply disruptions. Greenstone, Mylan, Amphastar Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Ltd. currently supply medroxyprogesterone acetate. Combined, Greenstone and Mylan account for more than 50 percent of the market.

15. Phenytoin chewable tablets are an anti-epileptic drug that slows down impulses in the brain that cause seizures. Only three suppliers provide phenytoin chewable tablets today: Greenstone, Mylan, and Taro Pharmaceutical Industries Ltd. The Combination would reduce the number of available suppliers and result in Greenstone and Mylan accounting for more than 40 percent of phenytoin chewable tablets sold.

16. Prazosin hydrochloride (HCl) capsules are an alpha-adrenergic blocker that treats hypertension by relaxing the veins and arteries so that blood can more easily pass. The market for prazosin HCl capsules is supplied by four companies: Greenstone, Mylan, Teva, and Novitium Pharma LLC. Across the three strengths of prazosin HCl available today, the Combination would reduce the number of available suppliers and result in the combined entity accounting for approximately half of prazosin HCl capsules sold.

17. Spironolactone hydrochlorothiazide (HCTZ) tablets are a diuretic used to treat hypertension. Only three suppliers provide spironolactone HCTZ tablets: Greenstone, Mylan, and Sun. The Combination would reduce the number of suppliers from three to two and result in Greenstone and Mylan accounting for more than 30 percent of the market.

18. Sucralfate tablets are used to treat and prevent ulcers in the small intestines. Prior to the proposed Combination, only three companies sold sucralfate tablets historically: Greenstone, Mylan, and Teva. While Mylan has stopped selling sucralfate recently, the proposed Combination likely alters Mylan's incentives to relaunch sucralfate tablets and would reduce the number of firms capable of selling sucralfate tablets from three to two.

19. Varenicline tartrate tablets are a smoking cessation aid offered under Pfizer's brand Chantix®. Currently, only branded Chantix® is available in the market. Mylan is one of a limited number of companies likely to share the Hatch-Waxman 180-day exclusivity period when the generic market forms. Should Upjohn or Greenstone launch an authorized generic of Pfizer's Chantix®, the Combination would likely allow the combined entity to reduce the small number of independent suppliers that would have sold generic varenicline tartrate tablets during the Hatch-Waxman exclusivity period absent the Combination.

V. ENTRY CONDITIONS

20. Entry into the relevant markets described in Paragraphs 10-19 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Combination. *De novo* entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Combination.

VI. EFFECTS OF THE COMBINATION

21. The effects of the Combination, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

a. by eliminating actual, direct, and substantial competition between Upjohn and Greenstone and Mylan and reducing the number of independent significant competitors in the markets for: (1) generic amlodipine besylate/atorvastatin calcium tablets; (2) generic eplerenone tablets; (3) generic gatifloxacin ophthalmic solution; (4) generic medroxyprogesterone acetate injectable solution; (5) generic phenytoin chewable tablets; (6) generic prazosin HCl capsules; and (7) generic spironolactone HCTZ tablets, thereby increasing the likelihood that: (a) Viatris would be able to unilaterally exercise market power in these markets; (b) the remaining competitors would engage in coordinated interaction between or among each other; and (c) customers would be forced to pay higher prices; and

b. by eliminating future competition between (1) Upjohn and Greenstone and (2) Mylan in the market for generic levothyroxine sodium tablets, generic sucralfate tablets, and generic varenicline tartrate tablets, thereby (a) increasing the likelihood that the combined entity would forego or delay relaunching this product, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of this product.

VII. VIOLATIONS CHARGED

22. The Combination described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

23. The Combination described in Paragraph 7, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this thirtieth day of October, 2020 issues its Complaint against said Respondents.

By the Commission, Commissioners Chopra and Slaughter dissenting.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission initiated an investigation of Respondent Pfizer Inc.'s ("Pfizer") proposal to spin off its Upjohn division and combine it with the assets of Respondent Mylan N.V. Upon consummation, the combination is expected to be renamed Viatris Inc. and will be comprised of certain legacy Pfizer assets held by Upjohn Inc. and its subsidiaries, Respondent Pfizer's Greenstone LLC business, and all of the assets of Respondent Mylan N.V. The Commission's Bureau of Competition prepared and furnished to each Respondent the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an Agreement Containing Consent Orders ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint; (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true; (3) waivers and other provisions as required by the Commission's Rules; and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and determined to accept the executed Consent Agreement to place it on the public record for a period of 30 days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

1. Respondent Pfizer Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017.

2. Respondent Upjohn Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upon completion of the combination, Upjohn Inc. is expected to be renamed Viatris Inc. and will become Respondent Viatris Inc. with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

3. Respondent Mylan N.V. is a public limited liability company organized, existing, and doing business under and by virtue of the laws of the Kingdom of the Netherlands with its executive offices and principal place of business located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Mylan N.V.'s United States address for service of process in this matter is as follows: 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

4. Respondent Utah Acquisition Sub Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upon completion of the combination, Utah Acquisition Sub Inc. will become a subsidiary of Respondent Viatris Inc. with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

I. Definitions

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and all other definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), shall apply:

A. "Decision and Order" means:

1. The proposed Decision and Order contained in the Consent Agreement in this matter, until the issuance of a final Decision and Order by the Commission; and

2. The final Decision and Order, once it is issued by the Commission in this matter.

B. "Orders" means the Decision and Order and Order to Maintain Assets.

II. Divestitures

IT IS FURTHER ORDERED that:

A. Prior to the Divestiture Date, Respondents shall provide the Acquirer with the opportunity to review Product Contracts related to each of the Divestiture Products so that the Acquirer can determine whether to assume each Product Contract;

provided, however, that in cases in which any Product Contract also relates to a Retained Product the Respondent shall, at the option of that Acquirer, assign or otherwise make available to that Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product.

B. Prior to the Divestiture Date, Respondents shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondents to divest the Divestiture Assets and to grant or assign rights to the Divestiture Products to the Acquirer, and to permit that Acquirer to continue in the related Divestiture Product Business in the United States without interruption or impairment.

C. As related to the Product Manufacturing Technology and any ingredient, material, or component used in the manufacture of the Divestiture Product, Respondents shall not enforce any agreement against a third party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the third party a license or other right to the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product. Such agreements include agreements that might limit the ability of a third party to disclose Confidential Business Information related to such Product Manufacturing Technology to the Acquirer. No later than 10 days after the Divestiture Date, Respondents shall grant a release to each third party that is subject to any such agreement that allows the third party to provide the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product to the Acquirer. Within 5 days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant third parties.

D. Respondents shall transfer the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer, with the consent of the Acquirer, or at the Acquirer's option, to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Respondent Pfizer shall be responsible for validating and qualifying the manufacture of these Products at either a facility that is retained by Respondent Pfizer after the Acquisition Date or at a facility owned or controlled by the Manufacturing Designee in order to obtain FDA Approvals to manufacture these Products from such facilities and Respondents shall bear all costs related to these transfers.

E. If, at any time during the term of the Authorized Generic Product License, the Acquirer notifies the Respondents that the Acquirer wants to move manufacturing of an Authorized Generic Product out of a facility owned or controlled by a Respondent, then such Respondent shall transfer the Product Manufacturing Technology to that Acquirer, or to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Such Respondent shall be responsible for ensuring the validation and qualification of the manufacture of these Products at the facility chosen by that Acquirer in order to obtain FDA Approvals to manufacture these Products from that facility. Such Respondent shall bear all costs related to this transfer.

F. No later than 10 days after the Divestiture Date, Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale of each of the Divestiture Products to assist the Acquirer of each of the Divestiture Products to transfer and integrate the related Divestiture Product Business.

G. No later than 10 days after the Divestiture Date, Respondents shall provide the following to the relevant Acquirer of each of the Divestiture Products:

1. A list of any finished batch or lot of the relevant Divestiture Product that any Respondent, any manufacturer for a Respondent, or regulatory Agency determined to be out-of-specification at any time during the three-year period immediately preceding the Divestiture Date, and, for each such batch or lot: (i) a detailed description of the known deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure); (ii) the corrective actions taken to remediate any cGMP deficiencies in that Divestiture Product; and (iii) to the extent known by any Respondent, the employees (whether current or former) responsible for taking such corrective actions;

2. A list by stock-keeping unit by Customer that contains the current net price per unit as packaged for sale (*i.e.*, the price net of all customer-level discounts, rebates, or promotions) for the relevant Divestiture Product for

each order sold to that Customer during the two-year period prior to the Divestiture Date;

3. A list of the inventory levels (weeks of supply) of the relevant Divestiture Product in the possession of each Customer to the extent known or available to any Respondent, as of the date prior to and closest to the Divestiture Date as is available;

4. A list of any pending reorder dates for the relevant Divestiture Product by Customer as of the Divestiture Date to the extent known by any Respondent;

5. A list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by law, to control, prohibit, or otherwise limit the use, including the use in Customer cross-referencing, of such NDC numbers by the Respondents, *unless* that Divestiture Product has not been marketed or sold in the United States prior to the Divestiture Date; and

6. The quantity and delivery terms in all unfilled Customer purchase orders for the relevant Divestiture Product as of the Divestiture Date.

H. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Product Releasees under any Patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to research and Develop, or manufacture anywhere in the world the Divestiture Product(s), or to distribute, market, sell, or offer for sale within the United States any such Divestiture Product.

I. Upon reasonable written request from the Acquirer to a Respondent, that Respondent shall provide, in a timely manner, assistance of knowledgeable employees of that Respondent (*i.e.*, employees of that Respondent that were involved in the Development of the Divestiture Products) to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a third party related to the Product Intellectual Property for the Divestiture Products acquired by that Acquirer from a Respondent. A Respondent shall make its employees available to that Acquirer for the fee provided in the relevant Divestiture Agreement, or if no fee is provided, at no greater than Direct Cost.

J. For any patent infringement suit that is filed or to be filed within the United States that is (i) filed by, or brought against, a Respondent prior to the Divestiture Date related to any Divestiture Product or (ii) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend against as of the Divestiture Date that is related to any Divestiture Product, that Respondent shall:

1. Cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of such patent infringement suit;

2. Waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any such patent infringement suit; and

3. Permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to such patent infringement suit.

III. Transition Services and Manufacturing by Respondents

IT IS FURTHER ORDERED that:

A. At the request of the Acquirer, in a timely manner, at no greater than Direct Cost or at such cost as provided in a Divestiture Agreement, Respondents shall provide transition services sufficient to enable the Acquirer of each of the Divestiture Products to operate the related Divestiture Product Business in substantially the same manner that Respondents have operated that Business prior to the Acquisition Date.

B. Upon reasonable written notice and request from the Acquirer of the rights to the Authorized Generic Products, Respondents shall manufacture, deliver and supply, or cause to be manufactured, delivered, and supplied, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, that Acquirer's requested supply of each of the Authorized Generic Products and any of the active pharmaceutical ingredients used in the Authorized Generic Products that are made by a Respondent, as applicable, hereinafter "Supplied Products." For the initial 10-year term of the Authorized Generic Agreement, the requested supply of Supplied Products shall be provided at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement.

C. The Respondents shall make representations and warranties to the Acquirer that the Supplied Products meet the relevant Agency-approved specifications.

D. The Respondents shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Supplied Products to meet cGMP, but the Respondents may make this obligation contingent upon the Acquirer giving the Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the Respondents may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such

settlement is consistent with the Respondents' responsibilities to supply the Supplied Products in the manner required by the Decision and Order;

provided further, however, that this obligation shall not require the Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondents to the Acquirer in a Divestiture Agreement.

E. The Respondents shall agree to hold harmless and indemnify the Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to deliver the Supplied Products to the Acquirer in a timely manner *unless* (i) Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents, and (ii) Respondents are able to cure the supply failure no later than 30 days after the receipt of notice from that Acquirer of a supply failure.

F. The Respondents shall give priority to supplying the Acquirer over the supplying of Products for any Respondent's own use or sale.

G. During the term of any agreement for a Respondent to supply the Supplied Products, upon written request of the Acquirer or a Monitor, the Respondent shall make available to the supplied Acquirer and a Monitor all records generated or created after the Divestiture Date that relate directly to the manufacture of the applicable Supplied Products.

H. The Respondents shall provide the Acquirer with the actual costs incurred or the price paid for active ingredients, components, and excipients the Respondents use to manufacture the applicable Supplied Products.

I. During the term of any agreement for a Respondent to supply the Supplied Products, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of each of the Supplied Products.

J. Respondents shall not be entitled to terminate any agreement to supply the Supplied Products due to (i) a breach by the Acquirer of a Divestiture Agreement, or (ii) that Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;

provided, however, that this Paragraph shall not prohibit a Respondent from seeking compensatory damages from the Acquirer for that Acquirer's breach of its payment obligations to the Respondent under the agreement.

K. The Respondents shall permit the Acquirer to terminate the agreement for the supply of the Supplied Products on a product-by-product basis, at any time, upon commercially reasonable notice, and without cost or penalty (other than costs or penalties due by the Respondent to third parties pursuant to the termination of such agreement, which may be the responsibility of that Acquirer).

L. In the event that that a Respondent becomes (i) unable to supply or produce a Supplied Product from the facility that has been supplying the Acquirer, and (ii) any Respondent has a different facility that is listed on the FDA Authorization for that Supplied Product and is still suitable for use to manufacture the Supplied Product, or any Respondent has a facility that manufactures the Therapeutic Equivalent of such Supplied Product, then such Respondent shall, at the option of the supplied Acquirer, provide a supply of either the Therapeutic Equivalent or the Supplied Product from the other facility under the same terms and conditions as contained in the Divestiture Agreement to supply.

M. During the term of any agreement for a Respondent to supply the Supplied Products, the Respondents shall provide consultation with knowledgeable employees of Respondents and training, at the written request of the supplied Acquirer and at a facility chosen by the supplied Acquirer, for the purposes of enabling that Acquirer (or its Manufacturing Designee) to obtain all Product Approvals to manufacture the applicable Supplied Products in final form in the same quality achieved by, or on behalf of, Respondents and in commercial quantities, in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of that Acquirer that its personnel (or its Manufacturing Designee's personnel) are adequately trained in the manufacture of the applicable Supplied Products.

N. For any Supplied Product that, after the Acquisition Date, is made in a facility owned by Respondent Upjohn or Respondent Viatris, Respondents shall transfer such manufacturing to a facility owned, controlled, or operated by Respondent Pfizer or, at the option of the Acquirer, to its Manufacturing Designee. Respondents shall bear all costs for this transfer including the cost to validate the Supplied Products at the changed facility and the costs for any changes in the specifications for any Supplied Product required by the FDA prior to the FDA's granting approval to market such Product from the changed site of manufacture.

O. For any Authorized Generic Product that, after the Acquisition Date, has as its source of the active pharmaceutical ingredient either Respondent Upjohn or Respondent Viatris: (i) Respondents shall give priority to supplying the active pharmaceutical ingredients for use in such Authorized Generic Product over supplying the active pharmaceutical ingredients for any Product for any Respondent's own use or sale, and (ii) at the Acquirer's option, Respondents shall bear the costs to qualify and obtain FDA regulatory approval to change the source of the active pharmaceutical ingredient(s).

IV. Asset Maintenance

IT IS FURTHER ORDERED that, until the Respondents have physically transferred the Eplerenone Divestiture Assets, granted the Authorized Generic Product License and assigned the rights to the Gatifloxacin Products to the Acquirer pursuant to Paragraph II of the Decision and Order, Respondents shall operate and maintain each of the respective Divestiture Assets and each of the respective Divestiture Product Businesses in the ordinary course of business consistent with past practices. Included in these obligations, Respondents shall:

A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses, to minimize the risk of loss of competitive potential of such Divestiture Product Businesses, to operate such Divestiture Product Businesses in a manner consistent with applicable laws and regulations, and to prevent the destruction, removal, wasting, or deterioration of any of the Divestiture Assets, except for ordinary wear and tear.

B. Not sell, transfer, encumber, or otherwise impair such Divestiture Assets, or terminate any of the operations of such Divestiture Product Businesses, other than in the ordinary course of business consistent with past practice or as prescribed in the Orders.

C. Make all payments required to be paid under any contract or lease when due, and pay all liabilities and satisfy all obligations associated with such Divestiture Product Businesses.

D. Provide such Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls, to perform routine or necessary maintenance, to repair or replace facilities and equipment, and to carry on, at least at their scheduled pace, all capital projects, business plans, promotional plans, capital expenditure plans, research and development plans, and commercial activities for such Divestiture Product Businesses.

E. Use best efforts to preserve the existing relationships and goodwill with suppliers, customers, employees, vendors, distributors, landlords, licensors, licensees, government entities, brokers, contractors, and others having business relations with such Divestiture Product Businesses.

F. Maintain the working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with such Divestiture Product Businesses, including by:

   1. Filling vacancies that occur in the regular and ordinary course of business consistent with past practice; and

   2. Not transferring any employees from such Divestiture Product Businesses to another of Respondents' businesses.

G. Maintain and preserve the Business Information of such Divestiture Product Businesses.

H. Provide the resources necessary for such Divestiture Product Businesses to respond to competition, prevent diminution in sales, and maintain its competitive strength.

I. Continue providing customary levels of support services to such Divestiture Product Businesses.

J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of such Divestiture Product Businesses, and operate such Divestiture Product Businesses in accordance and compliance with all regulatory obligations and requirements.

K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with such Divestiture Product Businesses.

Provided, *however*, Respondents may take actions that the Acquirer has requested or agreed to in writing and that has been approved in advance by a Monitor (in consultation with Commission staff), in all cases to facilitate that Acquirer's acquisition of the Divestiture Assets and rights in the Divestiture Products and consistent with the purposes of the Orders.

V. Employees

IT IS FURTHER ORDERED that:

A. Until 2 years after the Divestiture Date, Respondents shall cooperate with and assist the Acquirer to evaluate independently and offer employment to the Relevant Employees for the Divestiture Products acquired by that Acquirer.

B. Respondents shall:

1. No later than 10 days after a request from the Acquirer, provide to that Acquirer a list of all Relevant Employees and provide Employee Information for each Relevant Employee;

2. No later than 10 days after a request from the Acquirer, provide that Acquirer or its Manufacturing Designee an opportunity to meet individually and outside the presence or hearing of any employee or agent of Respondents with any of the Relevant Employees, and to make offers of employment to any of the Relevant Employees;

3. Remove any impediments within the control of Respondents that may deter Relevant Employees from accepting employment with the Acquirer

or its Manufacturing Designee, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee, and shall not make any counteroffer to a Relevant Employee who receives an offer of employment from that Acquirer or its Manufacturing Designee; *provided, however*, that nothing in the Orders shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee; and

4. Not interfere, directly or indirectly, with the hiring or employing by that Acquirer or its Manufacturing Designee of any Relevant Employees, not offer any incentive to such employees to decline employment with that Acquirer or its Manufacturing Designee, and not otherwise interfere with the recruitment of any Relevant Employees by that Acquirer.

C. Respondents shall continue to provide Relevant Employees compensation and benefits, including regularly scheduled raises and bonuses, until the Divestiture Date or as may be necessary to comply with the provisions of the Orders to provide manufacturing and supply of Divestiture Products or transition services to the Acquirer.

D. Respondents shall provide reasonable financial incentives for Relevant Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Relevant Employees by the Acquirer.

E. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and a Monitor, determines in its sole discretion that the Acquirer or its Manufacturing Designee should have the ability to interview, make offers of employment to, or hire any of Respondents' employees who were not included as Relevant Employees, but who either (i) were involved with any of the Divestiture Products, or (ii) provided manufacturing and supply of Divestiture Products or transition services to the Acquirer, then the Commission may notify Respondents that such employees are to be designated as Relevant Employees, and Paragraph IV of the Decision and Order shall apply to such employees as of that notification date.

F. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Relevant Employees who have accepted offers of employment with the Acquirer or its Manufacturing Designee to terminate his or her employment with the Acquirer or its Manufacturing Designee; *provided, however*, Respondents may:

1. Hire an employee whose employment has been terminated by the Acquirer;

2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more of Relevant Employees; and

3. Hire an employee who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of this Paragraph.

VI. Business Information

IT IS FURTHER ORDERED that:

A. Respondents shall transfer and deliver all Business Information related to a Divestiture Product Business to the Acquirer pursuant to the following:

1. Respondents shall deliver the Business Information to that Acquirer, at Respondents' expense, in good faith, in a timely manner (*i.e*. as soon as practicable, avoiding any delays in transmission), and in a manner that ensures the completeness and accuracy of all information and ensures its usefulness;

2. Pending complete delivery of all Confidential Business Information, Respondents shall provide that Acquirer with access to all Business Information and to employees who possess or are able to locate this information for the purposes of identifying the Business Information that contains Confidential Business Information and facilitating the delivery in a manner consistent with the Orders;

3. Not use, directly or indirectly, any such Confidential Business Information other than as necessary to comply with the following:

   a. The requirements of the Orders;

   b. Respondents' obligations to that Acquirer under the terms of the related Divestiture Agreements; or

   c. Applicable law;

4. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person *except* (i) that Acquirer, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent providing transition services, manufacturing Divestiture Products, or who are engaged in the transfer and delivery of the Product Manufacturing

Technology), (iii) the Commission, or (iv) a Monitor, and *except* to the extent necessary to comply with applicable law;

5. Not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information to the employees associated with the business that is being retained, owned, or controlled by a Respondent, other than those employees specifically authorized as described above;

6. Institute procedures and requirements to ensure that those employees of a Respondent that are authorized by that Acquirer to have access to such Confidential Business information:

   a. Do not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and

   b. Do not solicit, access, or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose; and

7. Take all actions necessary and appropriate to prevent access to, and the disclosure or use of, such Confidential Business Information by or to any Person(s) not authorized to access, receive, or use such information pursuant to the terms of the Orders or the Divestiture Agreements, including:

   a. Establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system or network controls and restrictions;

   b. To the extent practicable, maintaining such Confidential Business Information separate from other data or information of any Respondent; and

   c. Ensuring by other reasonable and appropriate means that such Confidential Business Information is not shared with a Respondent's personnel engaged in any Business related to the same or substantially the same type of Business as the Divestiture Products, including a Respondent's personnel engaged in the marketing and sale within the United States of Products Developed or in Development for the same or similar indications as the Divestiture Products or that use the same active pharmaceutical ingredients as the Divestiture Products.

B. As a condition of continued employment after the Divestiture Date, Respondents shall require each employee that has had responsibilities related to the marketing

or sales of the Divestiture Products within the one-year period prior to the Divestiture Date, and each employee that has responsibilities related to the Development, marketing, or sales of those Retained Products that are Developed or in Development for the same or similar indications as the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all such Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of any Respondent (other than as necessary to comply with the requirements of the Orders).

C. No later than 30 days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the above-described Confidential Business Information by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for 2 years after the Divestiture Date. Respondents shall provide a copy of their notifications to the Acquirer. Respondents shall maintain complete records of all such notifications at the respective Respondent's principal executive offices within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide that Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.

D. Each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to the Acquirer or access original documents provided to that Acquirer, except under circumstances in which copies of documents are insufficient or otherwise unavailable, and for the following purposes:

1. To assure such Respondent's compliance with any Divestiture Agreement, the Orders, any law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable government entity, or any taxation requirements; or

2. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of an Divestiture Product, the Divestiture Assets, or the Divestiture Product Business;

provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided further, however, that pursuant to this Paragraph, a Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VII. Additional Obligations

IT IS FURTHER ORDERED that, during the term of the license of any Authorized Generic Product to the Acquirer pursuant to Paragraph II of the Decision and Order, Respondent Pfizer shall retain and maintain each FDA Authorization that is the FDA Authorization for an Authorized Generic Product unless:

A. Respondent Pfizer transfers such FDA Authorization to the Acquirer;

B. The FDA requires the withdrawal of the FDA Authorization for safety or efficacy reasons;

C. Respondent Pfizer demonstrates, in consultation with that Acquirer and a Monitor, that a withdrawal of the FDA Authorization is necessary due to safety issues based on adverse events, serious adverse events, unexpected adverse events, or other pharmacovigilance reported to the FDA since the Divestiture Date; or

D. The Acquirer consents to the Respondent Pfizer's withdrawal of the FDA Authorization.

VIII. Monitor

IT IS FURTHER ORDERED that:

A. The Commission appoints F. William Rahe and William Hitchings of Quantic Regulatory Services Inc. as Monitors to observe and report on Respondents' compliance with the terms of the Orders. The Monitors shall serve pursuant to the agreement contained in the Monitor Agreement Appendix to the Orders, provided, however, such agreement shall not limit, or be construed to limit, the terms of the Monitor Paragraphs of the Orders.

B. No later than one day after the Commission issues this Order to Maintain Assets, Respondents shall:

1. Confer on the Monitors all rights, power, and authorities necessary to permit the Monitors to monitor Respondents' compliance with the terms of the Orders as set forth in the Monitor Paragraphs of the Orders; and

2. Consent to the terms and conditions regarding such rights, powers, and authorities of the Monitors set forth in the Monitor Paragraphs of the Orders.

C. The Monitors:

1. Shall have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;

2. Shall act in consultation with the Commission or its staff;

3. Shall serve as an independent third party and not as an employee, or agent of the Respondents or of the Commission;

4. Shall serve the expense of Respondents, without bond or other security;

5. May employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out that Monitor's duties and responsibilities;

6. Shall enter into a confidentiality agreement related to Commission materials and information received in connection with the performance of that Monitor's duties and each of that Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into such a confidentiality agreement;

7. Shall notify Respondents and staff of the Commission, in writing, of any potential financial, professional, personal, or other conflicts of interest within 5 days should they arise;

8. Within 30 days after this Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission, shall report in writing to the Commission regarding Respondents' compliance with their obligations under the Orders; and

9. Shall serve until that Monitor, in conjunction with Commission staff, determines that all obligations for the Respondents to provide manufacturing and supply of Divestiture Products have expired or been terminated and a final report is filed within 30-days after that date or until such other time as may be determined by the Commission or its staff.

D. Respondents shall (i) provide the Monitors full and complete access to all information and facilities, and, as necessary, make such arrangements with third parties, to allow the Monitors to monitor Respondents' compliance with its obligations under the Orders; and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitors to perform their duties pursuant to the Orders.

E. Respondents shall indemnify and hold the Monitors harmless against losses, claims, damages, liabilities, or expenses (including attorney's fees and out of pocket costs) that arise out of, or in connection with, any claim concerning the Monitors' performance of the Monitors' duties under the Orders, whether or not such claim results in liability, except, to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitors' gross negligence or willful misconduct. For purposes of this Paragraph, the term "Monitor" shall include all persons retained by the Monitors in the performance of their duties under the Orders.

F. Respondents may require the Monitors and each of the Monitors' consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement; provided, however, that such agreement does not restrict the Monitors from providing any information to the Commission.

G. Respondents shall not require nor compel the Monitors to disclose to Respondents the substance of communications with the Commission, including the Monitors' written reports submitted to the Commission, or any other Person with whom the Monitors communicate in the performance of their duties.

H. If the Commission determines that the Monitors have ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor and such substitute Monitor shall be afforded all rights, powers, and authorities and subject to all obligations of a Monitor under the Monitor Paragraphs of the Orders:

1. The Commission shall select the substitute Monitor, subject to the consent of Respondents which consent shall not be unreasonably withheld. Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor if, upon notice by staff of the Commission of the identity of the substitute Monitor to Respondents, Respondents have not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within 10 days after such notice; and

2. Not later than 5 days after the Commission appoints a substitute Monitor, Respondents shall enter into an agreement with the substitute Monitor that (i) contains substantially the same terms as the agreement attached as Monitor Agreement Appendix to the Orders or (ii) is approved by the Commission and confers on the substitute Monitor the rights, powers, and authority of a Monitor under the Monitor Paragraphs of the Orders.

I. The Commission may on its own initiative or at the request of a Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

IX. Divestiture Trustee

IT IS FURTHER ORDERED that:

A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets or the rights to the Divestiture Products as required by the Decision and Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of the Decision and Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by a Respondent to comply with the Orders.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

C. No later than 10 days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by the Decision and Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of the Orders.

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

Order to Maintain Assets

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by the Decision and Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.

2. The Divestiture Trustee shall have one year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one- year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission;

   provided, however, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by the Decision and Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to the Acquirer that receives the prior approval of the Commission as required by the Decision and Order;

   provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission;

provided further, however, that Respondents shall select such Person within 5 days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by the Decision and Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by the Decision and Order.

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement;

provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by the Decision and Order.

X. Prior Approvals

IT IS FURTHER ORDERED that:

A. Each Respondent (other than Respondent Pfizer) shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any rights or interests in the Levothyroxine Products, the Sucralfate Products or the Varenicline Products, or the Therapeutic Equivalent of any of these Products without the prior approval of the Commission.

B. Respondent Pfizer shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any voting or non-voting stock, equity, notes convertible into any voting or non-voting stock rights or interests, or debt in Respondent Viatris, Respondent Upjohn, or Respondent Mylan without the prior approval of the Commission.

XI. Compliance Reports

IT IS FURTHER ORDERED that:

A. Respondents shall:

1. Notify Commission staff via email at bccompliance@ftc.gov of the Acquisition Date and the Divestiture Dates no later than 5 days after the occurrence of each; and

2. Submit the complete copies of each of the Divestiture Agreements to the Commission at ElectronicFilings@ftc.gov and bccompliance@ftc.gov no later than 30 days after the Divestiture Date.

B. Respondents shall file verified written reports ("Compliance Reports") in accordance with the following:

1. Respondents shall submit interim Compliance Reports within 30 days after this Order to Maintain Assets is issued, and every 90 days thereafter until Respondents have completed all of the following: (i) the transfer and delivery of the Divestiture Assets and the rights to the Divestiture Products to the Acquirer, (ii) the transfer and delivery of all of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer's designated third-party contract manufacturer, (iii) the transfer and delivery of all Business Information to the Acquirer, and (iv) Respondent Pfizer or a third-party contract manufacturer (non-Respondent) designated by Pfizer is FDA approved to manufacture each of the Authorized Generic Products at a facility that is owned or controlled by Pfizer after the Acquisition Date or by Pfizer's designated third-party contract manufacturer; and Respondents shall submit annual Compliance Reports one year after the Order Date, and annually for the following 9 years on the anniversary of the Order Date; and additional Compliance Reports as the Commission or its staff may request;

2. Respondent Pfizer shall continue to submit interim Compliance Reports every 6 months regarding Respondent Pfizer's provision of manufacturing and supply of the Authorized Generic Products to the Acquirer, including a detailed explanation of any manufacturing disruptions or any failures to supply the quantity of ordered Product to that Acquirer, and any other related requirements of the Orders;

3. Each Respondent's Compliance Report shall contain sufficient information and documentation to enable the Commission to determine independently whether the Respondent is in compliance with the Orders. Conclusory statements that the Respondent has complied with its obligations under the Orders are insufficient. Respondents shall include in their Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance:

a. A detailed description of all substantive contacts, negotiations, or recommendations related to the transfer and delivery to the Acquirer of (i) the Divestiture Assets and the rights to the Divestiture Products, (ii) the Business Information related to each of the Divestiture Product Businesses, and (iii) the provision of manufacturing and supply of Authorized Generic Products to that Acquirer;

b. A detailed description of the transfer of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin

Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer's designated third-party contract manufacturer and progress toward the manufacturing of these products at a facility retained by Pfizer or Pfizer's designated third-party contract manufacturer; and

c. A detailed description of the timing for the completion of such obligations.

4. Each annual Compliance Report shall include the previous year's market information for each market alleged in the Complaint including the aggregate size of the market in units and in dollars; the monthly sales in units and in dollars for each market participant; the market share for each market participant calculated based on units and on dollars; and, to the extent known, an explanation of any significant changes in the total size of the market and any significant adverse impacts to the manufacture or supply of competing products to the market;

5. Respondents shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondents' obligations under the Orders and provide copies of these documents to Commission staff upon request.

C. Respondents shall verify each Compliance Report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or other officer or employee specifically authorized to perform this function. Respondents shall submit an original and 2 copies of each Compliance Report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall provide a copy of each Compliance Report to each Monitor.

XII. Change in Respondents

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least 30 days prior to:

A. The dissolution of: Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.;

B. Any proposed acquisition, merger, or consolidation of Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.; or

C. Any other change in Respondents including, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

XIII. Access

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with the Orders, subject to any legally recognized privilege, upon written request, and upon 5 days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. Access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with the Orders, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and

B. To interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

XIV. Purpose

IT IS FURTHER ORDERED that the purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability, and competitiveness of each of the Divestiture Product Businesses through its full transfer and delivery to the Acquirer; to minimize any risk of loss of competitive potential for each of the Divestiture Product Businesses; and to prevent the destruction, removal, wasting, deterioration, or impairment of the Eplerenone Divestiture Assets.

XV. Term

IT IS FURTHER ORDERED that, unless the Commission directs otherwise, this Order to Maintain Assets shall terminate on the earlier of:

A. 3 days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or

B. The day after all of the Eplerenone Divestiture Assets have been transferred to and are in the physical possession of the Acquirer, the rights to the Authorized Generic Products have been granted to the Acquirer, and the Gatifloxacin Products have been assigned to the Acquirer as required by and described in the Decision and Order.

By the Commission, Commissioners Chopra and Slaughter dissenting.

Order to Maintain Assets

NON-PUBLIC APPENDIX

MONITOR COMPENSATION

[cover page]

PUBLIC APPENDIX

MONITOR AGREEMENT

This Monitor Agreement ("Monitor Agreement") entered into among Quantic Regulatory Services, LLC ("Quantic"), and Mylan N.V. ("Mylan") and Pfizer Inc. ("Pfizer") (together with Mylan, the "Merging Parties"), provides as follows:

WHEREAS, the United States Federal Trade Commission (the "Commission"), in *In the Matter of Mylan N.V.*, has accepted or will shortly accept for Public Comment an *Agreement Containing Consent Orders* (the "Consent Agreement"), incorporating a Decision and Order ("Decision and Order") and an Order to Maintain Assets, with the Merging Parties (collectively, the "Orders"), which, among other things, require the Merging Parties to divest or transfer certain defined assets and maintain those assets pending such divestiture or transfer, and provide for the appointment of one or more Monitors to ensure that the Merging Parties comply with their obligations under the Orders;

WHEREAS, the Commission may appoint Quantic, and in particular William Hitchings and William Rahe, as such monitor (the "Monitor") pursuant to the Orders to monitor the Merging Parties' compliance with the terms of the Consent Agreement and Orders and with the Remedial (Divestiture) Agreement referenced in the Orders, and to monitor the efforts of the Commission-approved Acquirers (as defined in the Orders) to obtain all necessary FDA approvals, as applicable, and Quantic has consented to such appointment;

WHEREAS, the Orders further provide or will provide that the Merging Parties shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Monitor to carry out such duties and responsibilities pursuant to the Orders;

WHEREAS, this Monitor Agreement, although executed by the Monitor and the Merging Parties, is not effective for any purpose, including but not limited to imposing rights and responsibilities on the Merging Parties or the Monitor under the Orders, until it has been approved by the Commission; and

WHEREAS, the parties to this Monitor Agreement intend to be

legally bound; NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders. The term "Divestiture Products" means, individually and collectively, amlodipine besylate/atorvastatin calcium tablets, eplerenone tablets, gatifloxacin ophthalmic solution, medroxyprogesterone acetate injectable suspension, phenytoin chewable tablets, prazosin hydrochloride capsules, spironolactone/hydrochlorothiazide tablets, and mesalamine delayed release capsules, and any other Divestiture Product as required in the Orders.

Order to Maintain Assets

2. The Monitor shall have all of the powers and responsibilities conferred upon the Monitor by the Orders, including but not limited to:

   a. supervising the transfer of the Divestiture Products, including tangible assets, contracts, Product Intellectual Property and Confidential Business Information to Commission-approved Acquirers;

   b. supervising any redaction of Confidential Business Information retained by the Merging Parties as required by the Orders; and

   c. supervising the performance of any transition services, including Contract Manufacture, required by the Orders.

3. The Merging Parties hereby agrees that it will fully and promptly comply with all terms of the Orders requiring it to confer all rights, powers, authority and privileges upon the Monitor, or to impose upon itself any duties or obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor thereunder.

4. The Merging Parties further agrees that:

   a. it will use its best efforts to ensure that Prasco LLC ("Prasco") or any other Commission-approved Acquirer enters into an agreement with the Monitor at or about the Closing Date governing the facilitation of the Monitor's duties under the Orders and the exchange of information between Prasco or any other Commission-approved Acquirer and the Monitor;

   b. no later than ten (10) business days after the Commission approves this Monitor Agreement, it will provide the Monitor with the following, as applicable:

      (1) a complete inventory and description of the Divestiture Products, identifying, in particular, those Divestiture Products which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;

      (2) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Divestiture Products identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;

      (3) a complete inventory of all activities or operations worldwide that relate to the manufacture of the Products relating to the Divestiture Products, and which relate to the Merging Parties' compliance with the Orders, including processes and process

validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture;

(4) full and complete details of all dealings with any future Commission-approved Acquirer of the Divestiture Products (other than Prasco or any other entity accepted by the Commission), including copies of all correspondence and written reports of all contacts and discussions with any such future Commission-approved Acquirer and any draft and/or executed complete agreements, including any attached exhibits, schedules and appendices;

(5) a complete inventory of all Patents included in the Divestiture Products related to the manufacture or sale of the Divestiture Products in the United States, identifying actions needed to maintain such Patents and the person(s) responsible for such actions; and

(6) such other information as reasonably requested by the Monitor in order to carry out its duties and responsibilities under the Orders and Consent Agreement.

c. it will designate a senior individual as a primary contact for the Monitor and provide a written list of the principal individuals to be involved in the transitioning of the Divestiture Products to Prasco, together with their locations, telephone numbers, electronic mail addresses (if available), and responsibilities, and will provide the Monitor with written notice of any changes in such personnel occurring thereafter;

d. it will provide the Monitor with prompt notification of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Divestiture Products, and such meetings may be attended by the Monitor or its representative, at the Monitor's option or at the request of the Commission or staff of the Commission;

e. it will provide the Monitor with the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Merging Parties;

f. it will provide the Monitor with all correspondence, meeting minutes, telephone summaries, and reports, sent to or received from

the FDA relating to the Divestiture Products;

g. it will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Orders, simultaneous with the submission of such reports to the Commission;

h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, it will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as reasonably requested by the Monitor, electronic or hard copy reports to the Monitor reasonably describing the Merging Parties' activities and obligations under the Orders concerning the Divestiture Products including, without limitation to the extent applicable:

(1) all significant activities concerned with the manufacture, supply and technology transfer of the relevant Products that are identified in the Divestiture Products, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory;

(2) all minutes and records of significant meetings, action plans, and follow-ups to action plans and meetings with Prasco related to the manufacture, supply, and technology transfer of the Divestiture Products;

(3) all significant activities concerning the assistance, advice and consultation provided to Prasco generally as provided in the Decision and Order; and

(4) on request, the Merging Parties will provide the Monitor with any and all records that relate to the manufacture of the Products identified in the Divestiture Products with the right to use them to achieve the purposes of the Orders;

provided, however, that, at the time the Decision and Order becomes final, the reports described in this paragraph shall be due to the Monitor either as requested by the Monitor or within five (5) business days of the date that the Merging Parties files the Merging Parties' reports with the Commission as required pursuant to the Decision and Order;

i. it will comply with the Monitor's reasonable requests for onsite visits and audits of the Merging Parties' facilities (or any Respondent's or contract manufacturer's facility, to the extent within the Merging Parties' control) used to manufacture the Products identified in the

Divestiture Products;

j. it will comply with the Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Monitor Agreement, including, as applicable, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale and/or divestiture of any Divestiture Product(s) and, further including, actions necessary to maintain all necessary FDA approvals to manufacture and sell any of the Divestiture Products, to maintain the viability and marketability of the Divestiture Products, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Products (to the extent within the Merging Parties' control), and to prevent the destruction, removal, wasting, deterioration or impairment of the Divestiture Products, and will provide the Monitor with access to and hard copies of all other data, records or other information that the Monitor reasonably believes are necessary to the proper discharge of its responsibilities under the Orders; and

k. it will provide prompt notice of any meetings or events affecting or likely to affect the maintenance of the Divestiture Products, including, but not limited to, any and all meetings or communications with the FDA.

5. The Merging Parties shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and the Merging Parties related to the Orders or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be requested by the Monitor, of such communications.

6. The Merging Parties agrees that to the extent authorized by the Orders, the Monitor shall have the authority to employ, at the expense of the Merging Parties, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information.

7. The Merging Parties and the Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Monitor investigate and/or audit the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant to the Orders, and submit such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant

to the Orders.

8. The Monitor shall maintain the confidentiality of all information provided to the Monitor by the Merging Parties. Such information shall be used by the Monitor only in connection with the performance of the Monitor's duties pursuant to this Monitor Agreement and the Orders. Such information shall not be disclosed by the Monitor to any third party other than:

   a. persons employed by, or working with, the Monitor under this Monitor Agreement; or

   b. persons employed at the Commission and working on this matter.

9. Upon written request, the Monitor will inform the Commission and the Merging Parties of all persons employed by, or working with, the Monitor under this Monitor Agreement (other than, for the avoidance of doubt, representatives of the Commission, the Merging Parties or Prasco) to whom confidential information related to this Monitor Agreement has been disclosed.

10. Upon (i) termination of the Monitor's duties under this Monitor Agreement and the Orders, and (ii) written request by the Merging Parties, the Monitor shall promptly return to the Merging Parties all material provided to the Monitor by the Merging Parties that is confidential to the Merging Parties and that it is entitled to have returned to it under the Orders, and shall destroy any written material prepared by the Monitor that contains or reflects any confidential information of the Merging Parties, provided, that, notwithstanding the foregoing, the Monitor shall be entitled to keep one copy of such information in its confidential files and all electronic records thereof. Nothing herein shall abrogate the Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of ten (10) years after the termination of this Monitor Agreement;

11. To the extent that the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Orders, the Monitor shall ensure that, prior to being retained, such persons agree to confidentiality restrictions consistent with those set forth herein.

For the purposes of this Section and Sections 8, 9 and 10, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt or becomes known to the recipient from a source other than the Merging Parties,

or any director, officer, employee, agent, consultant or affiliate of the Merging Parties, when such source is entitled to make such disclosure to such recipient or such information was independently developed by the Monitor as evidenced by written records.

12. Nothing in this Monitor Agreement shall require the Merging Parties to disclose any material or information that is subject to a legally recognized privilege or that the Merging Parties is prohibited from disclosing by reason of law.

13. The Monitor shall be responsible for monitoring Respondents' compliance with their obligations as set forth in the Orders and the Divestiture Agreements (Remedial Agreements). In doing so, the Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or the Commission. The Monitor shall have all rights, duties, powers and authorities as required by the Orders, and nothing in the Monitor Agreement shall change, amend, modify, or otherwise limits those rights, duties, powers, and authorities. .

14. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Orders as it relates to the Merging Parties.

15. Mylan will pay the Monitor within thirty (30) days of receipt of an invoice in accordance with the fee schedule attached hereto as Confidential Exhibit A for all time spent in the performance of the Monitor's duties including all monitoring activities related to the efforts of Prasco with respect to the Divestiture Products (including any and all such activities performed prior to the date of this Monitor Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. Every six months such hourly rates should be reviewed and may be adjusted by agreement with the Merging Parties.

    a. In addition, Mylan will pay within thirty days of receipt of an invoice (i) all reasonable and customary out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, including any auto, train or air travel in the performance of the Monitor's duties, and international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties.

    b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and

any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.

c. The Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.

d. To the extent that the Monitor is requested to travel in the performance of the Monitor's duties, the Monitor shall use such travel time, to the extent practicable, to work on the FTC monitor process.

16. Mylan hereby confirms its obligation to indemnify the Monitor and hold the Monitor harmless in accordance with and to the extent required by the Orders (and, upon direction
by the Commission to the Monitor to divest any Divestiture Products).

Without in any way limiting the generality of the foregoing, Mylan shall indemnify the Monitor and any subcontractor and their respective consultants, agents, partners, principals, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses arising out of or in connection with, the performance of the Monitor's duties and obligations including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses are determined by final arbitration to result from the gross negligence or the willful misconduct of the Monitor.

17. The Monitor's maximum liability to the Merging Parties relating to services rendered pursuant to this Monitor Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the lesser of $75,000 or the total sum of the fees paid to the Monitor by the Mylan, except to the extent resulting from the gross negligence or the willful misconduct of the Monitor determined by final arbitration. IN NO CIRCUMSTANCES WHATSOEVER SHALL THE MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES.

18. The Merging Parties agrees that Mylan's obligations to indemnify the Monitor extend to any agreement that is entered between the Monitor and Prasco and relates to the Monitor's responsibilities under this Monitor Agreement and/or the Orders.

19. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Mylan shall be required, to notify Prasco and potential future Acquirers with respect to its appointment as the Monitor.

20. In the event of a disagreement or dispute between the Merging Parties and the Monitor concerning the Merging Parties' obligations under the Orders and, in the event that such disagreement or dispute cannot be resolved by the parties, either party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the case of any disagreement or dispute between the Merging Parties and the Monitor not relating to the Merging Parties' obligations under the Orders, and in the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Merging Parties' obligations pursuant to the Orders. Any fees and expenses of the arbitration shall be split between the parties.

21. This Monitor Agreement shall be subject to the substantive law of the Commonwealth of Pennsylvania (regardless of any other jurisdiction's choice of law principles).

22. This Monitor Agreement shall terminate no later than: (i) the date set forth in the relevant provision of the Orders; or (ii) on the date on which the Commission has appointed a substitute monitor pursuant to the Orders. The Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality, indemnity and limitation of liability provisions of this Monitor Agreement shall survive its termination.

23. In the event that, during the term of this Monitor Agreement, the Monitor becomes aware that it has a conflict of interest that could adversely affect the performance by the designated lead monitor for the Monitor, of any duty under this Monitor Agreement, the Monitor shall promptly inform both the Merging Parties and the Commission of such conflict.

24. It is understood that the Monitor will be serving under this Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between Monitor and the Merging Parties.

25. This Monitor Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.

26. This Monitor Agreement and the Orders contains the entire agreement between the parties hereto with respect to the matters described herein and

replaces and supersedes any and all prior agreements or understandings, whether written or oral. Any amendment, waiver, or modification of this Monitor Agreement shall not be valid unless in writing and signed by the parties, and approved by the Commission. Any such amendment, modification, or waiver may only be made in a manner consistent with the terms of the Orders. Purchase Order terms and conditions shall not be applicable.

27. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail, reputable overnight courier or fax (with acknowledgment of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Monitor, to:

Quantic Regulatory Services, LLC
Bethanne Seel
Office Manager
5N Regents Street
Suite 502
Livingston, NJ 07039

If to Mylan:

Mylan N.V.
Building 4, Trident Place
Mosquito Way, Hatfield
Hertfordshire, United Kingdom, AL10 9UL, or

1000 Mylan Boulevard, Canonsburg, PA 15317

Attention: Global General Counsel

With a copy to:

Cravath, Swaine & Moore LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019

Attention: Margaret D'Amico

If to Pfizer:

Pfizer Inc.
235 East 42nd Street

New York, New York 10017, USA

Attention: Global General Counsel

With a copy to:

Morgan, Lewis & Bockius LLP
101 Park Ave
New York, NY 10178

Attention: Harry T. Robins

If to the Commission:

Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, DC 20001
Attn.:
Telephone:
Fax:

28. This Monitor Agreement shall not become binding until it has been approved by the Commission and the Orders have been accepted for public comment.

29. This Monitor Agreement may be signed in counterparts, each of which shall be deemed an original but when taken together shall constitute one and the same agreement.

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Order to Maintain Assets

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 14th of September 2020.

Quantic Regulatory Services, LLC

Bethanne Seel
Office Manager

Mylan N.V.

Thomas D. Salus

Thomas D. Salus
Assistant Secretary

Pfizer Inc.

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Marc Brotman
Vice President & Assistant General Counsel Secretary

Order to Maintain Assets

Confidential Appendix A

DECISION

The Federal Trade Commission initiated an investigation of Respondent Pfizer Inc.'s ("Pfizer") proposal to spin off its Upjohn division and combine it with the assets of Respondent Mylan N.V. Upon consummation, the combination is expected to be renamed Viatris Inc. and will be comprised of certain legacy Pfizer assets held by Upjohn Inc. and its subsidiaries, Respondent Pfizer's Greenstone LLC business, and all of the assets of Respondent Mylan N.V. The Commission's Bureau of Competition prepared and furnished to each Respondent the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an Agreement Containing Consent Orders ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint; (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true; (3) waivers and other provisions as required by the Commission's Rules; and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the said Acts, and that a complaint should issue stating its charges in that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings, and issues the following Decision and Order ("Order"):

1. Respondent Pfizer Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017.

2. Respondent Upjohn Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upon completion of the combination, Upjohn Inc. is expected to be renamed Viatris Inc. and will become Respondent Viatris Inc. with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

3. Respondent Mylan N.V. is a public limited liability company organized, existing, and doing business under and by virtue of the laws of the Kingdom of the Netherlands with its executive offices and principal place of business located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Mylan N.V.'s United States address for service of process in this matter is as follows: 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

4. Respondent Utah Acquisition Sub Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42nd Street, New York, New York 10017. Upon completion of the combination, Utah Acquisition Sub Inc. will become a subsidiary of Respondent Viatris Inc. with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

I. Definitions

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

A. "Pfizer" means Pfizer Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Pfizer Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

B. "Upjohn" means Upjohn Inc., its directors, officers, employees, agents, representatives, successors (including Viatris Inc.), and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Upjohn Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

C. "Viatris" means Viatris Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Viatris Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

D. "Mylan" means Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Mylan N.V., and the

respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

E. "Utah Acquisition Sub" means Utah Acquisition Sub Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Utah Acquisition Sub Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

F. "Commission" means the Federal Trade Commission.

G. "Respondents" means Pfizer, Upjohn, Viatris, Mylan, and Utah Acquisition Sub.

H. "Acquirer(s)" means:

1. A Person specified by name in this Order to acquire particular assets or rights pursuant to this Order; or

2. Any other Person that the Commission approves to acquire particular assets or rights pursuant to this Order.

I. "Acquisition" means the transactions contemplated by *Separation and Distribution Agreement* by and between Pfizer Inc. and Upjohn Inc., dated as of July 29, 2019, and the *Business Combination Agreement* by and among Pfizer Inc., Upjohn Inc., Utah Acquisition Sub Inc., Mylan N.V., Mylan I B.V., and Mylan II B.V. dated as of July 29, 2019, as filed with the Commission.

J. "Acquisition Date" means the date the parties close on the *Business Combination Agreement* by and among Pfizer Inc., Upjohn Inc., Utah Acquisition Sub Inc., Mylan N.V., Mylan I B.V., and Mylan II B.V. dated as of July 29, 2019.

K. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes the FDA.

L. "Authorized Generic Products" mean the authorized generic versions of each of the following products:

1. "Medroxyprogesterone Products" mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorizations: NDA No. 02046 and NDA No. 012541, and any supplements, amendments, or revisions to these NDAs;

2. "Amlodipine/Atorvastatin Products" mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 021540, and any supplements, amendments, or revisions to this NDA;

3. "Phenytoin Products" mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: ANDA No. 084427, and any supplements, amendments, or revisions to this ANDA;

4. "Prazosin Products" mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 017442, and any supplements, amendments, or revisions to this NDA; and

5. "Spironolactone Products" mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 012616, and any supplements, amendments, or revisions to this NDA.

M. "Authorized Generic Product License" means an exclusive, royalty-free, fully paid-up right to market, promote, distribute, sell, and offer for sale a non-branded version of each of the Authorized Generic Products in the United States under the applicable FDA Authorization for a term of at least 10 years.

N. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, advertisement, importation, and sale of a Product.

O. "Business Information" means all written information, wherever located or stored, relating to or used in a Divestiture Product Business, including documents, graphic materials, and data and information in electronic format. Business Information includes records and information relating to research and development (including copies of Product Development Reports), manufacturing, process technology, engineering, product formulations, production, sales, marketing (including Product Marketing Materials), logistics, advertising, personnel, accounting, business strategy, information technology systems, customers, customer purchasing histories, customer preferences, delivery histories, delivery routing information, suppliers and all other aspects of the Divestiture Product Business. For clarity, Business Information includes any Respondent's rights and control over information and material provided by that Respondent to any other Person. Business Information includes Confidential Business Information.

P. "cGMP" means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

Q. "Confidential Business Information" means all Business Information that is not in the public domain.

R. "Customer" means any Person that is either a direct purchaser or who negotiates price on behalf of a direct purchaser (*e.g.*, group purchasing organization) of any Divestiture Product from a Respondent or the Acquirer.

S. "Development" means all new chemical entity research, and all studies of the safety or efficacy of a Product, including test method development and stability testing; toxicology; bioequivalency; bioavailability; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting studies of the safety or efficacy of a Product for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, labeling, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

T. "Direct Cost" means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Acquirer for its use of any of a Respondent's employees shall not exceed then-current average hourly wage rate for such employee.

U. "Divestiture Agreements" mean:

1. Asset Purchase Agreement by and between Mylan Pharmaceuticals Inc. and Prasco, LLC dated as of September 18, 2020; Authorized Generic License, Distribution, and Supply and Product Transfer Agreement by and between Pfizer Inc. and Prasco, LLC, dated as of September 18, 2020; Partial Assignment and Assumption Agreement by and between Upjohn US 2 LLC and Prasco, LLC, dated as of September 18, 2020; Product Transition Agreement by and between Upjohn Inc. and Prasco, LLC, dated as of September 18, 2020; Technology Transfer Agreement by and between Pfizer Inc. and Upjohn Inc. dated as of September 18, 2020; Amendment to the Form of Manufacturing and Supply Agreement between Pfizer Inc., Upjohn Inc., and Mylan N.V. dated as of September 18, 2020; Amendment No. 3 to the Separation and Distribution Agreement by and between Pfizer Inc. and Upjohn Inc. dated as of September 18, 2020; and all amendments, exhibits, attachments, agreements to the above referenced agreements; and

2. Any other agreement between a Respondent(s) and the Acquirer (or between a Divestiture Trustee and the Acquirer, or between Respondents

for the benefit of the Acquirer) that has been approved by the Commission to accomplish the requirements of this Order.

V. "Divestiture Assets" mean Respondents' equitable and legal right, title, and interests in and to all tangible and intangible assets that are not Excluded Assets, wherever located, relating to a Divestiture Product Business, including the following:

1. All Product Approvals and authorizations for the Divestiture Products, including all FDA Authorizations;

2. All studies of the safety or efficacy of the Product;

3. All Product Intellectual Property;

4. At the option of the Acquirer, Product Manufacturing Equipment;

5. All technological, scientific, chemical, biological, pharmacological, toxicological, regulatory materials and information, including studies of the safety, efficacy, stability, bioequivalency, bioavailability, and toxicology of a Product;

6. All website(s), Domain Names, and social media sites related exclusively to the Divestiture Product and the content thereon related exclusively to the Divestiture Product, and the content related exclusively to the Divestiture Product that is displayed on any website that is not dedicated exclusively to the Divestiture Product;

7. At the option of the Acquirer, Product Contracts;

8. All Business Information;

9. At the option of the Acquirer, all inventory and all ingredients, materials, or components used in the manufacture of the specified Divestiture Product in existence as of the Divestiture Date including, the active pharmaceutical ingredient(s), excipient(s), raw materials, packaging materials, work-in-process, and finished goods related to that Divestiture Product; and

10. At the option of the Acquirer, the right to fill any or all unfilled Customer purchase orders for the specified Divestiture Product as of the Divestiture Date.

W. "Divestiture Date" means the date on which a Respondent (or a Divestiture Trustee) closes on a transaction to assign, grant, license, divest, transfer, deliver,

or otherwise convey rights or assets related to a Divestiture Product to the Acquirer as required by Paragraph II of this Order.

X. "Divestiture Products" means the:

1. Authorized Generic Products;

2. Eplerenone Products; and

3. Gatifloxacin Products.

Y. "Divestiture Product Business" means the Business related to a Divestiture Product.

Z. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph X of this Order or Paragraph IX of the Order to Maintain Assets.

AA. "Domain Name" means the domain name(s) and the related uniform resource locator(s) and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration.

BB. "Employee Information" means the following, for each Relevant Employee, as and to the extent permitted by law:

1. With respect to each such employee, the following information:

a. Name, job title or position, date of hire, and effective service date;

b. Specific description of the employee's responsibilities;

c. Base salary or current wages;

d. Most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;

e. Employment status (*i.e.,* active or on leave or disability; full-time or part-time); and

f. All other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

2. At the option of the Acquirer, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the Relevant Employees.

CC. "Eplerenone Products" mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: ANDA 203896, and any supplements, amendments, or revisions to this ANDA.

DD. "Eplerenone Divestiture Assets" means all rights, title and interest in the Divestiture Product Business related to the Eplerenone Products, including all of the Divestiture Assets related to the Eplerenone Products.

EE. "Excluded Assets" mean:

1. Any real estate and the buildings and other permanent structures located on such real estate;

2. Corporate names or corporate trade dress of a Respondent or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by a Respondent or the related corporate logos thereof; or general registered images or symbols by which a Respondent can be identified or defined;

3. The portion of any Business Information that contains information about any of a Respondent's business other than a Divestiture Product Business, in those cases in which the redaction does not impair the usefulness of the information related to the Divestiture Product Business;

4. Any original document that a Respondent has a legal, contractual, or fiduciary obligation to retain the original; *provided, however,* that Respondents shall provide copies of the document to the Acquirer and shall provide that Acquirer access to the original document if copies are insufficient for regulatory or evidentiary purposes;

5. (i) Any tax asset relating to (a) the Divestiture Assets for pre-Divestiture Date tax periods or (b) any tax liability that any Respondent is responsible for arising out of the divestiture of the Divestiture Assets, (ii) all accounts receivable, notes receivable, rebates receivable and other miscellaneous receivables of any Respondent that are related to the Divestiture Product Business and arising out of the operation of the Divestiture Product Business prior to the Divestiture Date, and (iii) all cash, cash equivalents, credit cards and bank accounts of any Respondent; and

6. Any records or documents reflecting attorney-client, work product or similar privilege of any Respondent or otherwise relating to the Divestiture Assets as a result of legal counsel representing any Respondent in connection with the divestiture of the Divestiture Assets pursuant to this Order or the Divestiture Agreements.

FF. "FDA" means the United States Food and Drug Administration.

GG. "FDA Authorization(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. "FDA Authorization" also includes an "Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.

HH. "Gatifloxacin Product AG Assignment Agreement" means the Partial Assignment and Assumption Agreement by and between Upjohn US 2 LLC and Prasco, LLC, dated as of September 18, 2020.

II. "Gatifloxacin Products" mean an authorized generic version of the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA #022548, and any supplements, amendments, or revisions to this NDA.

JJ. "Levothyroxine Products" mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 021301, and any supplements, amendments, or revisions to these NDAs

KK. "Licensed Intellectual Property" means; (i) all Product Manufacturing Technology that is used (but not exclusively, predominantly, or primarily used) in the manufacture of a Divestiture Product, and (ii) copyrights used (but not exclusively, predominantly, or primarily used), to commercialize, distribute, market, advertise, or sell any Divestiture Product as of the applicable Divestiture Date.

LL. "Manufacturing Designee" means any Person other than a Respondent that has been designated by the Acquirer to perform any part of the manufacturing process, including the finish or packaging of a Divestiture Product on behalf of that Acquirer.

MM. "Monitor" means any monitor appointed pursuant to Paragraph IX of this Order or Paragraph VIII of the Order to Maintain Assets, hereinafter, Monitor Paragraphs.

NN. "NDC Number(s)" means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code and package size code for a specific Product.

OO. "Order Date" means the date on which the final Decision and Order in this matter is issued by the Commission.

PP. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.

QQ. "Orders" means this Decision and Order and the Order to Maintain Assets.

RR. "Patent(s)" means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the Divestiture Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

SS. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or government entity, and any subsidiaries, divisions, groups, or affiliates thereof.

TT. "Prasco" means (i) Prasco, LLC, a limited liability company organized, existing and doing business under the laws of the State of Ohio with its executive offices and principal place of business located at 6125 Commerce Court, Mason, Ohio 45040; and (ii) any Person controlled by or under common control of Prasco, LLC.

UU. "Product(s)" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient, or that is the subject of an FDA Authorization.

VV. "Product Approval(s)" means any approvals, registrations, permits, licenses, consents, authorizations, and other regulatory approvals, and pending applications and requests therefor, required by applicable Agencies, related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any FDA Authorization related to that Product.

WW. "Product Contracts" means all contracts, agreements, mutual understandings, arrangements, or commitments related to the Divestiture Product Business, including those:

1. Pursuant to which any third party, including a Customer, purchases, or has the option to purchase, a Product from a Respondent or negotiates the purchase price on behalf of another Customer;

2. Pursuant to which a Respondent had, or has as of the Divestiture Date, the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), from any third party for use in connection with the manufacture of a Product;

3. Relating to any study of the safety or efficacy of a Product;

4. With universities or other research institutions for the use of a Product in scientific research;

5. For the marketing of a Product or educational matters relating solely to the Products;

6. Pursuant to which a third party manufactures or plans to manufacture a Product as a finished dosage form on behalf of a Respondent;

7. Pursuant to which a third party provides or plans to provide any part of the manufacturing process, including, without limitation, the finish or packaging of a Product on behalf of a Respondent;

8. Pursuant to which a third party licenses any Product Intellectual Property or Product Manufacturing Technology related to a Product to a Respondent;

9. Pursuant to which a third party is licensed by a Respondent to use any of the Product Intellectual Property or Product Manufacturing Technology;

10. Constituting confidentiality agreements involving a Product;

11. Involving any royalty, licensing, covenant not to sue, or similar arrangement related to a Product;

12. Pursuant to which a third party provides any specialized services necessary to the research, Development, manufacture, or distribution of a Product to a Respondent including, consultation arrangements; and

13. Pursuant to which any third party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of a Product.

XX. "Product Development Reports" means information related to the Development of a Product, including:

1. Pharmacokinetic study reports;

2. Bioavailability study reports;

3. Bioequivalence study reports;

4. All correspondence, submissions, notifications, communications, registrations, or other filings made to, received from, or otherwise conducted with the FDA relating to the FDA Authorization(s);

5. Annual and periodic reports related to the above-described FDA Authorization(s), including any safety update reports;

6. FDA approved labeling or other Agency-approved labeling;

7. Currently used or planned product package inserts (including historical change of controls summaries);

8. FDA approved patient circulars;

9. Adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy;

10. Summaries of complaints from physicians or other health care providers;

11. Summaries of complaints from ultimate users of the Product;

12. Summaries of complaints from Customers;

13. Product recall reports filed with the FDA or any other Agency, and all reports, studies, and other documents related to such recalls;

14. Investigation reports and other documents related to any out of specification results for any impurities or defects found in any Product;

15. Reports from any Person (e.g., any consultant or outside contractor) engaged to investigate or perform testing for the purposes of resolving any Product or process issues, including, without limitation, identification and sources of impurities or defects;

16. Reports from vendors of the component(s), active pharmaceutical ingredient(s), excipient(s), packaging component(s), and detergent(s) used to produce any Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of any Product;

17. Analytical methods development records;

18. Manufacturing batch or lot records;

19. Stability testing records;

20. Change in control history; and

21. Executed validation and qualification protocols and reports.

YY. "Product Intellectual Property" means intellectual property of any kind (other than Licensed Intellectual Property), that is owned, licensed, held, or controlled by a Respondent as of the Divestiture Date, including Patents, patent applications, trademarks, service marks, copyrights, trade dress, commercial names, internet web sites, internet domain names, inventions, discoveries, know-how, trade secrets, and proprietary information.

ZZ. "Product Manufacturing Equipment" means equipment that is being used, or has been used to manufacture the specified Divestiture Product.

AAA. "Product Manufacturing Technology" means all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of a Product, including the following: all product specifications, processes, analytical methods, product designs, plans, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the conformance of any Product Approvals, conformance with any Agency requirements, and cGMP compliance, labeling and all other information related to the manufacturing process, and supplier lists.

BBB. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the United States as of the Divestiture Date that are owned or controlled by a Respondent, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), Customer information (including Customer net purchase information to

be provided on the basis of dollars and units for each month, quarter or year), sales forecasting models, educational materials, advertising and display materials, speaker lists, promotional and marketing materials, website content, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

CCC. "Product Releasee(s)" means any of the following Persons:

1. The Acquirer;

2. Any Person controlled by or under common control with that Acquirer;

3. Any Manufacturing Designee(s); and

4. Any licensees, sublicensees, manufacturers, suppliers, marketers, distributors, and Customers of that Acquirer, or of such Acquirer-affiliated entities, in each such case, as related to each Divestiture Product acquired by that Acquirer.

DDD. "Relevant Employees" includes:

1. Manufacturing Employees means all employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition Date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: (i) Developing and validating the commercial manufacturing process, (ii) formulating the manufacturing process performance qualification protocol, (iii) controlling the manufacturing process to assure performance Product quality, (iv) assuring that during routine manufacturing the process remains in a state of control, (v) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is capable of consistently delivering quality Products, (vi) managing the operation of the manufacturing process, or (vii) managing the transfer of the Product Manufacturing Technology to a different facility; and

2. Marketing Employees means all management-level employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: sales management, brand management, sales training, market research, or marketing and contracting with any of the following: drug wholesalers or distributers,

group purchasing organizations, pharmacy benefit organizations, managed care organizations, or hospitals, *excluding* administrative assistants.

EEE. "Retained Product(s)" means any Product(s) other than a Divestiture Product that is manufactured, in Development, marketed, sold, owned, controlled, or licensed by a Respondent anywhere in the world on or before the Acquisition Date and that has not been discontinued or permanently withdrawn from the market.

FFF. "Sucralfate Products" mean the Products in Development or manufactured anywhere in the world and authorized for marketing or sale in the United States pursuant to the following FDA Authorization: ANDA No. 074415, and any supplements, amendments, or revisions to this ANDA.

GGG. "Supply Cost" means the actual cost of materials, ingredients, packaging, direct labor, and direct overhead *excluding* any allocation or absorption of costs for excess or idle capacity, and *excluding* any intracompany transfer profits *plus* the actual cost of shipping and transportation in cases in which those costs are incurred by a Respondent.

HHH. "Technology Transfer Standards" mean requirements and standards sufficient to ensure that the information and assets required to be transferred and delivered are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, as related to the specified Divestiture Product(s), *inter alia*:

1. Designating employees or other Persons working on behalf of a Respondent knowledgeable about the Product Manufacturing Technology who will be responsible for communicating directly with the receiving Person, and a Monitor, for the purpose of effecting such delivery;

2. Preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the Product that are acceptable to the receiving Person;

3. Preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology to the receiving Person;

4. For any part of the manufacturing process that is performed by a Respondent, permitting employees of the receiving Person to visit the Respondent's facility where that process occurs for the purposes of evaluating and learning that process or discussing the process with employees of the Respondent involved in that process (including, without

limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, and methods to ensure batch or lot consistency); and

5. Providing, in a timely manner, assistance and advice to enable the receiving Person to:

a. Manufacture the Product in the quality and quantities achieved by a Respondent prior to the Acquisition Date;

b. Obtain any Product Approvals necessary for the receiving Person to manufacture the Product for the Acquirer in a manner that allows that Acquirer to distribute, market, and sell the Product in commercial quantities and to meet all Agency-approved specifications for the Product; and

c. Receive, integrate, and use all Product Manufacturing Technology used in, and all Product Intellectual Property that is related to, the manufacture of the Product.

III. "Therapeutic Equivalent" means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product or that otherwise meets the FDA's criteria for such classification.

JJJ. "Varenicline Products" mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 021928 and any supplements, amendments, or revisions to this NDA.

KKK. "United States" means the United States of America, and its territories, districts, commonwealths, and possessions.

II. Divestitures

IT IS FURTHER ORDERED that:

A. No later than 10 days after the Acquisition Date, Respondents shall, absolutely and in good faith, pursuant to the Divestiture Agreements:

1. Divest the Eplerenone Divestiture Assets and grant a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to use the related Licensed Intellectual Property in the related Divestiture Product Business to Prasco;

2. Grant the Authorized Generic Product License for each of the Authorized Generic Products to Prasco; and

3. Assign all rights granted to any Respondent to market, promote, distribute, sell, and offer for sale an authorized generic of the Gatifloxacin Products to Prasco; *provided, however* that Respondents may satisfy this requirement by providing an executed copy of a direct agreement between Prasco and the holder of the FDA Authorization of Gatifloxacin Products granting Prasco exclusive rights to market, promote, distribute, sell, and offer for sale an authorized generic of the Gatifloxacin Products;

provided, further, however, that, if within 12 months after the Order Date, the Commission determines, in consultation with the Acquirer and a Monitor, the Acquirer needs one or more Excluded Assets to operate any of the Divestiture Product Businesses in a manner that achieves the purposes of this Order, Respondents shall divest or license (as applicable) absolutely and in good faith, the needed Excluded Assets to that Acquirer.

B. With respect to the Authorized Generic Product License, Respondents shall:

1. Permit the Acquirer to terminate the license on a product-by-product basis without penalty;

2. Not terminate the license due to (i) a breach by the Acquirer, or (ii) the Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;

3. Not withdraw or discontinue the FDA Authorization for any of the Authorized Generic Products other than as permitted under this Order; and

4. Permit the Acquirer to acquire the FDA Authorization from the holder at no cost should the holder withdraw or discontinue the FDA Authorization for any reason.

C. If Respondents have divested any of the Divestiture Assets or granted or assigned rights to the Divestiture Products to the Acquirer who is named in this Order prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:

1. The named Acquirer is not an acceptable purchaser of any of the Divestiture Assets or rights related to the Divestiture Products, then Respondents shall immediately rescind the transaction with that Acquirer as directed by the Commission, and shall divest the respective Divestiture Assets or grant or assign the rights related to the Divestiture Products, as applicable, within 180 days after the Order Date, absolutely and in good faith, at no minimum price, to a different Acquirer that receives the prior

approval of the Commission, and only in a manner that receives the prior approval of the Commission; or

2. The manner in which the divestiture was accomplished is not acceptable, then Respondents shall make such modifications to the manner of divestiture of the Divestiture Assets or the grant or assignment of rights to the Divestiture Products, as applicable, to the Acquirer named in this Order (including, entering into additional agreements or arrangements) as the Commission determines are necessary to satisfy the requirements of this Order.

D. Prior to the Divestiture Date, Respondents shall provide the Acquirer with the opportunity to review Product Contracts related to each of the Divestiture Products so that the Acquirer can determine whether to assume each Product Contract;

provided, however, that in cases in which any Product Contract also relates to a Retained Product the Respondent shall, at the option of that Acquirer, assign or otherwise make available to that Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product.

E. Prior to the Divestiture Date, Respondents shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondents to divest the Divestiture Assets and to grant or assign rights to the Divestiture Products to the Acquirer, and to permit that Acquirer to continue in the related Divestiture Product Business in the United States without interruption or impairment.

F. As related to the Product Manufacturing Technology and any ingredient, material, or component used in the manufacture of the Divestiture Product, Respondents shall not enforce any agreement against a third party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the third party a license or other right to the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product. Such agreements include agreements that might limit the ability of a third party to disclose Confidential Business Information related to such Product Manufacturing Technology to the Acquirer. No later than 10 days after the Divestiture Date, Respondents shall grant a release to each third party that is subject to any such agreement that allows the third party to provide the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product to the Acquirer. Within 5 days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant third parties.

G. Respondents shall transfer the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer, with the consent of the Acquirer, or at the Acquirer's option, to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Respondent Pfizer shall be responsible for validating and qualifying the manufacture of these Products at either a facility that is retained by Respondent Pfizer after the Acquisition Date or at a facility owned or controlled by the Manufacturing Designee in order to obtain FDA Approvals to manufacture these Products from such facilities and Respondents shall bear all costs related to these transfers.

H. If, at any time during the term of the Authorized Generic Product License, the Acquirer notifies the Respondents that the Acquirer wants to move manufacturing of an Authorized Generic Product out of a facility owned or controlled by a Respondent, then such Respondent shall transfer the Product Manufacturing Technology to that Acquirer, or to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Such Respondent shall be responsible for ensuring the validation and qualification of the manufacture of these Products at the facility chosen by that Acquirer in order to obtain FDA Approvals to manufacture these Products from that facility. Such Respondent shall bear all costs related to this transfer.

I. No later than 10 days after the Divestiture Date, Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale of each of the Divestiture Products to assist the Acquirer of each of the Divestiture Products to transfer and integrate the related Divestiture Product Business.

J. No later than 10 days after the Divestiture Date, Respondents shall provide the following to the relevant Acquirer of each of the Divestiture Products:

1. A list of any finished batch or lot of the relevant Divestiture Product that any Respondent, any manufacturer for a Respondent, or regulatory Agency determined to be out-of-specification at any time during the three-year period immediately preceding the Divestiture Date, and, for each such batch or lot: (i) a detailed description of the known deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure); (ii) the corrective actions taken to remediate any cGMP deficiencies in that Divestiture Product; and (iii) to the extent known by any Respondent, the employees (whether current or former) responsible for taking such corrective actions;

2. A list by stock-keeping unit by Customer that contains the current net price per unit as packaged for sale (*i.e.*, the price net of all customer-level discounts, rebates, or promotions) for the relevant Divestiture Product for each order sold to that Customer during the two-year period prior to the Divestiture Date;

3. A list of the inventory levels (weeks of supply) of the relevant Divestiture Product in the possession of each Customer to the extent known or available to any Respondent, as of the date prior to and closest to the Divestiture Date as is available;

4. A list of any pending reorder dates for the relevant Divestiture Product by Customer as of the Divestiture Date to the extent known by any Respondent;

5. A list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by law, to control, prohibit, or otherwise limit the use, including the use in Customer cross-referencing, of such NDC numbers by the Respondents, *unless* that Divestiture Product has not been marketed or sold in the United States prior to the Divestiture Date; and

6. The quantity and delivery terms in all unfilled Customer purchase orders for the relevant Divestiture Product as of the Divestiture Date.

K. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Product Releasees under any Patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to research and Develop, or manufacture anywhere in the world the Divestiture Product(s), or to distribute, market, sell, or offer for sale within the United States any such Divestiture Product.

L. Upon reasonable written request from the Acquirer to a Respondent, that Respondent shall provide, in a timely manner, assistance of knowledgeable employees of that Respondent (*i.e.*, employees of that Respondent that were involved in the Development of the Divestiture Products) to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a third party related to the Product Intellectual Property for the Divestiture Products acquired by that Acquirer from a Respondent. A Respondent shall make its employees available to that Acquirer for the fee provided in the relevant Divestiture Agreement, or if no fee is provided, at no greater than Direct Cost.

M. For any patent infringement suit that is filed or to be filed within the United States that is (i) filed by, or brought against, a Respondent prior to the Divestiture Date related to any Divestiture Product or (ii) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend against as of

the Divestiture Date that is related to any Divestiture Product, that Respondent shall:

1. Cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of such patent infringement suit;

2. Waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any such patent infringement suit; and

3. Permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to such patent infringement suit.

III. Divestiture Agreements

IT IS FURTHER ORDERED that:

A. The Divestiture Agreements shall be incorporated by reference into this Order and made a part hereof, and any failure by a Respondent to comply with any term of the Divestiture Agreements shall constitute a violation of this Order; *provided however*, that the Divestiture Agreements shall not limit, or be construed to limit, the terms of this Order. To the extent any provision in the Divestiture Agreements varies from or conflicts with any provision in this Order such that the Respondents cannot fully comply with both, Respondents shall comply with this Order.

B. Respondents shall include in the Divestiture Agreements a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondents' obligations to the Acquirer pursuant to this Order.

C. Respondents shall not modify or amend any of the terms of any Divestiture Agreement without the prior approval of the Commission, *except* as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5).

IV. Transition Services and Manufacturing by Respondents

IT IS FURTHER ORDERED that:

A. At the request of the Acquirer, in a timely manner, at no greater than Direct Cost or at such cost as provided in a Divestiture Agreement, Respondents shall provide transition services sufficient to enable the Acquirer of each of the Divestiture Products to operate the related Divestiture Product Business in substantially the

same manner that Respondents have operated that Business prior to the Acquisition Date.

B. Upon reasonable written notice and request from the Acquirer of the rights to the Authorized Generic Products, Respondents shall manufacture, deliver and supply, or cause to be manufactured, delivered, and supplied, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, that Acquirer's requested supply of each of the Authorized Generic Products and any of the active pharmaceutical ingredients used in the Authorized Generic Products that are made by a Respondent, as applicable, hereinafter "Supplied Products." For the initial 10-year term of the Authorized Generic Agreement, the requested supply of Supplied Products shall be provided at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement.

C. The Respondents shall make representations and warranties to the Acquirer that the Supplied Products meet the relevant Agency-approved specifications.

D. The Respondents shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Supplied Products to meet cGMP, but the Respondents may make this obligation contingent upon the Acquirer giving the Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the Respondents may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondents' responsibilities to supply the Supplied Products in the manner required by this Order;

provided further, however, that this obligation shall not require the Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondents to the Acquirer in a Divestiture Agreement.

E. The Respondents shall agree to hold harmless and indemnify the Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to deliver the Supplied Products to the Acquirer in a timely manner *unless* (i) Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents, and (ii) Respondents are able to cure the supply failure no later than 30 days after the receipt of notice from that Acquirer of a supply failure.

F. The Respondents shall give priority to supplying the Acquirer over the supplying of Products for any Respondent's own use or sale.

G. During the term of any agreement for a Respondent to supply the Supplied Products, upon written request of the Acquirer or a Monitor, the Respondent shall make available to the supplied Acquirer and a Monitor all records generated or created after the Divestiture Date that relate directly to the manufacture of the applicable Supplied Products.

H. The Respondents shall provide the Acquirer with the actual costs incurred or the price paid for active ingredients, components, and excipients the Respondents use to manufacture the applicable Supplied Products.

I. During the term of any agreement for a Respondent to supply the Supplied Products, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of each of the Supplied Products.

J. Respondents shall not be entitled to terminate any agreement to supply the Supplied Products due to (i) a breach by the Acquirer of a Divestiture Agreement, or (ii) that Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;

provided, however, that this Paragraph shall not prohibit a Respondent from seeking compensatory damages from the Acquirer for that Acquirer's breach of its payment obligations to the Respondent under the agreement.

K. The Respondents shall permit the Acquirer to terminate the agreement for the supply of the Supplied Products on a product-by-product basis, at any time, upon commercially reasonable notice, and without cost or penalty (other than costs or penalties due by the Respondent to third parties pursuant to the termination of such agreement, which may be the responsibility of that Acquirer).

L. In the event that that a Respondent becomes (i) unable to supply or produce a Supplied Product from the facility that has been supplying the Acquirer, and (ii) any Respondent has a different facility that is listed on the FDA Authorization for that Supplied Product and is still suitable for use to manufacture the Supplied Product, or any Respondent has a facility that manufactures the Therapeutic Equivalent of such Supplied Product, then such Respondent shall, at the option of the supplied Acquirer, provide a supply of either the Therapeutic Equivalent or the Supplied Product from the other facility under the same terms and conditions as contained in the Divestiture Agreement to supply.

M. During the term of any agreement for a Respondent to supply the Supplied Products, the Respondents shall provide consultation with knowledgeable employees of Respondents and training, at the written request of the supplied Acquirer and at a facility chosen by the supplied Acquirer, for the purposes of enabling that Acquirer (or its Manufacturing Designee) to obtain all Product

Approvals to manufacture the applicable Supplied Products in final form in the same quality achieved by, or on behalf of, Respondents and in commercial quantities, in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of that Acquirer that its personnel (or its Manufacturing Designee's personnel) are adequately trained in the manufacture of the applicable Supplied Products.

N. For any Supplied Product that, after the Acquisition Date, is made in a facility owned by Respondent Upjohn or Respondent Viatris, Respondents shall transfer such manufacturing to a facility owned, controlled, or operated by Respondent Pfizer or, at the option of the Acquirer, to its Manufacturing Designee. Respondents shall bear all costs for this transfer including the cost to validate the Supplied Products at the changed facility and the costs for any changes in the specifications for any Supplied Product required by the FDA prior to the FDA's granting approval to market such Product from the changed site of manufacture.

O. For any Authorized Generic Product that, after the Acquisition Date, has as its source of the active pharmaceutical ingredient either Respondent Upjohn or Respondent Viatris: (i) Respondents shall give priority to supplying the active pharmaceutical ingredients for use in such Authorized Generic Product over supplying the active pharmaceutical ingredients for any Product for any Respondent's own use or sale, and (ii) at the Acquirer's option, Respondents shall bear the costs to qualify and obtain FDA regulatory approval to change the source of the active pharmaceutical ingredient(s).

V. Asset Maintenance

IT IS FURTHER ORDERED that, until the Respondents have physically transferred the Eplerenone Divestiture Assets, granted the Authorized Generic Product License and assigned the rights to the Gatifloxacin Products to the Acquirer pursuant to Paragraph II of this Order, Respondents shall operate and maintain each of the respective Divestiture Assets and each of the respective Divestiture Product Businesses in the ordinary course of business consistent with past practices. Included in these obligations, Respondents shall:

A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses, to minimize the risk of loss of competitive potential of such Divestiture Product Businesses, to operate such Divestiture Product Businesses in a manner consistent with applicable laws and regulations, and to prevent the destruction, removal, wasting, or deterioration of any of the Divestiture Assets, except for ordinary wear and tear.

B. Not sell, transfer, encumber, or otherwise impair such Divestiture Assets, or terminate any of the operations of such Divestiture Product Businesses, other than in the ordinary course of business consistent with past practice or as prescribed in the Orders.

C. Make all payments required to be paid under any contract or lease when due, and pay all liabilities and satisfy all obligations associated with such Divestiture Product Businesses.

D. Provide such Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls, to perform routine or necessary maintenance, to repair or replace facilities and equipment, and to carry on, at least at their scheduled pace, all capital projects, business plans, promotional plans, capital expenditure plans, research and development plans, and commercial activities for such Divestiture Product Businesses.

E. Use best efforts to preserve the existing relationships and goodwill with suppliers, customers, employees, vendors, distributors, landlords, licensors, licensees, government entities, brokers, contractors, and others having business relations with such Divestiture Product Businesses.

F. Maintain the working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with such Divestiture Product Businesses, including by:

1. Filling vacancies that occur in the regular and ordinary course of business consistent with past practice; and

2. Not transferring any employees from such Divestiture Product Businesses to another of Respondents' businesses.

G. Maintain and preserve the Business Information of such Divestiture Product Businesses.

H. Provide the resources necessary for such Divestiture Product Businesses to respond to competition, prevent diminution in sales, and maintain its competitive strength.

I. Continue providing customary levels of support services to such Divestiture Product Businesses.

J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of such Divestiture Product Businesses, and operate such Divestiture Product Businesses in accordance and compliance with all regulatory obligations and requirements.

K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with such Divestiture Product Businesses.

Provided, however, Respondents may take actions that the Acquirer has requested or agreed to in writing and that has been approved in advance by a Monitor (in

consultation with Commission staff), in all cases to facilitate that Acquirer's acquisition of the Divestiture Assets and rights in the Divestiture Products and consistent with the purposes of the Orders.

VI. Employees

IT IS FURTHER ORDERED that:

A. Until 2 years after the Divestiture Date, Respondents shall cooperate with and assist the Acquirer to evaluate independently and offer employment to the Relevant Employees for the Divestiture Products acquired by that Acquirer.

B. Respondents shall:

1. No later than 10 days after a request from the Acquirer, provide to that Acquirer a list of all Relevant Employees and provide Employee Information for each Relevant Employee;

2. No later than 10 days after a request from the Acquirer, provide that Acquirer or its Manufacturing Designee an opportunity to meet individually and outside the presence or hearing of any employee or agent of Respondents with any of the Relevant Employees, and to make offers of employment to any of the Relevant Employees;

3. Remove any impediments within the control of Respondents that may deter Relevant Employees from accepting employment with the Acquirer or its Manufacturing Designee, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee, and shall not make any counteroffer to a Relevant Employee who receives an offer of employment from that Acquirer or its Manufacturing Designee; *provided, however*, that nothing in the Orders shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee; and

4. Not interfere, directly or indirectly, with the hiring or employing by that Acquirer or its Manufacturing Designee of any Relevant Employees, not offer any incentive to such employees to decline employment with that Acquirer or its Manufacturing Designee, and not otherwise interfere with the recruitment of any Relevant Employees by that Acquirer.

C. Respondents shall continue to provide Relevant Employees compensation and benefits, including regularly scheduled raises and bonuses, until the Divestiture Date or as may be necessary to comply with the provisions of the Orders to

provide manufacturing and supply of Divestiture Products or transition services to the Acquirer.

D. Respondents shall provide reasonable financial incentives for Relevant Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Relevant Employees by the Acquirer.

E. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and a Monitor, determines in its sole discretion that the Acquirer or its Manufacturing Designee should have the ability to interview, make offers of employment to, or hire any of Respondents' employees who were not included as Relevant Employees, but who either (i) were involved with any of the Divestiture Products, or (ii) provided manufacturing and supply of Divestiture Products or transition services to the Acquirer, then the Commission may notify Respondents that such employees are to be designated as Relevant Employees, and Paragraph VI of this Order shall apply to such employees as of that notification date.

F. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Relevant Employees who have accepted offers of employment with the Acquirer or its Manufacturing Designee to terminate his or her employment with the Acquirer or its Manufacturing Designee; *provided, however*, Respondents may:

1. Hire an employee whose employment has been terminated by the Acquirer;

2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more of Relevant Employees; and

3. Hire an employee who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of this Paragraph.

VII. Business Information

IT IS FURTHER ORDERED that:

A. Respondents shall transfer and deliver all Business Information related to a Divestiture Product Business to the Acquirer pursuant to the following:

1. Respondents shall deliver the Business Information to that Acquirer, at Respondents' expense, in good faith, in a timely manner (*i.e.* as soon as practicable, avoiding any delays in transmission), and in a manner that

ensures the completeness and accuracy of all information and ensures its usefulness;

2. Pending complete delivery of all Confidential Business Information, Respondents shall provide that Acquirer with access to all Business Information and to employees who possess or are able to locate this information for the purposes of identifying the Business Information that contains Confidential Business Information and facilitating the delivery in a manner consistent with the Orders;

3. Not use, directly or indirectly, any such Confidential Business Information other than as necessary to comply with the following:

   a. The requirements of the Orders;

   b. Respondents' obligations to that Acquirer under the terms of the related Divestiture Agreements; or

   c. Applicable law;

4. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person *except* (i) that Acquirer, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent providing transition services, manufacturing Divestiture Products, or who are engaged in the transfer and delivery of the Product Manufacturing Technology), (iii) the Commission, or (iv) a Monitor, and *except* to the extent necessary to comply with applicable law;

5. Not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information to the employees associated with the business that is being retained, owned, or controlled by a Respondent, other than those employees specifically authorized as described above;

6. Institute procedures and requirements to ensure that those employees of a Respondent that are authorized by that Acquirer to have access to such Confidential Business information:

   a. Do not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and

   b. Do not solicit, access, or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose; and

7. Take all actions necessary and appropriate to prevent access to, and the disclosure or use of, such Confidential Business Information by or to any Person(s) not authorized to access, receive, or use such information pursuant to the terms of the Orders or the Divestiture Agreements, including:

   a. Establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system or network controls and restrictions;

   b. To the extent practicable, maintaining such Confidential Business Information separate from other data or information of any Respondent; and

   c. Ensuring by other reasonable and appropriate means that such Confidential Business Information is not shared with a Respondent's personnel engaged in any Business related to the same or substantially the same type of Business as the Divestiture Products, including a Respondent's personnel engaged in the marketing and sale within the United States of Products Developed or in Development for the same or similar indications as the Divestiture Products or that use the same active pharmaceutical ingredients as the Divestiture Products.

B. As a condition of continued employment after the Divestiture Date, Respondents shall require each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one-year period prior to the Divestiture Date, and each employee that has responsibilities related to the Development, marketing, or sales of those Retained Products that are Developed or in Development for the same or similar indications as the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all such Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of any Respondent (other than as necessary to comply with the requirements of the Orders).

C. No later than 30 days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the above-described Confidential Business Information by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for 2

years after the Divestiture Date. Respondents shall provide a copy of their notifications to the Acquirer. Respondents shall maintain complete records of all such notifications at the respective Respondent's principal executive offices within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide that Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.

D. Each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to the Acquirer or access original documents provided to that Acquirer, except under circumstances in which copies of documents are insufficient or otherwise unavailable, and for the following purposes:

1. To assure such Respondent's compliance with any Divestiture Agreement, the Orders, any law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable government entity, or any taxation requirements; or

2. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of an Divestiture Product, the Divestiture Assets, or the Divestiture Product Business;

provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided further, however, that pursuant to this Paragraph, a Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VIII. Additional Obligations

IT IS FURTHER ORDERED that, during the term of the license of any Authorized Generic Product to the Acquirer pursuant to Paragraph II of this Order, Respondent Pfizer shall retain and maintain each FDA Authorization that is the FDA Authorization for an Authorized Generic Product unless:

A. Respondent Pfizer transfers such FDA Authorization to the Acquirer;

B. The FDA requires the withdrawal of the FDA Authorization for safety or efficacy reasons;

C. Respondent Pfizer demonstrates, in consultation with that Acquirer and a Monitor, that a withdrawal of the FDA Authorization is necessary due to safety issues based on adverse events, serious adverse events, unexpected adverse events, or other pharmacovigilance reported to the FDA since the Divestiture Date; or

D. The Acquirer consents to the Respondent Pfizer's withdrawal of the FDA Authorization.

IX. Monitor

IT IS FURTHER ORDERED that:

A. The Commission appoints F. William Rahe and William Hitchings of Quantic Regulatory Services Inc. as Monitors to observe and report on Respondents' compliance with the terms of the Orders. The Monitors shall serve pursuant to the agreement contained in the Monitor Agreement Appendix to the Orders, *provided, however*, such agreement shall not limit, or be construed to limit, the terms of the Monitor Paragraphs of the Orders.

B. No later than one day after the Commission issues the Order to Maintain Assets, Respondents shall:

1. Confer on the Monitors all rights, power, and authorities necessary to permit the Monitors to monitor Respondents' compliance with the terms of the Orders as set forth in the Monitor Paragraphs of the Orders; and

2. Consent to the terms and conditions regarding such rights, powers, and authorities of the Monitors set forth in the Monitor Paragraphs of the Orders.

C. The Monitors:

1. Shall have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;

2. Shall act in consultation with the Commission or its staff;

3. Shall serve as an independent third party and not as an employee, or agent of the Respondents or of the Commission;

4. Shall serve the expense of Respondents, without bond or other security;

5. May employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out that Monitor's duties and responsibilities;

6. Shall enter into a confidentiality agreement related to Commission materials and information received in connection with the performance of that Monitor's duties and each of that Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into such a confidentiality agreement;

7. Shall notify Respondents and staff of the Commission, in writing, of any potential financial, professional, personal, or other conflicts of interest within 5 days should they arise;

8. Within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission, shall report in writing to the Commission regarding Respondents' compliance with their obligations under the Orders; and

9. Shall serve until that Monitor, in conjunction with Commission staff, determines that all obligations for the Respondents to provide manufacturing and supply of Divestiture Products have expired or been terminated and a final report is filed within 30-days after that date or until such other time as may be determined by the Commission or its staff.

D. Respondents shall (i) provide the Monitors full and complete access to all information and facilities, and, as necessary, make such arrangements with third parties, to allow the Monitors to monitor Respondents' compliance with its obligations under the Orders; and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitors to perform their duties pursuant to the Orders.

E. Respondents shall indemnify and hold the Monitors harmless against losses, claims, damages, liabilities, or expenses (including attorney's fees and out of pocket costs) that arise out of, or in connection with, any claim concerning the Monitors' performance of the Monitors' duties under the Orders, whether or not such claim results in liability, *except*, to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitors' gross negligence or willful misconduct. For purposes of this Paragraph, the term "Monitor" shall include all persons retained by the Monitors in the performance of their duties under the Orders.

F. Respondents may require the Monitors and each of the Monitors' consultants, accountants, attorneys, and other representatives and assistants to enter into a

customary confidentiality agreement; *provided, however,* that such agreement does not restrict the Monitors from providing any information to the Commission.

G. Respondents shall not require nor compel the Monitors to disclose to Respondents the substance of communications with the Commission, including the Monitors' written reports submitted to the Commission, or any other Person with whom the Monitors communicate in the performance of their duties.

H. If the Commission determines that the Monitors have ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor and such substitute Monitor shall be afforded all rights, powers, and authorities and subject to all obligations of a Monitor under the Monitor Paragraphs of the Orders:

1. The Commission shall select the substitute Monitor, subject to the consent of Respondents which consent shall not be unreasonably withheld. Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor if, upon notice by staff of the Commission of the identity of the substitute Monitor to Respondents, Respondents have not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within 10 days after such notice; and

2. Not later than 5 days after the Commission appoints a substitute Monitor, Respondents shall enter into an agreement with the substitute Monitor that (i) contains substantially the same terms as the agreement attached as Monitor Agreement Appendix to the Orders or (ii) is approved by the Commission and confers on the substitute Monitor the rights, powers, and authority of a Monitor under the Monitor Paragraphs of the Orders.

I. The Commission may on its own initiative or at the request of a Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

X. Divestiture Trustee

IT IS FURTHER ORDERED that:

A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets or the rights to the Divestiture Products as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither

the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by a Respondent to comply with the Orders.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

C. No later than 10 days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.

2. The Divestiture Trustee shall have one year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one- year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission;

   provided, however, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books,

records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to the Acquirer that receives the prior approval of the Commission as required by this Order;

provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission;

provided further, however, that Respondents shall select such Person within 5 days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement;

provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

XI. Prior Approvals

IT IS FURTHER ORDERED that,

A. Each Respondent (other than Respondent Pfizer) shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any rights or interests in

the Levothyroxine Products, the Sucralfate Products or the Varenicline Products, or the Therapeutic Equivalent of any of these Products without the prior approval of the Commission.

B. Respondent Pfizer shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any voting or non-voting stock, equity, notes convertible into any voting or non-voting stock rights or interests, or debt in Respondent Viatris, Respondent Upjohn, or Respondent Mylan without the prior approval of the Commission.

XII. Compliance Reports

IT IS FURTHER ORDERED that:

A. Respondents shall:

1. Notify Commission staff via email at bccompliance@ftc.gov of the Acquisition Date and the Divestiture Dates no later than 5 days after the occurrence of each; and

2. Submit the complete copies of each of the Divestiture Agreements to the Commission at ElectronicFilings@ftc.gov and bccompliance@ftc.gov no later than 30 days after the Divestiture Date.

B. Respondents shall file verified written reports ("Compliance Reports") in accordance with the following:

1. Respondents shall submit interim Compliance Reports within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter until Respondents have completed all of the following: (i) the transfer and delivery of the Divestiture Assets and the rights to the Divestiture Products to the Acquirer, (ii) the transfer and delivery of all of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer's designated third-party contract manufacturer, (iii) the transfer and delivery of all Business Information to the Acquirer, and (iv) Respondent Pfizer or a third-party contract manufacturer (non-Respondent) designated by Pfizer is FDA approved to manufacture each of the Authorized Generic Products at a facility that is owned or controlled by Pfizer after the Acquisition Date or by Pfizer's designated third-party contract manufacturer; and Respondents shall submit annual Compliance Reports one year after the Order Date, and annually for the following 9 years on the anniversary of the Order Date; and additional Compliance Reports as the Commission or its staff may request;

2. Respondent Pfizer shall continue to submit interim Compliance Reports every 6 months regarding Respondent Pfizer's provision of manufacturing and supply of the Authorized Generic Products to the Acquirer, including a detailed explanation of any manufacturing disruptions or any failures to supply the quantity of ordered Product to that Acquirer, and any other related requirements of the Orders;

3. Each Respondent's Compliance Report shall contain sufficient information and documentation to enable the Commission to determine independently whether the Respondent is in compliance with the Orders. Conclusory statements that the Respondent has complied with its obligations under the Orders are insufficient. Respondents shall include in their Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance:

   a. A detailed description of all substantive contacts, negotiations, or recommendations related to the transfer and delivery to the Acquirer of (i) the Divestiture Assets and the rights to the Divestiture Products, (ii) the Business Information related to each of the Divestiture Product Businesses, and (iii) the provision of manufacturing and supply of Authorized Generic Products to that Acquirer;

   b. A detailed description of the transfer of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer's designated third-party contract manufacturer and progress toward the manufacturing of these products at a facility retained by Pfizer or Pfizer's designated third-party contract manufacturer; and

   c. A detailed description of the timing for the completion of such obligations.

4. Each annual Compliance Report shall include the previous year's market information for each market alleged in the Complaint including the aggregate size of the market in units and in dollars; the monthly sales in units and in dollars, separately for each strength, for each market participant; the market share for each market participant calculated based on units and on dollars; and, to the extent known, an explanation of any significant changes in the total size of the market and any significant adverse impacts to the manufacture or supply of competing products to the market;

5. Respondents shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling

Respondents' obligations under the Orders and provide copies of these documents to Commission staff upon request.

C. Respondents shall verify each Compliance Report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or other officer or employee specifically authorized to perform this function. Respondents shall submit an original and 2 copies of each Compliance Report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall provide a copy of each Compliance Report to each Monitor.

XIII. Change in Respondents

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least 30 days prior to:

A. The dissolution of: Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.;

B. Any proposed acquisition, merger, or consolidation of Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.; or

C. Any other change in Respondents including, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

XIV. Access

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with the Orders, subject to any legally recognized privilege, upon written request, and upon 5 days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. Access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with the Orders, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and

B. To interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

XV. Purpose

IT IS FURTHER ORDERED that the purpose of this Order is to remedy in a timely and sufficient manner the lessening of competition as alleged in the Commission's Complaint by:

A. Ensuring that the Acquirer can continue to use the Divestiture Assets and rights in the Divestiture Products granted or assigned pursuant to this Order for the purposes of each of the respective Divestiture Product Businesses within the United States; and

B. Creating a viable and effective competitor in the respective Divestiture Product Businesses within the United States.

XVI. Term

IT IS FURTHER ORDERED that this Order shall terminate on January 25, 2031.

By the Commission, Acting Chairwoman Slaughter and Commissioner Chopra dissenting.

NON-PUBLIC APPENDIX I

AGREEMENTS RELATED TO THE DIVESTITURES

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NON-PUBLIC APPENDIX

MONITOR COMPENSATION

[cover page]

PUBLIC APPENDIX

MONITOR AGREEMENT

This Monitor Agreement ("Monitor Agreement") entered into among Quantic Regulatory Services, LLC ("Quantic"), and Mylan N.V. ("Mylan") and Pfizer Inc. ("Pfizer") (together with Mylan, the "Merging Parties"), provides as follows:

WHEREAS, the United States Federal Trade Commission (the "Commission"), in *In the Matter of Mylan N.V.*, has accepted or will shortly accept for Public Comment an *Agreement Containing Consent Orders* (the "Consent Agreement"), incorporating a Decision and Order ("Decision and Order") and an Order to Maintain Assets, with the Merging Parties (collectively, the "Orders"), which, among other things, require the Merging Parties to divest or transfer certain defined assets and maintain those assets pending such divestiture or transfer, and provide for the appointment of one or more Monitors to ensure that the Merging Parties comply with their obligations under the Orders;

WHEREAS, the Commission may appoint Quantic, and in particular William Hitchings and William Rahe, as such monitor (the "Monitor") pursuant to the Orders to monitor the Merging Parties' compliance with the terms of the Consent Agreement and Orders and with the Remedial (Divestiture) Agreement referenced in the Orders, and to monitor the efforts of the Commission-approved Acquirers (as defined in the Orders) to obtain all necessary FDA approvals, as applicable, and Quantic has consented to such appointment;

WHEREAS, the Orders further provide or will provide that the Merging Parties shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Monitor to carry out such duties and responsibilities pursuant to the Orders;

WHEREAS, this Monitor Agreement, although executed by the Monitor and the Merging Parties, is not effective for any purpose, including but not limited to imposing rights and responsibilities on the Merging Parties or the Monitor under the Orders, until it has been approved by the Commission; and

WHEREAS, the parties to this Monitor Agreement intend to be

legally bound; NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders. The term "Divestiture Products" means, individually and collectively, amlodipine besylate/atorvastatin calcium tablets, eplerenone tablets, gatifloxacin ophthalmic solution, medroxyprogesterone acetate injectable suspension, phenytoin chewable tablets, prazosin hydrochloride capsules, spironolactone/hydrochlorothiazide tablets, and mesalamine delayed release capsules, and any other Divestiture Product as required in the Orders.

2. The Monitor shall have all of the powers and responsibilities conferred upon the Monitor by the Orders, including but not limited to:

   a. supervising the transfer of the Divestiture Products, including tangible assets, contracts, Product Intellectual Property and Confidential Business Information to Commission-approved Acquirers;

   b. supervising any redaction of Confidential Business Information retained by the Merging Parties as required by the Orders; and

   c. supervising the performance of any transition services, including Contract Manufacture, required by the Orders.

3. The Merging Parties hereby agrees that it will fully and promptly comply with all terms of the Orders requiring it to confer all rights, powers, authority and privileges upon the Monitor, or to impose upon itself any duties or obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor thereunder.

4. The Merging Parties further agrees that:

   a. it will use its best efforts to ensure that Prasco LLC ("Prasco") or any other Commission-approved Acquirer enters into an agreement with the Monitor at or about the Closing Date governing the facilitation of the Monitor's duties under the Orders and the exchange of information between Prasco or any other Commission-approved Acquirer and the Monitor;

   b. no later than ten (10) business days after the Commission approves this Monitor Agreement, it will provide the Monitor with the following, as applicable:

      (1) a complete inventory and description of the Divestiture Products, identifying, in particular, those Divestiture Products which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;

      (2) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Divestiture Products identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;

      (3) a complete inventory of all activities or operations worldwide that relate to the manufacture of the Products relating to the Divestiture Products, and which relate to the Merging Parties' compliance with the Orders, including processes and process

validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture;

(4) full and complete details of all dealings with any future Commission-approved Acquirer of the Divestiture Products (other than Prasco or any other entity accepted by the Commission), including copies of all correspondence and written reports of all contacts and discussions with any such future Commission-approved Acquirer and any draft and/or executed complete agreements, including any attached exhibits, schedules and appendices;

(5) a complete inventory of all Patents included in the Divestiture Products related to the manufacture or sale of the Divestiture Products in the United States, identifying actions needed to maintain such Patents and the person(s) responsible for such actions; and

(6) such other information as reasonably requested by the Monitor in order to carry out its duties and responsibilities under the Orders and Consent Agreement.

c. it will designate a senior individual as a primary contact for the Monitor and provide a written list of the principal individuals to be involved in the transitioning of the Divestiture Products to Prasco, together with their locations, telephone numbers, electronic mail addresses (if available), and responsibilities, and will provide the Monitor with written notice of any changes in such personnel occurring thereafter;

d. it will provide the Monitor with prompt notification of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Divestiture Products, and such meetings may be attended by the Monitor or its representative, at the Monitor's option or at the request of the Commission or staff of the Commission;

e. it will provide the Monitor with the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Merging Parties;

f. it will provide the Monitor with all correspondence, meeting minutes, telephone summaries, and reports, sent to or received from

the FDA relating to the Divestiture Products;

g. it will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Orders, simultaneous with the submission of such reports to the Commission;

h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, it will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as reasonably requested by the Monitor, electronic or hard copy reports to the Monitor reasonably describing the Merging Parties' activities and obligations under the Orders concerning the Divestiture Products including, without limitation to the extent applicable:

(1) all significant activities concerned with the manufacture, supply and technology transfer of the relevant Products that are identified in the Divestiture Products, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory;

(2) all minutes and records of significant meetings, action plans, and follow-ups to action plans and meetings with Prasco related to the manufacture, supply, and technology transfer of the Divestiture Products;

(3) all significant activities concerning the assistance, advice and consultation provided to Prasco generally as provided in the Decision and Order; and

(4) on request, the Merging Parties will provide the Monitor with any and all records that relate to the manufacture of the Products identified in the Divestiture Products with the right to use them to achieve the purposes of the Orders;

provided, however, that, at the time the Decision and Order becomes final, the reports described in this paragraph shall be due to the Monitor either as requested by the Monitor or within five (5) business days of the date that the Merging Parties files the Merging Parties' reports with the Commission as required pursuant to the Decision and Order;

i. it will comply with the Monitor's reasonable requests for onsite visits and audits of the Merging Parties' facilities (or any Respondent's or contract manufacturer's facility, to the extent within the Merging Parties' control) used to manufacture the Products identified in the

Divestiture Products;

j. it will comply with the Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Monitor Agreement, including, as applicable, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale and/or divestiture of any Divestiture Product(s) and, further including, actions necessary to maintain all necessary FDA approvals to manufacture and sell any of the Divestiture Products, to maintain the viability and marketability of the Divestiture Products, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Products (to the extent within the Merging Parties' control), and to prevent the destruction, removal, wasting, deterioration or impairment of the Divestiture Products, and will provide the Monitor with access to and hard copies of all other data, records or other information that the Monitor reasonably believes are necessary to the proper discharge of its responsibilities under the Orders; and

k. it will provide prompt notice of any meetings or events affecting or likely to affect the maintenance of the Divestiture Products, including, but not limited to, any and all meetings or communications with the FDA.

5. The Merging Parties shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and the Merging Parties related to the Orders or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be requested by the Monitor, of such communications.

6. The Merging Parties agrees that to the extent authorized by the Orders, the Monitor shall have the authority to employ, at the expense of the Merging Parties, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information.

7. The Merging Parties and the Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Monitor investigate and/or audit the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant to the Orders, and submit such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant

to the Orders.

8. The Monitor shall maintain the confidentiality of all information provided to the Monitor by the Merging Parties. Such information shall be used by the Monitor only in connection with the performance of the Monitor's duties pursuant to this Monitor Agreement and the Orders. Such information shall not be disclosed by the Monitor to any third party other than:

   a. persons employed by, or working with, the Monitor under this Monitor Agreement; or

   b. persons employed at the Commission and working on this matter.

9. Upon written request, the Monitor will inform the Commission and the Merging Parties of all persons employed by, or working with, the Monitor under this Monitor Agreement (other than, for the avoidance of doubt, representatives of the Commission, the Merging Parties or Prasco) to whom confidential information related to this Monitor Agreement has been disclosed.

10. Upon (i) termination of the Monitor's duties under this Monitor Agreement and the Orders, and (ii) written request by the Merging Parties, the Monitor shall promptly return to the Merging Parties all material provided to the Monitor by the Merging Parties that is confidential to the Merging Parties and that it is entitled to have returned to it under the Orders, and shall destroy any written material prepared by the Monitor that contains or reflects any confidential information of the Merging Parties, provided, that, notwithstanding the foregoing, the Monitor shall be entitled to keep one copy of such information in its confidential files and all electronic records thereof. Nothing herein shall abrogate the Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of ten (10) years after the termination of this Monitor Agreement;

11. To the extent that the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Orders, the Monitor shall ensure that, prior to being retained, such persons agree to confidentiality restrictions consistent with those set forth herein.

For the purposes of this Section and Sections 8, 9 and 10, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt or becomes known to the recipient from a source other than the Merging Parties,

or any director, officer, employee, agent, consultant or affiliate of the Merging Parties, when such source is entitled to make such disclosure to such recipient or such information was independently developed by the Monitor as evidenced by written records.

12. Nothing in this Monitor Agreement shall require the Merging Parties to disclose any material or information that is subject to a legally recognized privilege or that the Merging Parties is prohibited from disclosing by reason of law.

13. The Monitor shall be responsible for monitoring Respondents' compliance with their obligations as set forth in the Orders and the Divestiture Agreements (Remedial Agreements). In doing so, the Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or the Commission. The Monitor shall have all rights, duties, powers and authorities as required by the Orders, and nothing in the Monitor Agreement shall change, amend, modify, or otherwise limits those rights, duties, powers, and authorities. .

14. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Orders as it relates to the Merging Parties.

15. Mylan will pay the Monitor within thirty (30) days of receipt of an invoice in accordance with the fee schedule attached hereto as Confidential Exhibit A for all time spent in the performance of the Monitor's duties including all monitoring activities related to the efforts of Prasco with respect to the Divestiture Products (including any and all such activities performed prior to the date of this Monitor Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. Every six months such hourly rates should be reviewed and may be adjusted by agreement with the Merging Parties.

    a. In addition, Mylan will pay within thirty days of receipt of an invoice (i) all reasonable and customary out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, including any auto, train or air travel in the performance of the Monitor's duties, and international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties.

    b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and

any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.

c. The Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.

d. To the extent that the Monitor is requested to travel in the performance of the Monitor's duties, the Monitor shall use such travel time, to the extent practicable, to work on the FTC monitor process.

16. Mylan hereby confirms its obligation to indemnify the Monitor and hold the Monitor harmless in accordance with and to the extent required by the Orders (and, upon direction
by the Commission to the Monitor to divest any Divestiture Products).

Without in any way limiting the generality of the foregoing, Mylan shall indemnify the Monitor and any subcontractor and their respective consultants, agents, partners, principals, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses arising out of or in connection with, the performance of the Monitor's duties and obligations including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses are determined by final arbitration to result from the gross negligence or the willful misconduct of the Monitor.

17. The Monitor's maximum liability to the Merging Parties relating to services rendered pursuant to this Monitor Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the lesser of $75,000 or the total sum of the fees paid to the Monitor by the Mylan, except to the extent resulting from the gross negligence or the willful misconduct of the Monitor determined by final arbitration. IN NO CIRCUMSTANCES WHATSOEVER SHALL THE MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES.

18. The Merging Parties agrees that Mylan's obligations to indemnify the Monitor extend to any agreement that is entered between the Monitor and Prasco and relates to the Monitor's responsibilities under this Monitor Agreement and/or the Orders.

19. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Mylan shall be required, to notify Prasco and potential future Acquirers with respect to its appointment as the Monitor.

20. In the event of a disagreement or dispute between the Merging Parties and the Monitor concerning the Merging Parties' obligations under the Orders and, in the event that such disagreement or dispute cannot be resolved by the parties, either party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the case of any disagreement or dispute between the Merging Parties and the Monitor not relating to the Merging Parties' obligations under the Orders, and in the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Merging Parties' obligations pursuant to the Orders. Any fees and expenses of the arbitration shall be split between the parties.

21. This Monitor Agreement shall be subject to the substantive law of the Commonwealth of Pennsylvania (regardless of any other jurisdiction's choice of law principles).

22. This Monitor Agreement shall terminate no later than: (i) the date set forth in the relevant provision of the Orders; or (ii) on the date on which the Commission has appointed a substitute monitor pursuant to the Orders. The Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality, indemnity and limitation of liability provisions of this Monitor Agreement shall survive its termination.

23. In the event that, during the term of this Monitor Agreement, the Monitor becomes aware that it has a conflict of interest that could adversely affect the performance by the designated lead monitor for the Monitor, of any duty under this Monitor Agreement, the Monitor shall promptly inform both the Merging Parties and the Commission of such conflict.

24. It is understood that the Monitor will be serving under this Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between Monitor and the Merging Parties.

25. This Monitor Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.

26. This Monitor Agreement and the Orders contains the entire agreement between the parties hereto with respect to the matters described herein and

replaces and supersedes any and all prior agreements or understandings, whether written or oral. Any amendment, waiver, or modification of this Monitor Agreement shall not be valid unless in writing and signed by the parties, and approved by the Commission. Any such amendment, modification, or waiver may only be made in a manner consistent with the terms of the Orders. Purchase Order terms and conditions shall not be applicable.

27. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail, reputable overnight courier or fax (with acknowledgment of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Monitor, to:

Quantic Regulatory Services, LLC
Bethanne Seel
Office Manager
5N Regents Street
Suite 502
Livingston, NJ 07039

If to Mylan:

Mylan N.V.
Building 4, Trident Place
Mosquito Way, Hatfield
Hertfordshire, United Kingdom, AL10 9UL, or

1000 Mylan Boulevard, Canonsburg, PA 15317

Attention: Global General Counsel

With a copy to:

Cravath, Swaine & Moore LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019

Attention: Margaret D'Amico

If to Pfizer:

Pfizer Inc.
235 East 42nd Street

New York, New York 10017, USA

Attention: Global General Counsel

With a copy to:

Morgan, Lewis & Bockius LLP
101 Park Ave
New York, NY 10178

Attention: Harry T. Robins

If to the Commission:

Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, DC 20001
Attn.:
Telephone:
Fax:

28. This Monitor Agreement shall not become binding until it has been approved by the Commission and the Orders have been accepted for public comment.

29. This Monitor Agreement may be signed in counterparts, each of which shall be deemed an original but when taken together shall constitute one and the same agreement.

[Remainder of Page Intentionally Left Blank.]

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 14th of September 2020.

Quantic Regulatory Services, LLC

Bethanne Seel
Office Manager

Mylan N.V.

Thomas D. Salus

Thomas D. Salus
Assistant Secretary

Pfizer Inc.

Marc Brotman
Vice President & Assistant General Counsel Secretary

Decision and Order

Confidential Appendix A

Concurring Statement

STATEMENT OF COMMISSIONER CHRISTINE S. WILSON

Today, the Commission announces that it has voted 3-2 to issue a complaint and accept a settlement to remedy the threats to competition arising from Mylan's proposed acquisition of Pfizer's off-patent drug business.

The experienced staff of the Federal Trade Commission thoroughly investigated all cognizable theories of harm to competition during more than a year of review. Their extensive investigation put to rest some concerns and produced grounds for other concerns. Staff negotiated comprehensive remedies to address the potential anticompetitive effects identified during their exhaustive investigation – as they have done in many transactions in the pharmaceutical sector, including *Bristol-Myers Squibb/Celgene* and *AbbVie/Allergan*. Yet, as Commissioners Slaughter and Chopra did in those merger reviews, they are again opposing the settlement of this enforcement action.

Prices for pharmaceuticals and biologics deserve the attention of the American public and the federal government. As I stated in connection with the announcement of the FTC's settlement with Bristol-Myers and Celgene, within its limited *civil* authority as a competition agency, the Commission vigorously pursues a comprehensive agenda to address anticompetitive mergers and unlawful conduct in the pharmaceutical industry.[1] I continue to encourage those government entities with the appropriate mandates to fix the many problems in this sector that lie beyond our jurisdiction.

1 Statement of Commissioner Christine S. Wilson, *In the Matter of Bristol-Myers Squibb Company / Celgene Corporation*, File No. 191-0061, Nov. 15, 2019, available at https://www ftc.gov/system/files/documents/public_statements/1554278/bms-celgene_-_wilson_statement.pdf.

Dissenting Statement

STATEMENT OF COMMISSIONER ROHIT CHOPRA JOINED BY COMMISSIONER REBECCA KELLY SLAUGHTER

Summary

- The FTC's record when it comes to reviewing pharmaceutical mergers suggests that the agency will simply never seek to block a merger. Instead, the agency's approach is to strike narrow settlements. This encourages market actors to propose even more unlawful mergers.

- Both Pfizer and Mylan have been accused of collusion in the generic drug business. We must assess whether this merger will enhance their ability to conspire and collude.

- Rajiv Malik, who will be president of the merged entity, is currently a defendant charged with antitrust misconduct. The Commission's silence about his role is deeply problematic.

Drug prices are out of control, and in too many instances, are out of reach for patients who depend on them. Competition from generic drugs pushes down high prices. That's why it's critical to combat abuse of intellectual property that allows branded drug makers to block generic entry. But we should also be deeply concerned that patients can't reap the full benefits from generic competition, given the alleged collusion in the generic drug industry to drive up prices.

Any investigation of massive mergers in the generic business must take this into account.

Today, the Federal Trade Commission has voted to settle allegations that Mylan's (NASDAQ: MYL) proposed $12 billion acquisition of Pfizer's (NYSE: PFE) generic drug business is unlawful.[1] The combined firm would become the largest generic pharmaceutical firm in the world and offer approximately 3,000 drug products that treat a broad range of diseases and conditions.[2] The FTC's proposed settlement requires divestiture of seven individual products, as well as other provisions.

When it comes to pharmaceutical mergers, I am unable to identify a single instance in recent history where the agency has filed a complaint in federal court seeking to halt a prescription drug company merger. This lack of litigation creates the strong impression that the FTC simply looks to strike settlement deals involving individual product divestitures. Virtually

1 Pfizer, Press Release, Mylan and Upjohn, a Division of Pfizer, to Combine, Creating a New Champion for Global Health Uniquely Positioned to Fulfill the World's Need for Medicine (July 29, 2019, 2:45AM), https://www.pfizer.com/news/press-release/press-release-detail/mylan_and_upjohn_a_division_of_pfizer_to_combine_creating_a_new_champion_for_global_health_uniquely_positioned_to_fulfill_the_world_s_need_for_medicine.

2 *See* Mylan & Upjohn Investor Presentation, A New Champion for Global Health at 17 (July 29, 2019), https://www.championforglobalhealth.com/-/media/championforglobalhealth/pdf/mylanupjohninvestorpresentation072919.pdf; *see also* Mylan & Upjohn Fact Sheet, A New Champion for Global Health (n.d.a.), https://www.championforglobalhealth.com/-/media/championforglobalhealth/pdf/MylanUpjohnFactsheet072919.pdf

every market participant I have spoken to in this industry believes that there is simply no risk of the FTC blocking an unlawful pharmaceutical merger outright.

I respectfully disagree with the status quo approach the Commission applied to this pharmaceutical merger. The use here is especially concerning, since both firms and two of Mylan's top executives have been accused of a wide-ranging price fixing and market allocation conspiracy in the generic drug industry.[3] With an expanded empire of generic drug products, these alleged antitrust crimes may be even easier to perpetrate by the new entity.[4]

In this statement, I focus on how mergers involving companies competing across a large number of product lines can exacerbate the risk of collusive conspiracies, particularly in industries where middlemen may not have an incentive to keep prices low.[5] I also focus on issues we must always confront. For example, the Commission should always look to testimony from top executives at companies proposing to merge in order to fully understand the range of potential effects on competition. The Commission can only make a conclusion about the risk of collusion and any impacts on competition when it has a full range of data and evidence.

Conditions for Collusion

When competitors enter into agreements to fix prices, rig bids, and divvy up markets, they can face civil and criminal charges. Pfizer and Mylan are defendants in several state attorneys general and private plaintiff lawsuits alleging market allocation and price fixing in the generic drug industry.[6] They are also under investigation for criminal market allocation and price fixing by the Department of Justice.[7] Over thirty additional generic drug companies are defendants in the same state attorneys general suits, including well-known drug firms Sandoz, Actavis, Teva, and Allergan, among others. Patients have allegedly paid many billions of dollars

3 *See* Compl., *Connecticut v. Teva Pharms. USA, Inc.*, Case No. 3:19-cv-00710 (D. Conn. filed May 10, 2019) ¶ 50; *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34, Civ. Action No. 17-3768 (E.D. Pa. filed June 15, 2018).

4 The Department of Justice also charged Teva with criminally conspiring to fix prices, rig bids, and allocate customers for generic drugs. Five previous corporate cases were resolved by deferred prosecution agreements; Teva and its co-conspirator Glenmark are awaiting trial. Four executives have also been charged; three have entered guilty pleas, and one is awaiting trial. *See* Press Release, Dep't. of Just., Seventh Generic Drug Manufacturer Is Charged In Ongoing Criminal Antitrust Investigation (Aug. 25, 2020), https://www.justice.gov/opa/pr/seventh-generic-drug-manufacturer-charged-ongoing-criminal-antitrust-investigation.

5 Most generic drugs are sold by their manufacturers to group purchasing organizations and large retail purchasers, who negotiate pricing contracts for their members that ultimately purchase the products. These contracts typically have inflation-based provisions that allow for potentially greater compensation when prices are higher. *See In re Generic Pharms. Pricing Antitrust Litig.* ¶ 74.

6 *See e.g.*, Pl. States' Consol. Am. Compl., *In re Generic Pharms. Pricing Antitrust Litig.*; Compl., *Connecticut v. Teva Pharms.*; Compl., *Connecticut v. Sandoz, Inc.*, Civ. Action No. 3:20-cv-802 (D. Conn. filed June 10, 2020).

7 *See* Pfizer Inc., Current Report (Form 8-K) (Aug. 6, 2020) at 175; Mylan N.V., Annual Report (Form 10-K) (Dec. 31, 2019) at 153.

in overcharges for the generic drugs involved, causing a significant negative impact on our national health and economy.[8]

Typically, collusion is easier to pull off when a market has only a few big players, since coordination is more difficult with more actors.[9] However, there are many generic drug companies that operate in the United States. So why might there be widespread misconduct?

One potential explanation is that these companies compete with each other in multiple different product markets. The enormous profit potential for these firms from collusion likely contributes to their incentives to engage in mutually beneficial coordination. By trading favorable competitive terms in one market for favorable competitive terms in another market, it may be easier for competing firms to reach mutually beneficial terms of trade and punish each other for any deviations.[10]

Pfizer and Mylan allegedly did just that.[11] In addition to colluding within individual generic drug product markets, Pfizer's Greenstone division, Mylan, and others are charged with trading customers across *different* drug markets.[12] They allegedly allowed price increases on generic drugs without competing, based on a quid pro quo from competitors on different drug products.[13] Given these allegations, it is important that we closely investigate how this transaction could increase the ability of the merged entity to engage in similar – or even more harmful – collusive conduct.

For example, the merged entity would become the top supplier of generic drugs by global revenues, with an enormous number of products and a broad range of competitors with which to engage in quid pro quo collusive arrangements.[14] With more generic drugs in the hands of one competitor, it may be easier to form a cartel and punish those who don't adhere to its terms.

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8 Compl., *Connecticut v. Teva Pharms. USA, Inc.* ¶ 5.

9 This concept is reflected in the FTC's Horizontal Merger Guidelines. U.S. DEP'T OF JUST. & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES § 7.2 (Aug. 19, 2010), https://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf.

10 *See* Federico Ciliberto & Jonathan W. Williams, *Does multimarket contact facilitate tacit collusion? Inference on conduct parameters in the airline* industry, 45 RAND J. OF ECON. 764 – 791 (2014) (noting that such multimarket contact facilitates tacit collusion in the U.S. airline industry).

11 Compl., *In re Generic Pharms. Pricing Antitrust Litig*. ¶¶ 103 – 105 (describing Defendant Malik's willingness to "play fair" and give up two large customers to Heritage because Heritage had previously allowed Mylan to enter another market without competition); *see also* Compl., *Connecticut v. Sandoz, Inc.* ¶ 1299.

12 *Id.*

13 Compl., *In re Generic Pharms. Pricing Antitrust Litig*. ¶ 101; *see also* Compl., *Connecticut v. Teva Pharms* ¶ 12.

14 Beth Snyder Bulik, *Mylan and Pfizer roll out tricolor branding for their giant generics combo, Viatris*, FIERCEPHARMA (July 9, 2020, 10:06 AM), https://www fiercepharma.com/marketing/mylan-and-pfizer-debuts-new-viatris-generics-merged-brand-unveils-tri-color-logo-for.

Despite this risk, the Commission's analysis is silent with respect to the alleged price fixing conduct.[15]

The FTC often acts without the benefit of the experience of other law enforcement partners.[16] In all matters the Commission should avoid a go-it-alone approach and collaborate with other agencies to help shed light on the mechanisms involved in the allegations. Together, we should closely assess whether the likelihood of harm increases post-merger.

Investigating Executives

In any matter where a company has a history of potential wrongdoing, a key method to determine the motivations for a merger and to predict how it will affect competition is to seek sworn testimony from key executives. This is especially critical to understand how sales, pricing, and market forces are working. This evidence is also helpful if the agency must prepare a lawsuit.

While filings submitted by merging parties shed light on many aspects of a transaction, they do not always provide a complete picture of the deal rationale, pricing models, and boardroom behavior. The state allegations of price fixing and market allocation make clear that individual executives play a key role in sales and price setting, so it is critical that we fully understand this element of the competitive process.

For example, what is their involvement in developing a pricing model? Do they approve deviations from this pricing model? How do they decide which new markets to enter? In what contexts do they interact with their competitors? There are a long list of questions that are absolutely essential in an inquiry like this.

In this transaction, one of the alleged masterminds of the ongoing price fixing and market allocation schemes is Rajiv Malik, Mylan's current president, who is a named defendant in one of the state lawsuits.[17] A second Mylan executive, Vice President of Sales James Nesta, is also a named defendant in one of the cases.[18] The merging parties have publicly announced that Mr. Malik will retain the top executive role in the expanded generic drug empire, if the transaction

15 *See, e.g.*, Analysis Of Agreement Containing Consent Orders To Aid Public Comment, *In the Matter of Pfizer Inc./Mylan N.V.*, File No. 1910182 (Oct. 29, 2020).

16 *See* Statement of Commissioner Rohit Chopra In the Matter of AbbVie, Inc./Allergan plc, Comm'n File No. 1910169, 2, 19 (May 5, 2020), https://www ftc.gov/system/files/documents/public_statements/1574583/191-0169_dissenting_statement_of_commissioner_rohit_chopra_in_the_matter_of_abbvie-allergan_redacted.pdf; *see also* Statement of Commissioner Rohit Chopra In the Matter of Social Finance, Inc., Comm'n File No. 1623917 (Oct. 29, 2018), https://www ftc.gov/system/files/documents/public_statements/1418711/162_3197_statement_of_commissioner_chopra_on_sofi_10-29-18.pdf.

17 Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34.

18 *See* Compl., *Connecticut v. Teva Pharms. USA, Inc*. ¶ 50.

closes.[19] As president, he will be in charge of the merged entity's sales and marketing operations.[20] He will also serve on the merged company's board.[21]

Mr. Malik's role in the alleged price fixing scheme is significant. He allegedly conceived and directed many of the schemes.[22] In one example, he is alleged to have agreed to cede market share in one market to a specific competitor in exchange for an agreement from that competitor to allow Mylan to enter a different market without competition.[23]

Despite the obvious alarm bells raised by Mr. Malik's planned role in the merged firm, the Commission's analysis does not discuss his involvement in the ongoing price fixing and market allocation allegations in the industry or his future plans for the company. In my view, the Commission owes the public a clear explanation about Mr. Malik's role.

In matters like this, it is critical that the Commission rely on a wide range of data and evidence, including testimony from key executives.[24]

Conclusion

I am concerned that executives in the pharmaceutical industry routinely propose anticompetitive mergers without any fear that their transactions will ever be blocked. In my view, the status quo approach of seeking settlements through divestitures of individual products is myopic and misses some of the fundamental elements of how firms compete in this industry. I am also not aware of any instance where the Commission publicly relied on the testimony under oath of a pharmaceutical executive in approving a pharmaceutical divestiture settlement.

Unless we change our approach, anticompetitive mergers in the pharmaceutical industry will continue unabated, and we will all suffer for it. I appreciate the diligence of our staff, who work at the direction of the Commission. Unfortunately, the directives of the Commission are deeply flawed, favoring routine over rigor. For all these reasons, I respectfully dissent.

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19 *See* Pfizer Press Release, *supra* note 1.

20 Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 34.

21 *See* Pfizer Press Release, *supra* note 1.

22 Compl., *In re Generic Pharms. Pricing Antitrust Litig.* ¶ 10.

23 *Id.* ¶ 188.

24 This is particularly important in industries where the Commission cannot rely on evidence and testimony from customers who act as middlemen. We know from the allegations in the state attorneys general lawsuits that drug wholesalers and large retailers allegedly benefit when generic drug prices are higher. These firms have contractual provisions allowing for potentially greater compensation when prices are higher. *Id*. ¶¶ 71 – 75.

ANALYSIS OF CONSENT ORDERS TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Pfizer Inc., Upjohn Inc., Viatris Inc., Mylan N.V., and Utah Acquisition Sub Inc., that is designed to remedy the anticompetitive effects resulting from the proposed combination of Upjohn and Mylan. Under the terms of the Consent Agreement, the parties are required to divest Upjohn's generic drug rights and assets related to six products to Prasco, LLC. The Consent Agreement also requires the parties to divest Mylan's rights and assets related to eplerenone tablets to Prasco. Further, the Consent Agreement requires prior Commission approval before Upjohn, Mylan, or Viatris may gain an interest in or exercise control over any third party's rights to (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets.

The Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw the Consent Agreement, modify it, or make final the proposed Decision and Order ("Order").

Pursuant to agreements dated July 29, 2019, Pfizer proposes to spin off its Upjohn business, which includes legacy Pfizer branded products and the authorized generic business, Greenstone, LLC. Upjohn will combine with Mylan to form a new entity, Viatris ("Proposed Combination"). The Commission alleges in its Complaint that the Proposed Combination, if consummated, would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, as amended, and Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended, by lessening current competition in the following seven U.S. markets: (1) amlodipine besylate/atorvastatin calcium tablets, (2) eplerenone tablets, (3) gatifloxacin ophthalmic solution, (4) medroxyprogesterone acetate injectable solution, (5) phenytoin chewable tablets, (6) prazosin hydrochloride ("HCl") capsules, and (7) spironolactone hydrochlorothiazide ("HCTZ") tablets. The Commission also alleges that the Proposed Combination would violate the aforementioned statutes by lessening future competition in the markets for: (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Combination.

I. The Products and Structure of the Markets

In human pharmaceutical markets, price generally decreases as the number of generic competitors increases. Prices continue to decrease incrementally with the entry of the second, third, fourth, and even fifth generic competitor. And in markets prone to supply shortages, additional entry after the fifth generic competitor continues to affect price and ensures more stable supply. Accordingly, the reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Combination would reduce current competition in the markets for seven products where Greenstone distributes the authorized generic version of the branded drug:

- Amlodipine besylate/atorvastatin calcium tablets combine a calcium channel blocker to treat hypertension with a lipid-lowering agent to treat high cholesterol. Only four companies sell generic amlodipine besylate/atorvastatin calcium tablets: Greenstone, Mylan, Dr. Reddy's Laboratories Ltd., and Apotex Inc.

- Eplerenone is a diuretic that is prescribed as an adjunctive therapy when treating hypertension or congestive heart failure after a heart attack. Significant sellers of eplerenone include Greenstone, Mylan, Breckenridge Pharmaceutical, Inc., and Accord Healthcare Inc.

- Gatifloxacin ophthalmic solution is an eye drop that treats bacterial conjunctivitis caused by susceptible strains of certain bacteria. The market for gatifloxacin has faced historical supply disruptions. Five companies supply this product today: Greenstone, Mylan, Sandoz International GmbH, Akorn, Inc., and Lupin Ltd.

- Medroxyprogesterone acetate is an injectable solution used to treat certain types of dysfunctional uterine bleeding. Injectable products, such as medroxyprogesterone acetate, have recently experienced shortages and supply disruptions. Greenstone, Mylan, Amphastar Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Ltd. currently supply medroxyprogesterone acetate.

- Phenytoin chewable tablets are an anti-epileptic drug that slows down impulses in the brain that cause seizures. Only three suppliers provide phenytoin chewable tablets today: Greenstone, Mylan, and Taro Pharmaceutical Industries Ltd.

- Prazosin HCl capsules are an alpha-adrenergic blocker that treats hypertension by relaxing the veins and arteries so that blood can more easily pass. The market for prazosin HCl capsules is supplied by four companies: Greenstone, Mylan, Teva, and Novitium Pharma LLC.

- Spironolactone HCTZ tablets are a diuretic used to treat hypertension. Only three suppliers provide spironolactone HCTZ tablets: Greenstone, Mylan, and Sun.

The Proposed Combination also would reduce future competition in the following generic markets:

- Levothyroxine sodium tablets are offered in a host of strengths and are prescribed to treat hypothyroidism or as an adjunct therapy for patients undergoing treatment for thyroid cancer. Suppliers for levothyroxine sodium tablets vary by strength. Should Upjohn or Greenstone launch an authorized generic of Pfizer's levothyroxine sodium branded product (Levoxyl®), the Proposed Combination likely would reduce the number of independent suppliers from three to two in some strengths.

- Sucralfate tablets are used to treat and prevent ulcers in the small intestines. Only three companies sold sucralfate tablets historically: Greenstone, Mylan, and Teva. More recently, Mylan discontinued sales of sucralfate. The Proposed Combination likely alters Mylan's incentives to relaunch sucralfate tablets and would reduce the number of firms capable of selling sucralfate tablets from three to two.

- Varenicline tartrate tablets are a smoking cessation aid offered under Pfizer's brand Chantix®. Currently, only branded Chantix® is available in the market. Mylan is one of a limited number of companies likely to share the Hatch-Waxman 180-day exclusivity period when the generic market forms. Should Upjohn or Greenstone launch an authorized generic of Pfizer's Chantix®, the Proposed Combination would significantly reduce the number of independent generic suppliers.

II. Entry

Entry into the markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Combination. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and time-consuming.

III. Competitive Effects

The Proposed Combination would likely cause significant anticompetitive harm to consumers in the relevant generic pharmaceutical markets by eliminating current and/or future competition in concentrated existing generic markets or in future generic markets. In generic pharmaceuticals markets, price is heavily influenced by the number of participants with sufficient supply. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the prices of the generic pharmaceutical products at issue continue to decrease with new entry even after a number of suppliers have entered these generic markets.

The evidence shows that anticompetitive effects are likely to result from the Proposed Combination due to a decrease in the number of independent competitors in the markets at issue. In each of the current generic drug markets, industry participants have indicated that the presence of Greenstone and Mylan as independent competitors has allowed them to negotiate lower prices and, in some markets, has improved surety of supply.

In five of the markets where Upjohn and Mylan currently compete (amlodipine besylate/atorvastatin calcium tablets, eplerenone tablets, phenytoin chewable tablets, prazosin HCl capsules, and spironolactone HCTZ tablets), the Proposed Combination likely would reduce competition by combining two of only four or fewer current suppliers, likely leading to higher prices. In two of the markets where Upjohn and Mylan currently compete and where significant product shortages have occurred (gatifloxacin ophthalmic solution and medroxyprogesterone

acetate injectable solution), the Proposed Combination would eliminate an independent supplier. Customers have indicated that preserving competition between Upjohn and Mylan, particularly in markets prone to shortages, is important to maintaining adequate supplies and competitive prices.

In addition, the Proposed Combination likely would delay or forego the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in the markets for generic levothyroxine sodium tablets, sucralfate tablets, and varenicline tartrate tablets.

Absent the Consent Agreement, the Proposed Combination would eliminate significant current and future competition between the parties and likely cause U.S. consumers to pay higher prices for the aforementioned generic pharmaceutical products.

IV. The Consent Agreement and Order

The proposed Order effectively remedies the competitive concerns raised by the Proposed Combination for the ten generic pharmaceutical product areas at issue. Pursuant to the proposed Order, the parties are required to divest to Prasco Upjohn's authorized generic rights and assets related to six products. The proposed Order also requires the parties to divest Mylan's rights and assets related to eplerenone tablets to Prasco. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Proposed Combination is consummated. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

Further, the proposed Order requires prior Commission approval before Upjohn, Mylan, or Viatris may gain an interest in or exercise control over any third party's rights to the following products: (1) levothyroxine sodium tablets, (2) sucralfate tablets, and (3) varenicline tartrate tablets.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Combination. Prasco is a capable purchaser with management and employees who have experience marketing and distributing generic pharmaceutical products. It will be able to replicate the competition otherwise lost from the Proposed Combination.

The proposed Order contains several provisions to help ensure that the divestitures are successful. As to the products and rights being divested to Prasco, generic drug manufacturing will continue to be performed by the same entity as prior to the Proposed Combination, reducing the risk of any interruption in supply to Prasco. In some instances, Pfizer—which will be an independent entity, separate from Viatris after the Proposed Combination—will serve as Prasco's contract manufacturer, allowing Prasco to step into the shoes of Upjohn/Greenstone. Should Prasco decide to move manufacturing to another contract manufacturer, the proposed Order requires the parties to provide transitional services to assist Prasco or its designated contract manufacturer in establishing manufacturing capabilities and securing all necessary FDA approvals. These transitional services include technical assistance to manufacture the currently

marketed products in substantially the same manner and quality employed or achieved by the parties. To the extent that Pfizer will manufacture relevant products on behalf of both Viatris and Prasco, the proposed Order requires that supply to Prasco is provided at a pre-determined cost and is prioritized over supply to Viatris. For amlodipine besylate/atorvastatin calcium tablets, Viatris will provide the active pharmaceutical ingredient ("API") used in Prasco's product. The proposed Order requires that Viatris provide Prasco with API at a pre-determined cost and that it prioritizes Prasco's use of API over its own. Moreover, the proposed Order requires a firewall between Viatris's API business and its commercial business to prevent the sharing of commercially sensitive information. Under the proposed Order, the Commission also will appoint two Monitors.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

SKYMED INTERNATIONAL, INC.
D/B/A
SKYMED TRAVEL AND CAR RENTAL PRO

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4732; File No. 192 3140
Complaint, January 26, 2021 – Decision, January 26, 2021

This consent order addresses SkyMed International, Inc.'s information security practices and notifications. The complaint alleges that SkyMed violated Section 5 of the Federal Trade Commission Act by using unreasonable security practices that led to the exposure of a cloud database containing approximately 130,000 membership records with consumers' personal information stored in plain text. The complaint further alleges that SkyMed engaged in deceptive acts when it notified current and former members about the database exposure, and when displaying a seal on every page of its website that attested to its purported compliance with the Health Insurance Portability and Accountability Act. The consent order prohibits SkyMed from making false or deceptive statements regarding: (1) the extent to which it is a member of, complies with, is endorsed by, or otherwise participates in any privacy or security program sponsored by a government or third party; (2) the extent of any data security incident involving consumers' personal information; (3) the extent of any investigation, and the results thereof, relating to a data security incident; (4) the extent to which SkyMed collects, maintains, uses, discloses, deletes, or permits or denies access to consumers' personal information; and (5) the extent to which SkyMed otherwise protects the privacy, security, availability, confidentiality, or integrity of consumers' personal information.

Participants

For the *Commission*: *Brian Berggren* and *Miles Plant.*

For the *Respondents*: *Andrea Bland, Russell Duncan,* and *Melissa Ventrone, Clark Hill PLC.*

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that SkyMed International, Inc., a Nevada corporation, has violated the provisions of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent SkyMed International, Inc. ("Respondent"), also doing business as SkyMed Travel and as Car Rental Pro, is a Nevada corporation with its principal office or place of business at 9089 E. Bahia Drive, Suite 100, Scottsdale, Arizona 85260.

2. The acts and practices of Respondent, as alleged in this Complaint, have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

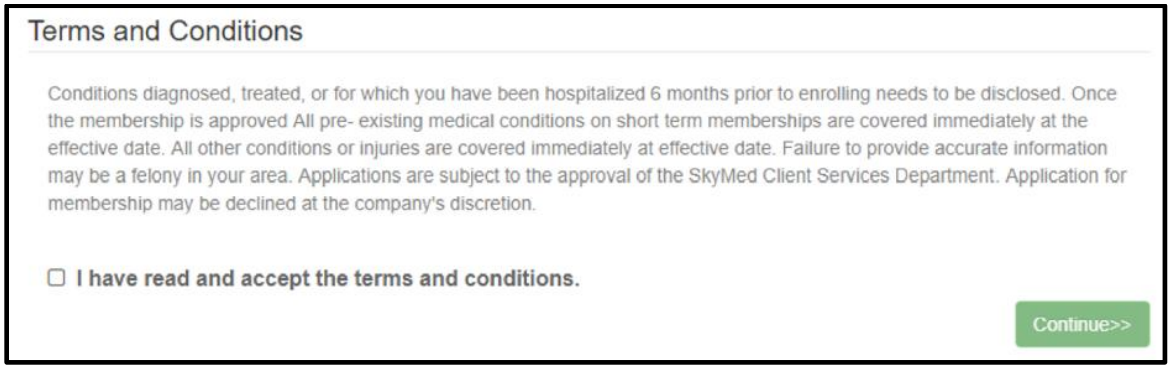
Respondent's Business Practices

3. Respondent advertises, offers for sale, and sells nationwide a wide array of emergency travel membership plans that cover up to eighteen different emergency travel and medical evacuation services for members who sustain serious illnesses or injuries during travel in certain geographic areas. These services include hospital-to-hospital air transportation, vehicle return, visitor transportation, repatriation for recuperation near home, medical escort flights, and transportation of children.

4. Membership plans provide coverage on a short-term, yearly, or multi-year basis for both single members and entire families. Depending on the term, number of members, and the medical evacuation services covered, membership plans cost between $299 and $8,990.

5. Consumers purchase membership plans through either an online application on Respondent's website or a paper application submitted to an authorized sales representative. In both instances, Respondent collects a significant amount of personal information from applicants, including name, date of birth, sex, home address, email address, phone number, emergency contact information, passport number, and payment card information.

6. Both the online and written applications also mandate that consumers provide Respondent with detailed health information—i.e., a list of prescribed medications and medical conditions, as well as all hospitalizations in the previous six months. Consumers cannot purchase membership plans without providing Respondent this information. In fact, in the online application, Respondent requires that consumers agree to the following terms and conditions:

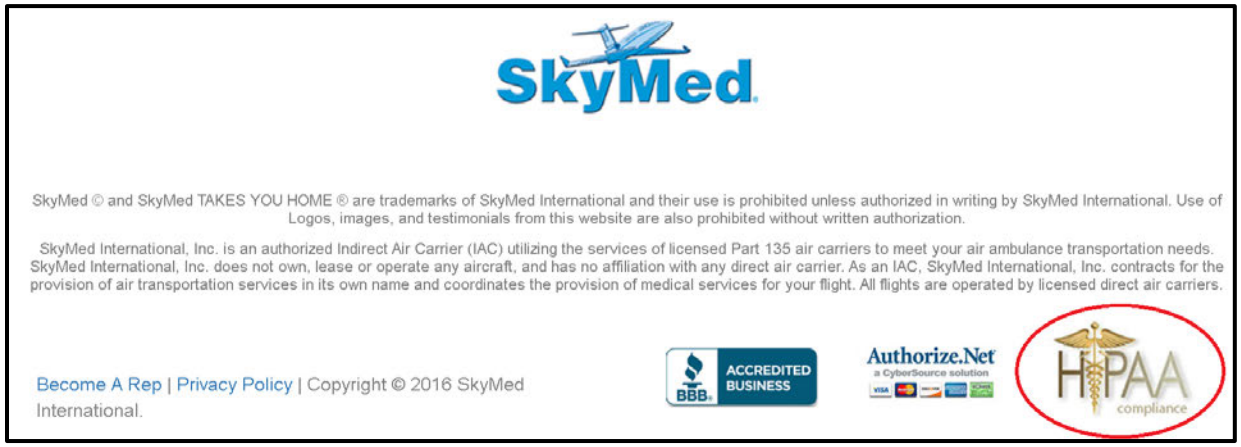


7. Likewise, the written application includes similar terms and conditions, and applicants must give Respondent express permission to obtain their medical records.

8. Thousands of consumers have signed up for Respondent's membership plans, meaning Respondent has collected a trove of personal information, including sensitive health information, about these consumers.

Respondent's Deceptive HIPAA Seal

9. Respondent has prominently displayed seals on every page of its website. From 2014 to April 30, 2019, Respondent displayed a seal—in close proximity to two seals provided by third parties—that attested to Respondent's purported compliance with the Health Insurance Portability and Accountability Act ("HIPAA"), a statute that sets forth privacy and information security protections for health data. This seal is circled in red below:



10. By displaying the "HIPAA Compliance" seal on every page of its website, Respondent signaled to consumers that a government agency or other third party had reviewed Respondent's information practices and determined that they met HIPAA's requirements.

11. In reality, no government agency or other third party had reviewed Respondent's information practices for compliance with HIPAA, let alone determined that the practices met the requirements of HIPAA. Respondent has since admitted that the "seal should not have been on the website" and removed the seal from all pages of its website on or around April 30, 2019.

Respondent's Information Security Practices

12. Respondent has engaged in a number of practices that failed to provide reasonable security for the personal information it collected, including sensitive health information. Among other things, Respondent:

a. failed to develop, implement, or maintain written organizational information security standards, policies, procedures, or practices;

b. failed to provide adequate guidance or training for employees or third-party contractors regarding information security and safeguarding consumers' personal information;

c. stored consumers' personal information on Respondent's network and databases in plain text, without reasonable data access controls or authentication protections;

d. failed to assess the risks to the personal information stored on its network and databases, such as by conducting periodic risk assessments or performing vulnerability and penetration testing of the network and databases;

e. failed to have a policy, procedure, or practice for inventorying and deleting consumers' personal information stored on Respondent's network that is no longer necessary; and

f. failed to use data loss prevention tools to regularly monitor for unauthorized attempts to transfer or exfiltrate consumers' personal information outside of Respondent's network boundaries.

Respondent's Failure to Secure Consumers' Personal Information

13. Respondent's failure to provide reasonable security for the personal information it collected led to exposure of some of the information in a cloud database. In March 2019, a security researcher, using a publicly available search engine, discovered an unsecured cloud database maintained by Respondent. According to the security researcher, the database, which could be located and accessed by anyone on the internet, contained approximately 130,000 membership records with consumers' personal information stored in plain text, including information populated in certain fields for names, dates of birth, gender, home addresses, email addresses, phone numbers, membership information and account numbers, and health information (i.e., "hospitalized," "hos_explanation," "prescription," "prescription_list," and "medical").

14. On March 27, 2019, the security researcher notified Respondent about the existence of the database and provided screenshots showing that the database contained consumers' personal information. The security researcher also informed Respondent that anyone could easily alter, download, or even delete the personal information contained therein. In response to the notification, Respondent deleted the database, including the records contained therein.

15. Respondent failed to detect this unsecured and publicly accessible cloud database for more than five months. In fact, before Respondent received the security researcher's notification, Respondent had no idea that the publicly accessible cloud database even existed, let alone that it contained consumers' personal information stored in plain text. Thus, had the exposure not been discovered by the security researcher, it would have continued.

Respondent's Notification to Consumers Regarding the Security Incident

16. On May 2, 2019, Respondent notified current and former membership plan holders of this security incident via email. Respondent advised consumers that it had received information from a security researcher about a publicly accessible database containing the consumers' information.

17. Respondent represented that it "immediately took proactive measures to determine the validity of [the security researcher's] allegation, including [by] engaging legal and independent third parties." It also claimed to have investigated the incident, stating:

> Our investigation learned that some old data may have been exposed temporarily as we migrated data from an old system to a new system. At this time, the exposed data has been removed and appears to be limited to only a portion of our information and was restricted to names, street and email addresses, phone and membership ID numbers. **There was no medical or payment-related information visible and no indication that the information has been misused**. (emphasis in original).

18. Multiple consumers responded to Respondent's email notification. Some consumers inquired further about the security incident and the specific personal information exposed, including whether Respondent would be providing identity theft and credit monitoring services. Others requested that Respondent delete all of their personal information. Some consumers praised Respondent for communicating the findings of the investigation into the security incident.

19. Contrary to its representations to consumers described in Paragraph 17, Respondent's investigation did not determine that consumers' health information was neither stored on the cloud database, nor improperly accessed by an unauthorized third party. Rather, Respondent's investigation merely sought to confirm that the database at issue was online and publicly accessible. Upon confirming as much, Respondent immediately deleted the database without ever verifying the types of personal information stored therein. At no point did Respondent examine the actual information stored in the cloud database, identify the consumers placed at risk by the exposure, or look for evidence of other unauthorized access to the database.

Injury to Consumers

20. Respondent's failure to provide reasonable security for consumers' personal information has caused or is likely to cause substantial injury to those consumers. The information collected by Respondent, including consumers' medical conditions, prescription medications, and previous hospitalizations, together with identifying information such as their names, postal and email addresses, dates of birth, phone numbers, and passport numbers, is highly sensitive. Disclosure of such information, without authorization, is likely to cause stigma, embarrassment, and/or emotional distress. Exposure of this information may also affect a consumer's ability to obtain and/or retain employment, housing, health insurance, or disability insurance. Consumers could lose their jobs, health insurance, or housing if their health information becomes public knowledge.

21. Here, the unsecured cloud database containing more than 130,000 records of consumers' personal information, as described in Paragraph 13, was publicly available on the Internet for at least five months. Due to Respondent's failure to use data loss prevention tools and lack of access controls and authentication protections for its networks, consumers' personal information, including health information, may have been exposed in other instances—beyond

the incident described in Paragraphs 13 to 15—without Respondent's knowledge. Even if consumers' personal information had not actually been exposed, Respondent's failure to secure the vast amount of information it has collected has caused or is likely to cause substantial injury to consumers. In particular, health information is valuable on the open market, and wrongdoers frequently seek to purchase consumers' health information on the dark web.

22. The harms described in Paragraphs 20 to 21 were not reasonably avoidable by consumers, as consumers had no way to know about Respondent's information security failures described in Paragraph 12.

23. Respondent could have prevented or mitigated these information security failures through readily available, and relatively low-cost, measures.

COUNT I – DECEPTION

HIPAA Seal Misrepresentation

24. Through the means described in Paragraphs 9 and 10, Respondent represented, expressly or by implication, directly or indirectly, that a government agency or other third party had reviewed Respondent's information practices and determined that they met HIPAA's requirements.

25. In truth and fact, as described in Paragraph 11, no government agency or other third party had ever reviewed Respondent's information practices and determined that Respondent's practices met HIPAA's requirements. Therefore, the representation set forth in Paragraph 24 is false or misleading.

COUNT II – DECEPTION

Security Incident Response Misrepresentation

26. Through the means described in Paragraph 17, Respondent has represented, directly or indirectly, expressly or by implication, that its investigation into a security researcher's report about an unsecured cloud database determined that consumers' health information was neither stored on the database, nor improperly accessed by an unauthorized third party other than the researcher who reported its exposure.

27. In truth and in fact, as described in Paragraph 19, Respondent's investigation did not determine whether consumers' health information was stored on the cloud database or improperly accessed by an unauthorized third party. Therefore, the representation set forth in Paragraph 26 is false or misleading.

COUNT III – UNFAIRNESS

Unfair Information Security Practices

28. Through the means described in Paragraph 12, Respondent failed to employ reasonable measures to protect consumers' personal information, which caused or is likely to cause substantial injury to consumers that is not outweighed by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers themselves, as described in Paragraphs 20 to 23. This practice is an unfair act or practice.

VIOLATIONS OF SECTION 5 OF THE FTC ACT

29. The acts and practices of Respondent, as alleged in this Complaint, constitute unfair and/or deceptive acts or practices, in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twenty-sixth day of January, 2021, has issued this complaint against Respondent.

By the Commission.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondent named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violations of the Federal Trade Commission Act, 15 U.S.C. § 45(a)(1).

Respondent and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: (1) statements by Respondent that it neither admits nor denies any of the allegations in the draft Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, it admits the facts necessary to establish jurisdiction; and (2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of thirty (30) days for the receipt and consideration

of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondent is SkyMed International, Inc., also doing business as SkyMed Travel and as Car Rental Pro, a corporation with its principal office or place of business at 9089 E. Bahia Drive, Suite 100, Scottsdale, AZ 85260.

2. The Commission has jurisdiction over the subject matter of this proceeding and over Respondent, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "Affected Consumers" means all consumers that received an email from Respondent on or around May 2, 2019 with the subject line, "IMPORTANT MESSAGE relative to SkyMed data exposure."

B. "Covered Incident" means any instance in which (a) any United States federal, state, or local law or regulation requires Respondent to notify any U.S. federal, state, or local government entity that information collected or received, directly or indirectly, by Respondent from or about an individual consumer was, or is reasonably believed to have been, accessed or acquired without authorization; or (b) individually identifiable Health Information from or about an individual consumer was, or is reasonably believed to have been, accessed, acquired, or publicly exposed without authorization.

C. "Health Information" means information relating to the health of an individual consumer, including but not limited to medical history information, prescription information, hospitalization information, clinical laboratory testing information, health insurance information, or physician exam notes.

D. "Personal Information" means individually identifiable information from or about an individual consumer, including: (a) a first and last name; (b) a home or physical address, including street name and name of city or town; (c) an email address or other online contact information; (d) a mobile or other telephone number; (e) a date of birth; (f) a government-issued identification number, such as a driver's license, military identification, passport, or Social Security number, or other personal identification number; (g) credit card or other financial account

information; (h) Health Information; or (i) user account credentials, such as a login name and password.

E. "Respondent" means SkyMed International, Inc., its successors and assigns, and Global Emergency Travel Services, and its successors and assigns.

Provisions

I. Prohibition Against Misrepresentations

IT IS ORDERED that Respondent; Respondent's officers, agents, employees, and attorneys; and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with any product or service, must not misrepresent in any manner, expressly or by implication:

A. The extent to which Respondent is a member of, adheres to, complies with, is certified by, is endorsed by, or otherwise participates in any privacy or security program sponsored by a government or any third party, including any self-regulatory or standard- setting organization;

B. The extent of any Covered Incident or unauthorized disclosure, misuse, loss, theft, alteration, destruction, or other compromise of Personal Information;

C. The extent of any investigation and the results thereof, whether conducted by Respondent, a governmental agency, or a third party, into any Covered Incident or unauthorized disclosure, misuse, loss, theft, alteration, destruction, or other compromise of Personal Information;

D. The extent to which Respondent collects, maintains, uses, discloses, deletes, or permits or denies access to any Personal Information; and

E. The extent to which Respondent otherwise protects the privacy, security, availability, confidentiality, or integrity of any Personal Information.

II. Required Notice to Consumers About Respondent's Security Incident Response

IT IS FURTHER ORDERED that, within fourteen (14) days after the effective date of this Order, Respondent must directly notify all Affected Consumers by sending an email, consisting solely of an exact copy of the notice attached hereto as Exhibit A ("Notice"), with the subject line "Update: May 2019 Data Exposure." Respondent shall not include with the Notice any other information, documents, or attachments.

III. Mandated Information Security Program

IT IS FURTHER ORDERED that Respondent, in connection with the collection, maintenance, use, disclosure, or provision of access to Personal Information, must, within thirty

(30) days of issuance of this Order, establish and implement, and thereafter maintain, a comprehensive Information Security Program ("Information Security Program") that protects the security, confidentiality, and integrity of Personal Information. To satisfy this requirement, Respondent must, at a minimum:

A. Document in writing the content, implementation, and maintenance of the Information Security Program;

B. Provide the written program and any evaluations thereof or updates thereto to Respondent's board of directors or governing body or, if no such board or equivalent governing body exists, to a senior officer of Respondent responsible for Respondent's Information Security Program at least once every twelve (12) months and promptly (not to exceed thirty (30) days) after a Covered Incident;

C. Designate a qualified employee or employees to coordinate and be responsible for the Information Security Program;

D. Assess and document, at least once every twelve (12) months and promptly (not to exceed thirty (30) days) following a Covered Incident, internal and external risks to the security, confidentiality, or integrity of Personal Information that could result in the (1) unauthorized collection, maintenance, use, disclosure of, or provision of access to, Personal Information; or the (2) misuse, loss, theft, alteration, destruction, or other compromise of such information;

E. Design, implement, maintain, and document safeguards that control for the internal and external risks Respondent identifies to the security, confidentiality, or integrity of Personal Information identified in response to sub-Provision III.D. Each safeguard must be based on the volume and sensitivity of the Personal Information that is at risk, and the likelihood that the risk could be realized and result in the (1) unauthorized collection, maintenance, use, disclosure of, or provision of access to, Personal Information; or the (2) misuse, loss, theft, alteration, destruction, or other compromise of such information. Such safeguards must also include:

1. Policies, procedures, and technical measures to systematically inventory Personal Information in Respondent's control and delete Personal Information that is no longer necessary;

2. Policies, procedures, and technical measures to log and monitor access to repositories of Personal Information in Respondent's control;

3. Encryption of, at a minimum, all passport numbers, financial account information, and Health Information in Respondent's control.

4. Training of all of Respondent's employees, at least once every twelve (12) months, on how to safeguard Personal Information;

5. Technical measures to monitor all of Respondent's networks, including all systems and assets within those networks, to identify data security events, including unauthorized attempts to exfiltrate Personal Information from those networks; and

6. Data access controls for all repositories of Personal Information in Respondent's control, such as (a) restricting inbound connections to approved IP addresses, (b) requiring authentication to access them, and (c) limiting employee access to what is needed to perform that employee's job function.

F. Assess, at least once every twelve (12) months and promptly (not to exceed thirty (30) days) following a Covered Incident, the sufficiency of any safeguards in place to address the risks to the security, confidentiality, or integrity of Personal Information, and modify the Information Security Program based on the results;

G. Test and monitor the effectiveness of the safeguards in place at least once every twelve (12) months and promptly (not to exceed thirty (30) days) following a Covered Incident, and modify the Information Security Program based on the results. Such testing and monitoring must include: (1) vulnerability testing of Respondent's network once every four (4) months and promptly (not to exceed thirty (30) days) after a Covered Incident, and (2) periodic penetration testing of Respondent's network and promptly (not to exceed thirty (30) days) after a Covered Incident;

H. Select and retain service providers capable of safeguarding Personal Information they access through or receive from Respondent, and contractually require service providers to implement and maintain safeguards for Personal Information; and

I. Evaluate and adjust the Information Security Program in light of any changes to Respondent's operations or business arrangements, a Covered Incident, or any other circumstances that Respondent knows or has reason to know may have an impact on the effectiveness of the Information Security Program. At a minimum, Respondent must evaluate the Information Security Program at least once every twelve (12) months and modify the Information Security Program based on the results.

IV. Information Security Assessments by a Third Party

IT IS FURTHER ORDERED that, in connection with compliance with Provision III of this Order, titled Mandated Information Security Program, Respondent must obtain initial and biennial assessments ("Assessments"):

A. The Assessments must be obtained from a qualified, objective, independent third-party professional ("Assessor"), who: (1) uses procedures and standards generally accepted in the profession; (2) conducts an independent review of the Information

Security Program; and (3) retains all documents relevant to each Assessment for five (5) years after completion of such Assessment and will provide such documents to the Commission within ten (10) days of receipt of a written request from a representative of the Commission. No documents may be withheld on the basis of a claim of confidentiality, proprietary or trade secrets, work product protection, attorney client privilege, statutory exemption, or any similar claim.

B. For each Assessment, Respondent must provide the Associate Director for Enforcement for the Bureau of Consumer Protection at the Federal Trade Commission with the name, affiliation, and qualifications of the proposed Assessor, who the Associate Director shall have the authority to approve in his sole discretion.

C. The reporting period for the Assessments must cover: (1) the first 180 days after the issuance date of the Order for the initial Assessment; and (2) each two-year period thereafter for twenty (20) years after issuance of the Order for the biennial Assessments.

D. Each Assessment must, for the entire assessment period:

1. determine whether Respondent has implemented and maintained the Information Security Program required by Provision III;

2. assess the effectiveness of Respondent's implementation and maintenance of sub- Provisions III.A-I;

3. identify any gaps or weaknesses in, or instances of material noncompliance with, the Information Security Program;

4. address the status of gaps or weaknesses in, or instances of material non-compliance with, the Information Security Program that were identified in any prior Assessment required by this Order; and

5. identify specific evidence (including, but not limited to, documents reviewed, sampling and testing performed, and interviews conducted) examined to make such determinations, assessments, and identifications, and explain why the evidence that the Assessor examined is (a) appropriate for assessing an enterprise of Respondent's size, complexity, and risk profile; and (b) sufficient to justify the Assessor's findings. No finding of any Assessment shall rely solely on assertions or attestations by Respondent's management. The Assessment must be signed by the Assessor, state that the Assessor conducted an independent review of the Information Security Program and did not rely solely on assertions or attestations by Respondent's management, and state the number of hours that each member of the assessment team worked on the Assessment. To the extent Respondent revises, updates, or adds one or more safeguards

required under Provision III in the middle of an Assessment period, the Assessment must assess the effectiveness of the revised, updated, or added safeguard(s) for the time period in which it was in effect, and provide a separate statement detailing the basis for each revised, updated, or additional safeguard.

E. Each Assessment must be completed within sixty (60) days after the end of the reporting period to which the Assessment applies. Unless otherwise directed by a Commission representative in writing, Respondent must submit the initial Assessment to the Commission within ten (10) days after the Assessment has been completed via email to DEbrief@ftc.gov or by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin, "In re SkyMed International, FTC File No. 1923140." All subsequent biennial Assessments must be retained by Respondent until the Order is terminated and provided to the Associate Director for Enforcement within ten (10) days of request.

V. Cooperation with Third-Party Information Security Assessor

IT IS FURTHER ORDERED that Respondent, whether acting directly or indirectly, in connection with any Assessment required by Provision IV must:

A. Provide or otherwise make available to the Assessor all information and material in its possession, custody, or control that is relevant to the Assessment for which there is no reasonable claim of privilege;

B. Provide or otherwise make available to the Assessor information about Respondent's networks and all of Respondent's IT assets so that the Assessor can determine the scope of the Assessment, and visibility to those portions of the networks and IT assets deemed in scope; and

C. Disclose all material facts to the Assessor, and not misrepresent in any manner, expressly or by implication, any fact material to the Assessor's: (1) determination of whether Respondent has implemented and maintained the Information Security Program required by Provision III; (2) assessment of the effectiveness of the implementation and maintenance of sub-Provisions III.A-I; or (3) identification of any gaps or weaknesses in, or instances of material noncompliance with, the Information Security Program.

VI. Annual Certification

IT IS FURTHER ORDERED that Respondent must:

A. One year after the issuance date of this Order, and each year thereafter, provide the Commission with a certification from a senior corporate manager, or, if no

such senior corporate manager exists, a senior officer of Respondent responsible for Respondent's Information Security Program that: (1) Respondent has established, implemented, and maintained the requirements of this Order; (2) Respondent is not aware of any material noncompliance that has not been (a) corrected or (b) disclosed to the Commission; and (3) includes a brief description of all Covered Incidents that Respondent verified or confirmed during the certified period. The certification must be based on the personal knowledge of the senior corporate manager, senior officer, or subject matter experts upon whom the senior corporate manager or senior officer reasonably relies in making the certification.

B. Unless otherwise directed by a Commission representative in writing, submit all annual certifications to the Commission pursuant to this Order via email to DEbrief@ftc.gov or by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin, "In re SkyMed International, FTC File No. 1923140."

VII. Covered Incident Reports

IT IS FURTHER ORDERED that Respondent, within thirty (30) days after Respondent's discovery of a Covered Incident, must submit a report to the Commission. The report must include, to the extent possible:

A. The date, estimated date, or estimated date range when the Covered Incident occurred;

B. A description of the facts relating to the Covered Incident, including the causes and scope of the Covered Incident, if known;

C. A description of each type of information that was affected or triggered any notification obligation to the U.S. federal, state, or local government entity;

D. The number of consumers whose information triggered any notification obligation to the U.S. federal, state, or local government entity;

E. The acts that Respondent has taken to date to remediate the Covered Incident and protect Personal Information from further exposure or access, and protect affected individuals from identity theft or other harm that may result from the Covered Incident; and

F. A representative copy of each materially different notice sent by Respondent to consumers or to any U.S. federal, state, or local government entity.

Unless otherwise directed by a Commission representative in writing, all Covered Incident reports to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by

overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin, "In re SkyMed International, FTC File No. 1923140."

VIII. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondent obtain acknowledgments of receipt of this Order:

A. Respondent, within ten (10) days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For twenty (20) years after the issuance date of this Order, Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order, and all agents, and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in Provision IX. Delivery must occur within ten (10) days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within thirty (30) days, a signed and dated acknowledgment of receipt of this Order.

IX. Compliance Report and Notices

IT IS FURTHER ORDERED that Respondent make timely submissions to the Commission:

A. One year after the issuance date of this Order, Respondent must submit a compliance report, sworn under penalty of perjury, in which Respondent must: (1) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (2) identify all of Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (3) describe the activities of each business, including the goods and services offered, what Personal Information is collected, and the means of advertising, marketing, and sales; (4) describe in detail whether and how Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes that Respondent made to comply with the Order; and (5) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

B. Respondent must submit a compliance notice, sworn under penalty of perjury, within fourteen (14) days of any change in the following: (1) any designated point of contact; or (2) the structure of Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

C. Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Respondent within fourteen (14) days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin, "In re SkyMed International, FTC File No. 1923140."

X. Recordkeeping

IT IS FURTHER ORDERED that Respondent must create certain records for twenty (20) years after the issuance date of the Order, and retain each such record for five (5) years, unless otherwise specified below. Specifically, Respondent must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. Personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name, addresses, telephone numbers, job title or position, dates of service, and (if applicable) the reason for termination;

C. Copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. A copy of each unique advertisement or other marketing material making a representation subject to this Order;

E. A copy of each widely disseminated representation by Respondent that describes the extent to which Respondent maintains or protects the privacy, security, availability, confidentiality, or integrity of any Personal Information, including any representation concerning a change in any website or other service controlled by Respondent that relates to privacy, security, availability, confidentiality, or integrity of Personal Information;

F. For five (5) years after the date of preparation of each Assessment required by this Order, all materials and evidence that the Assessor considered, reviewed, relied upon or examined to prepare the Assessment, whether prepared by or on behalf of Respondent, including all plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, and any other materials concerning Respondent's compliance with related Provisions of this Order, for the compliance period covered by such Assessment;

G. For five (5) years from the date received, copies of all subpoenas and other communications with law enforcement, if such communications relate to Respondent's compliance with this Order;

H. For five (5) years from the date created or received, all records, whether prepared by or on behalf of Respondent, that tend to show any lack of compliance by Respondent with this Order; and

I. All records necessary to demonstrate full compliance with each Provision of this Order, including all submissions to the Commission.

XI. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondent's compliance with this Order:

A. Within ten (10) days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit representatives of the Commission to interview anyone affiliated with Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, without the necessity of identification or prior notice. Nothing in this Order limits the

Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

XII. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate twenty (20) years from the date of its issuance, (which date may be stated at the end of this Order, near the Commission's seal), or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than twenty (20) years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Exhibit A

[To appear with the SkyMed logo]

Dear [Customer]:

In May 2019, we notified you by email that your personal information saved in a SkyMed database was exposed between October 2018 and March 2019. We said that there was no evidence that anyone had misused it. We also said that your health information and your financial information were not exposed.

We have since learned that the exposed database may have contained some members' health information, possibly including yours, and which may have included whether you were hospitalized or took any prescription medications. In addition, the other personal information exposed in the database included:

- your name
- your mailing address
- your email address
- your date of birth
- your phone number
- your membership number

Your Social Security number was not exposed. Neither was your financial information.

We've since put in place a new information security program to protect your information. If you have any questions or comments about this data exposure or what we do to protect your information, please contact us at [[email address]].

Eleanore Klein
President, SkyMed Group of Companies

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order from SkyMed International, Inc., also doing business as SkyMed Travel and Car Rental Pro ("SkyMed").

The proposed consent order ("Proposed Order") has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission again will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's Proposed Order.

SkyMed is a Nevada corporation with its principal place of business in Arizona. SkyMed provides emergency travel membership plans that cover travel and medical evacuation services for members who sustain serious illnesses or injuries during travel in certain geographic areas.

SkyMed has thousands of members. In applying for a membership, a consumer provides his or her name, date of birth, sex, home address, email address, phone number, emergency contact information, passport number, payment card information, a list of prescribed medications and medical conditions, and a list of all hospitalizations in the previous six months.

The Commission's proposed three-count complaint alleges that SkyMed violated Section 5(a) of the Federal Trade Commission Act by engaging in both unfair and deceptive acts or practices.

First, the proposed complaint alleges that SkyMed engaged in a number of unreasonable security practices that led to the exposure of a cloud database containing approximately 130,000 membership records with consumers' personal information stored in plain text. Specifically, the proposed complaint alleges that SkyMed:

- failed to develop, implement, or maintain written organizational information security standards, policies, procedures, or practices;
- failed to provide adequate guidance or training for employees or contractors regarding information security and safeguarding consumers' personal information;
- stored consumers' personal information on SkyMed's network and databases in plain text, without reasonable data access controls or authentication protections;
- failed to assess the risks to the personal information stored on its network and databases, such as by conducting periodic risk assessments or performing vulnerability and penetration testing of the network and databases;
- failed to have a policy, procedure, or practice for inventorying and deleting consumers' personal information stored on SkyMed's network that is no longer necessary; and
- failed to use data loss prevention tools to regularly monitor for unauthorized attempts to transfer or exfiltrate consumers' personal information outside of SkyMed's network boundaries.

The proposed complaint alleges SkyMed could have addressed each of these failures by implementing readily available and relatively low-cost security measures.

The proposed complaint alleges that SkyMed's failures caused or are likely to cause substantial injury to consumers that is not outweighed by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers themselves. Such practice constitutes an unfair act or practice under Section 5 of the FTC Act.

Second, the proposed complaint alleges that SkyMed engaged in a deceptive act when it notified current and former members about the database exposure. In an email to customers,

SkyMed represented that it had investigated the incident and learned that no consumer health information had been exposed in the incident, and that no one had misused the information. In reality, SkyMed did not examine the information stored in the cloud database, identify the consumers placed at risk by the exposure, or look for evidence of unauthorized access to the database. Rather, it merely identified the database and deleted it.

Third, the proposed complaint alleges that SkyMed engaged in a deceptive practice by displaying a seal on every page of its website that attested to its purported compliance with the Health Insurance Portability and Accountability Act, a statute that sets forth privacy and information security protections for health data. SkyMed's display of the seal signaled to consumers that a government agency or other third party had determined that SkyMed's information practices met HIPAA's requirements. The truth is that no government agency or other third party reviewed SkyMed's information practices for compliance with HIPAA, let alone determined that the practices met the requirements of HIPAA.

The Proposed Order contains injunctive relief addressing the alleged unfair and deceptive conduct.

Part I prohibits SkyMed from making false or deceptive statements regarding: (1) the extent to which it is a member of, complies with, is endorsed by, or otherwise participates in any privacy or security program sponsored by a government or third party; (2) the extent of any data security incident involving consumers' personal information; (3) the extent of any investigation, and the results thereof, relating to a data security incident; (4) the extent to which SkyMed collects, maintains, uses, discloses, deletes, or permits or denies access to consumers' personal information; and (5) the extent to which SkyMed otherwise protects the privacy, security, availability, confidentiality, or integrity of consumers' personal information.

Part II requires that SkyMed provide notice to all consumers that it previously emailed concerning the database exposure that their personal information, including potentially their health information, may have been exposed in the incident.

Part III requires SkyMed to establish and implement, and thereafter maintain, a comprehensive information security program that protects the security, confidentiality, and integrity of consumers' personal information.

Part IV requires SkyMed to obtain initial and biennial data security assessments for twenty years.

Part V of the Proposed Order requires SkyMed to disclose all material facts to the assessor and prohibits SkyMed from misrepresenting any fact material to the assessments required by Part IV.

Part VI requires SkyMed to submit an annual certification from a senior corporate manager (or senior officer responsible for its information security program) that SkyMed has implemented the requirements of the Order and is not aware of any material noncompliance that has not been corrected or disclosed to the Commission.

Part VII requires SkyMed to notify the Commission any time (1) it is required to make a notification to a federal, state, or local government that personal information has been breached or disclosed, or (2) individually identifiable health information from or about a consumer was, or is reasonably believed to have been, accessed, acquired, or publicly exposed without authorization.

Parts VIII through XI are reporting and compliance provisions, which include recordkeeping requirements and provisions requiring SkyMed to provide information or documents necessary for the Commission to monitor compliance.

Part XII states that the Proposed Order will remain in effect for twenty years, with certain exceptions.

The purpose of this analysis is to aid public comment on the Proposed Order. It is not intended to constitute an official interpretation of the complaint or Proposed Order, or to modify in any way the Proposed Order's terms.

Complaint

IN THE MATTER OF

BIONATROL HEALTH, LLC, ISLE REVIVE, LLC D/B/A ISLE REVIVE CBD, MARCELO TORRE, AND ANTHONY MCCABE

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4733; File No. 202 3114
Complaint, January 28, 2021 – Decision, January 28, 2021

This consent order addresses Bionatrol Health, LLC's advertising for products containing cannabidiol, including Bionatrol Full-Spectrum CBD Oil Extract. The complaint alleges that that Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by disseminating false and unsubstantiated advertisements claiming that their CBD Products, among other things: are safe for all users; treat pain better than prescription medicine like OxyContin; prevent and treat age-related cognitive decline, chronic pain, including arthritis pain, heart disease, hypertension, and migraines; and are "medically proven" to (a) improve anxiety, insomnia, chronic pain, hypertension, and cardiovascular health; (b) treat depression and bipolar disorder; (c) reduce age-related cognitive decline; (d) improve memory recall; and (e) reduce arthritis pain, migraines, and headaches. The complaint further alleges that Respondents misrepresented the cost to purchase one bottle of their CBD Oil Extract and unfairly charged consumers' credit cards for the additional cost without their express informed consent. The consent order prohibits Respondents from making any representation about the efficacy of any covered product, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

Participants

For the *Commission*: *Keith Fentonmiller*.

For the *Respondents*: *Karl Kronenberger, Kronenberger Rosenfeld, LLP*.

COMPLAINT

The Federal Trade Commission, having reason to believe that Bionatrol Health, LLC, a corporation, Isle Revive, LLC, also d/b/a Isle Revive CBD, a corporation, Marcelo Torre, individually and as an owner and manager of Bionatrol Health, LLC and Isle Revive, LLC, and Anthony McCabe (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Bionatrol Health, LLC ("Bionatrol") is a Utah corporation with its principal place of business at 1269 W. Spencer Rd., Pleasant Grove, Utah 84062. Bionatrol's business registration with the State of Utah expired on May 14, 2020.

2. Respondent Isle Revive, LLC ("Isle Revive"), also doing business as Isle Revive CBD, is a Utah corporation with its principal place of business at 1269 W. Spencer Rd., Pleasant Grove, Utah 84062. The company's business registration status with the State of Utah is in a delinquent status. Isle Revive processed payments from consumers who purchased CBD products from Bionatrol and, as recently as April 2020, offered Bionatrol Full-Spectrum CBD Oil Extract for sale at www.islerevivecbd.com.

3. Respondent Marcelo Torre has managed Bionatrol and serves as the company's registered agent. Torre also has owned and managed Isle Revive. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices alleged in this complaint. Torre resides in Salt Lake City, Utah.

4. Respondent Anthony McCabe was the manager and owner of Bionatrol. He also managed and owned part or all of Isle Revive. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices alleged in this complaint. McCabe resides in San Diego, California.

5. Respondents Bionatrol and Isle Revive (collectively, "Corporate Respondents") have operated as a common enterprise while engaging in the unlawful acts and practices alleged below. Corporate Respondents have conducted the business practices described below through an interrelated network of companies that have common ownership, officers, business functions, business and mailing addresses, and unified advertising and marketing. Because these Corporate Respondents have operated as a common enterprise, each of them is jointly and severally liable for the acts and practices alleged below. Respondents Torre and McCabe formulated, directed, controlled, had the authority to control, or participated in the acts and practices of the common enterprise alleged in this Complaint.

6. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

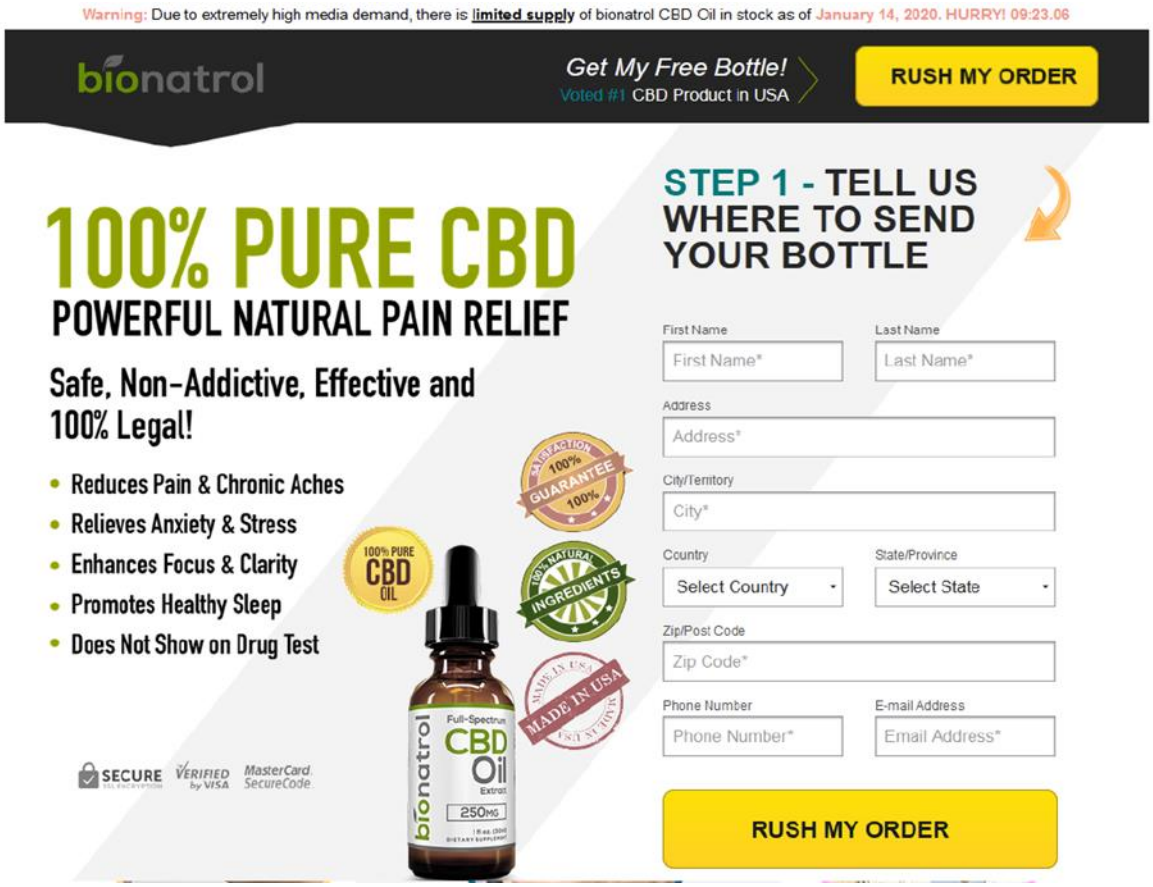
Respondents' Marketing of CBD Products

7. Cannabidiol ("CBD") is a substance naturally occurring in, and that can be extracted from, the hemp plant, *cannabis sativa*. Respondents advertised, promoted, offered for sale, sold, and distributed products containing CBD ("CBD Products") that are intended for human use. These CBD Products are "food" and/or "drugs," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

8. Through the website bionatrolcbd.com, Respondents sold Full-Spectrum CBD Oil Extract in bundles of one, three, and five bottles for, respectively, $64.99 (plus $7.95 shipping), $149.97, and $199.95. During the ordering process, the website offered "upsells" for, among other things, one bottle of Full-Spectrum CBD Oil Extract Sleep Aid capsules at a cost of $49.99 and one bottle of Full-Spectrum CBD Gummies at a cost of $54.95.

Complaint

9. From approximately December 2019 through April 2020, Respondents disseminated or caused to be disseminated advertisements for CBD Products, including but not necessarily limited to the attached Exhibits A through C. Respondents promoted CBD Products through a variety of means, including through their websites bionatrolcbd.com and islerevivecbd.com and an Instagram account at www.instagram.com/bionatrol_cbd. These advertisements contained the following statements and depictions:



[Ex. A (excerpt from www.bionatrolcbd.com) (captured Jan. 14, 2020)]

# # #

[Ex. A (excerpt from www.bionatrolcbd.com) (captured Jan. 14, 2020)]

# # #

THE SCIENCE OF

CBD (CANNABIDOIL) [sic]

The endocannabinoid system (ECS) regulates everything from relaxation to eating, sleeping, inflammation and even cognitive function…. CBD Oil has been medically proven to positively regulate your ECS addressing issues such as **anxiety, insomnia, chronic pain, hypertension and even cardiovascular issues.**

- **Physical Benefits:** Stimulates an anti-inflammatory response which helps reduce all forms of chronic aches and pains. . . .

- **Psychological Benefits:** Helps positively regulate mood patterns which help reduce anxiety and stress. It also promotes better sleep cycles and in some cases may offer a safe remedy for depression and bipolar disorders.

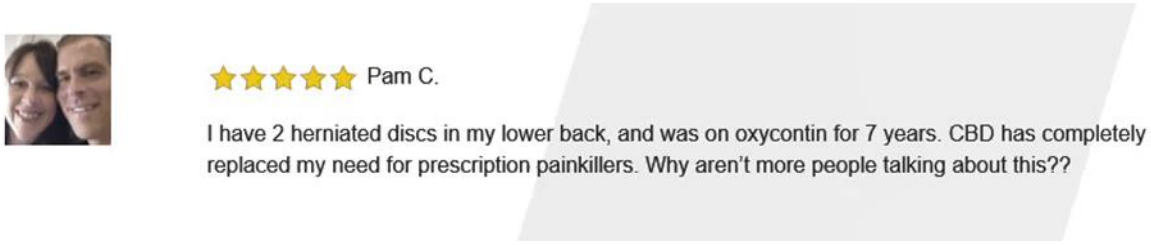
- **Neurological Benefits:** Our CBD Oil's positive impact on the neural system helps reduce age-related cognitive decline. It also helps support focus, alertness & memory recall while reducing the frequency of migraines and headaches.

[Ex. A (excerpt from www.bionatrolcbd.com) (captured Jan. 14, 2020)]

# # #

[Ex. B (excerpt from www.bionatrolcbd.com, identified by Respondents as BIO00018)]

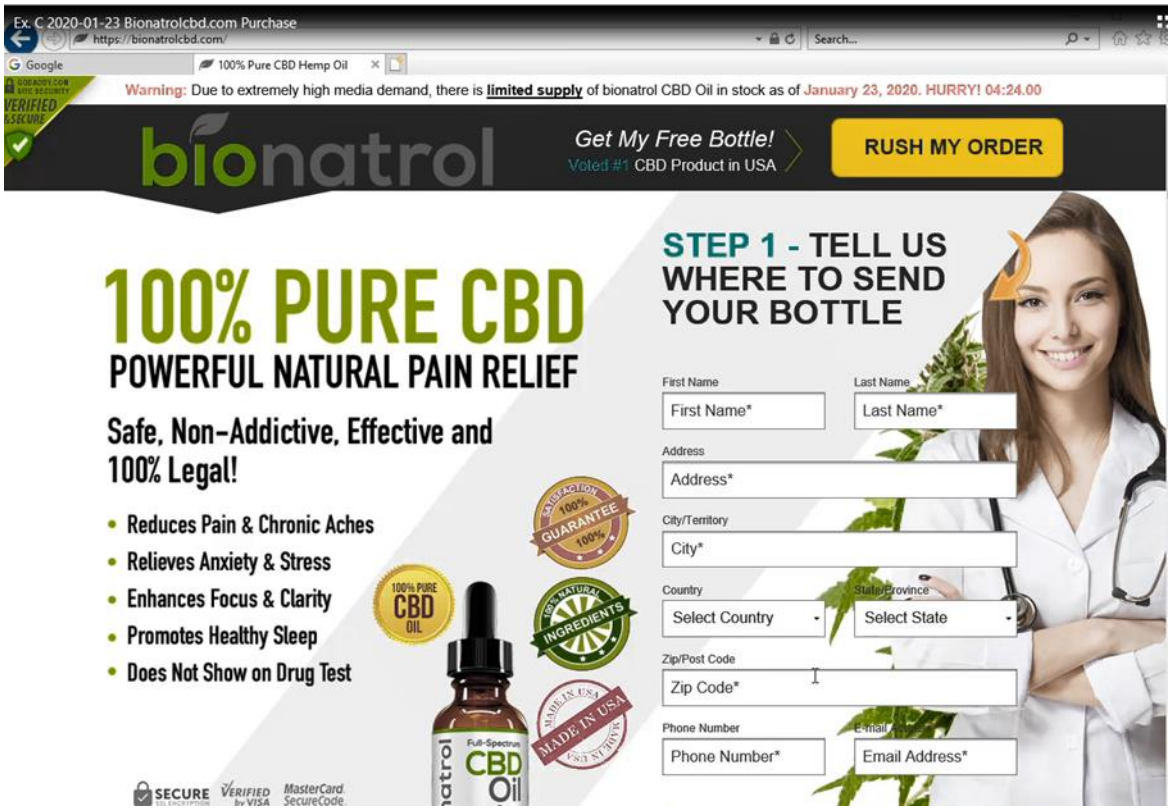
# # #



[Ex. C (partial screen grab from recording of purchase at www.bionatrolcbd.com on Jan. 23, 2020, time index 0:14)]

10. Respondents have not conducted any studies demonstrating that their CBD products cure, treat, alleviate, or prevent diseases or health conditions. There are no competent and reliable human clinical studies in the scientific literature to substantiate that these products or their ingredients cure, treat, mitigate, or prevent the diseases or health conditions mentioned in the advertising excerpts set forth in Paragraph 9

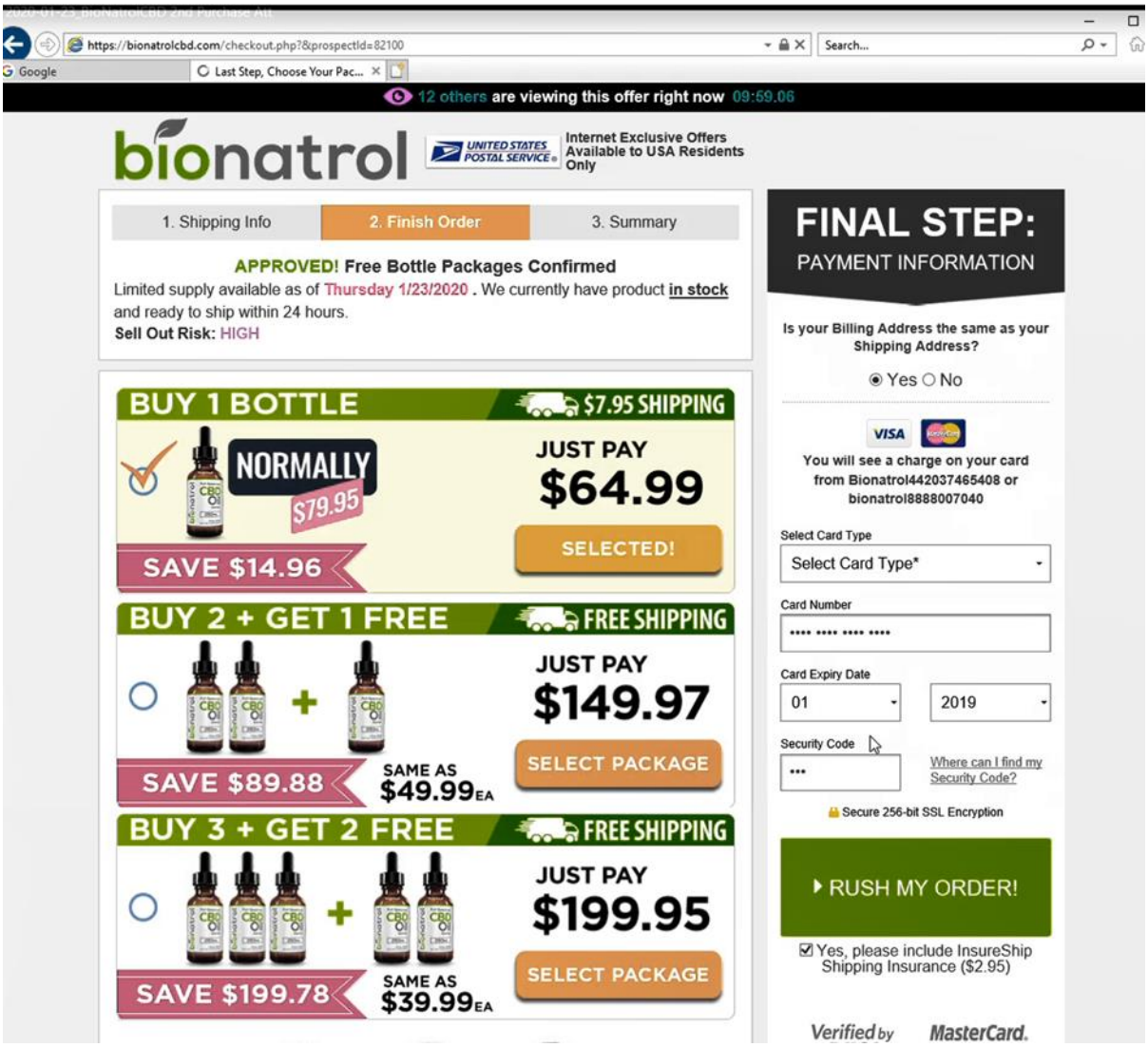
11. Consumers who visited www.bionatrolcbd.com saw a webpage, a portion of which is depicted below, with the statements "Get My Free Bottle!" and "STEP 1 – TELL US WHERE TO SEND YOUR BOTTLE," and a request for the consumers' contact information.



[Ex. C (partial screen grab from recording of purchase at www.bionatrolcbd.com on Jan. 23, 2020, time index 0:01)]

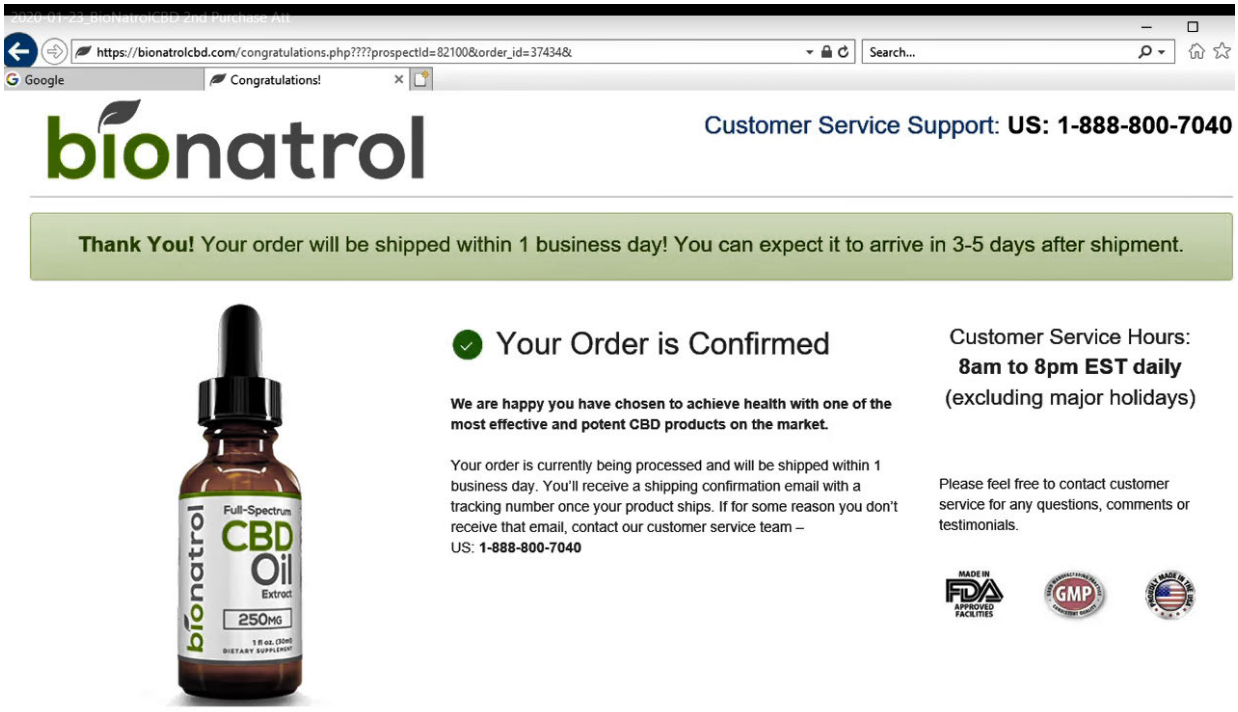
12. After inputting the contact information and clicking the "Rush My Order" button for the free bottle of CBD oil, consumers were presented with a screen, a portion of which is depicted below, that stated, "APPROVED! Free Bottle Packages Confirmed" and presented three purchase options: "BUY 1 BOTTLE" for $64.99 plus $7.95 shipping, "BUY 2 + GET 1 FREE" for $149.97 and free shipping, or "BUY 3 + GET 2 FREE" for $199.95 and free shipping. The radial button next to the BUY 1 BOTTLE offer was prechecked, and consumers could not uncheck it. To advance the order, consumers had to input their name, address, and credit card information. A disclosure above the information fields stated, "You will see a charge on your credit card from Bionatrol…."

Complaint



[Ex. C (partial screen grab from recording of purchase at www.bionatrolcbd.com on Jan. 23, 2020, time index 3:27-31 and 4:00-03)]

13. Clicking the "RUSH MY ORDER" button took consumers through a series of "upsell" offers for other products before they were presented with an order confirmation screen. That screen, a portion of which is depicted below, showed an image of a single bottle of CBD oil and provided no information about the quantity of bottles ordered or the amount, if any, charged to the consumers' credit card.



[Ex. C (partial screen grab from recording of purchase at www.bionatrolcbd.com on Jan. 23, 2020, time index 5:50)]

14. Upon completion of the ordering process for a single bottle, Respondents emailed consumers a purchase confirmation. The email memorialized the purchase of the "Bionatrol CBD Oil 3+2 Package" and indicated that Bionatrol had charged $199.95 to the consumer's credit card. In at least one instance, the name listed on the credit card billing statement was "Isle Revive CBD."

Count I

False or Unsubstantiated Efficacy Claims

15. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBD Products, including through the means described in Paragraph 9 of this Complaint, Respondents have represented, directly or indirectly, expressly or by implication, that CBD Products:

a. treat, alleviate, or cure age-related cognitive decline; bipolar disorder; chronic pain, including arthritis pain; depression; heart disease; hypertension; and migraines;

b. prevent age-related cognitive decline; chronic pain, including arthritis pain; heart disease; hypertension; and migraines;

c. can replace the need for prescription painkillers like oxycontin; and

d. are safe for all consumers.

16. The representations set forth in Paragraph 15 are false or misleading, or were not substantiated at the time the representations were made.

Count II

False Establishment Claims

17. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBD Products, including through the means described in Paragraph 9 of this Complaint, Respondents have represented, directly or indirectly, expressly or by implication, that studies or scientific research prove that CBD Products:

a. improve alertness, focus, and memory recall;

b. treat, alleviate, or cure age-related cognitive decline; anxiety; bipolar disorder; chronic pain, including arthritis pain; depression; heart disease; hypertension; inflammation; insomnia; and migraines; and

c. prevent age-related cognitive decline; anxiety; chronic pain, including arthritis pain; heart disease; hypertension; inflammation; insomnia; and migraines.

18. In fact, studies or scientific research do not prove that CBD Products:

a. improve alertness, focus, and memory recall;

b. treat, alleviate, or cure age-related cognitive decline; anxiety; bipolar disorder; chronic pain, including arthritis pain; depression; heart disease; hypertension; inflammation; insomnia; and migraines; and

c. prevent age-related cognitive decline; anxiety; chronic pain, including arthritis pain; heart disease; hypertension; inflammation; insomnia; and migraines.

Therefore, the representations set forth in Paragraph 17 are false or misleading.

Count III

Deceptive Pricing

19. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBD products, including through the means described in Paragraphs 11-14 of this Complaint, Respondents represented, directly or indirectly, expressly or by implication, that they would send consumers one bottle of Full-Spectrum CBD Oil Extract for $64.99 plus $7.95 shipping.

20. In fact, consumers who ordered one bottle of Full-Spectrum CBD Oil Extract were charged $199.95 and sent five bottles. Therefore, the representations set forth in Paragraph 19, above, are false or misleading.

Count IV

Unfairly Charging Consumers without Authorization

21. In connection with the advertising, marketing, promotion, offering for sale, or sale of CBD products, including through the means described in Paragraphs 11-14 of this Complaint, Respondents have caused charges to be submitted for payment to the credit cards of consumers without the express informed consent of those consumers.

22. Respondents' actions caused or were likely to cause substantial injury to consumers that consumers could not reasonably avoid themselves and that was not outweighed by countervailing benefits to consumers or competition. Therefore, Respondents' practices as described in Paragraph 21, above, constitute unfair acts or practices.

Violations of Sections 5 and 12

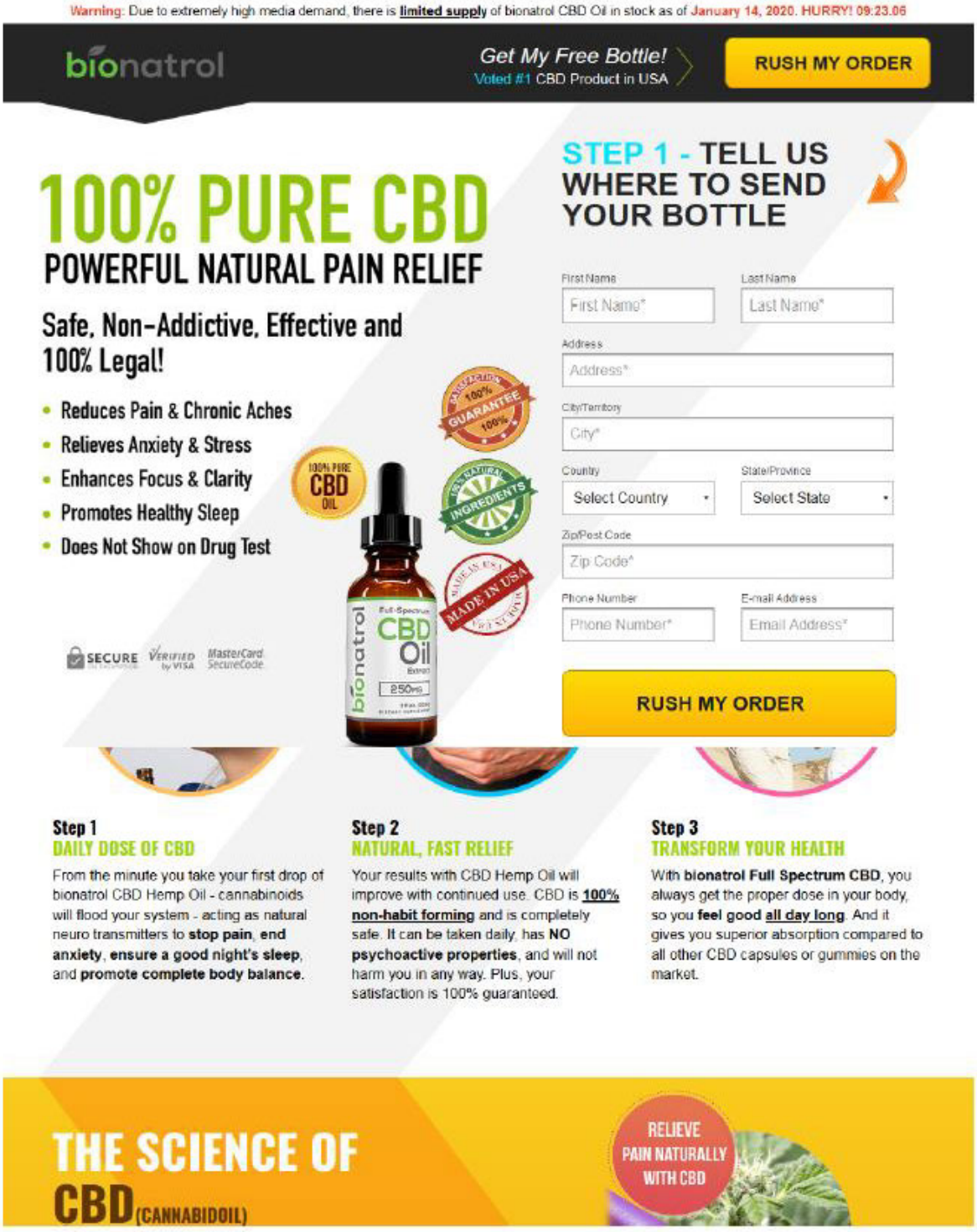
23. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twenty-eighth day of January, 2021, has issued this Complaint against Respondents.

By the Commission.

Complaint

Exhibit A



FTC Cmplt. Ex. A-1

The endocannabinoid system (ECS) regulates everything from relaxation to eating, sleeping, inflammation and even cognitive function. In a nutshell, the ECS is responsible for making sure the entire body is working optimally. CBD Oil has been medically proven to positively regulate your ECS addressing issues such as **anxiety, insomnia, chronic pain, hypertension and even cardiovascular issues**.

- **Physical Benefits:** Stimulates an anti-inflammatory response which helps reduce all forms of chronic aches and pains. Regular use also helps support joint health, mobility, and flexibility.
- **Psychological Benefits:** Helps positively regulate mood patterns which help reduce anxiety and stress. It also promotes better sleep cycles and in some cases may offer a safe remedy for depression and bipolar disorders.
- **Neurological Benefits:** Our CBD Oil's positive impact on the neural system helps reduce age-related cognitive decline. It also helps support focus, alertness & memory recall while reducing the frequency of migraines and headaches.

wonderful - it's obvious that you're using the finest oil out there. It's really refreshing to meet a company who cares so much about quality.

★★★★★ Julie S.

What a wonderful gift this made to my boys. (They're both in grad school, and going through finals). Your CBD not only helped significantly improve their grades, but, and I know this is going to sound a bit strange - they both seem more focused and responsible. Like they're really growing up!

★★★★★ Ted E.

This is hands down the best pain relief I've ever had. Plus no side-effects, and the pain in my shoulder is about 90% gone now.

★★★☆☆ Pete G.

I love your CBD Tincture, I really do, and would have given you 5 stars, but the last time few times I visited your website, you were out of stock. Please get more in soon, this is the only thing that's helped with my knees. (I've had 7 surgeries on them now).

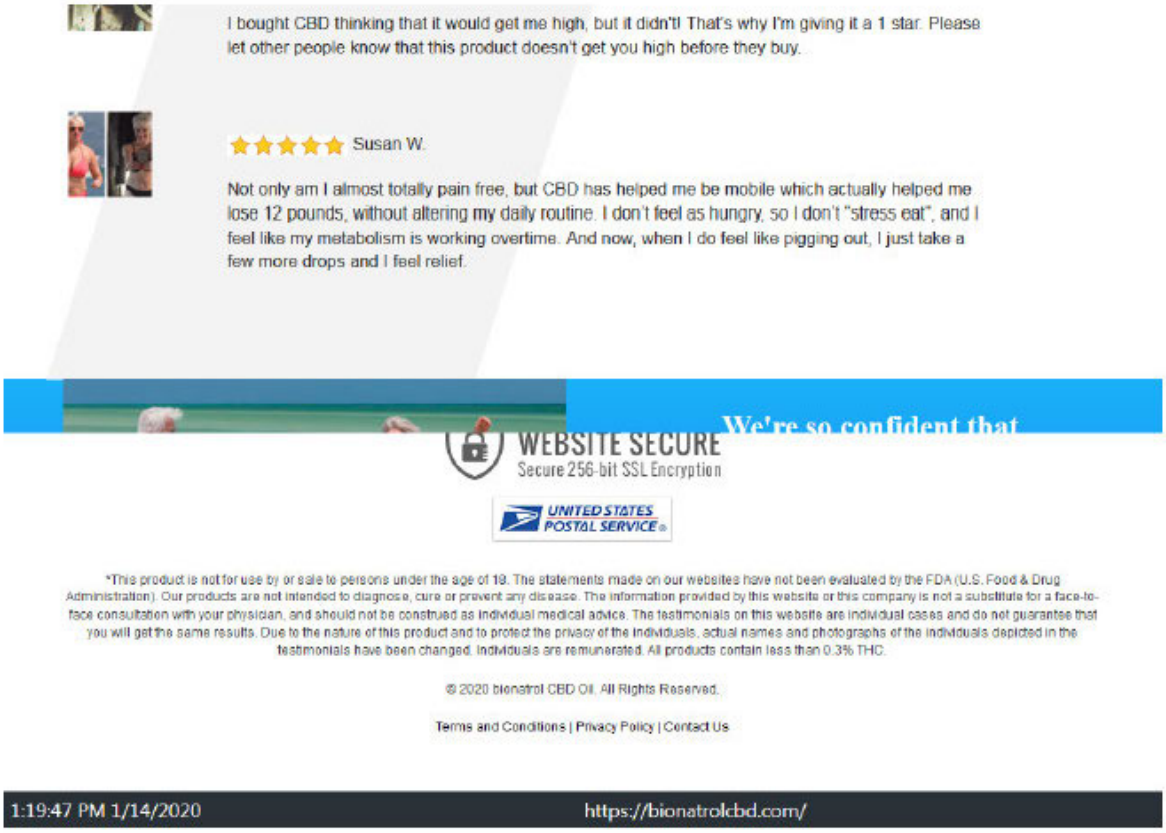
★★★★★ Nancy K.

The chronic pain in my wrist and in my hip is GONE. And if it ever starts to flare up (which is quite rare now), all I do is take a few drops, and the pain melts away in minutes.

★☆☆☆☆ Buddha Lover

FTC Cmplt. Ex. A-2

Complaint



FTC Cmplt. Ex. A-3

Exhibit B

FTC Cmplt. Ex B-1

Complaint

FTC Cmplt. Ex B-2

Exhibit C

VIDEO RECORDING

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

    a. Respondent Bionatrol Health, LLC ("Bionatrol") is a Utah corporation with its principal place of business at 1269 W. Spencer Rd., Pleasant Grove, Utah 84062. Bionatrol's business registration with the State of Utah expired on May 14, 2020.

    b. Respondent Isle Revive, LLC ("Isle Revive"), also doing business as Isle Revive CBD, is a Utah corporation with its principal place of business at 1269 W. Spencer Rd., Pleasant Grove, Utah 84062. The company's

business registration status with the State of Utah is in a delinquent status. Isle Revive processed payments from consumers who purchased CBD products from Bionatrol and, as recently as April 2020, offered Bionatrol Full-Spectrum CBD Oil Extract for sale at www.islerevivecbd.com.

c. Respondent Marcelo Torre has managed Bionatrol and serves as the company's registered agent. Torre also has owned and managed Isle Revive. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices alleged in this complaint. Torre resides in Salt Lake City, Utah.

d. Respondent Anthony McCabe was the manager and owner of Bionatrol. He also managed and owned part or all of Isle Revive. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices alleged in this complaint. McCabe resides in San Diego, California.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions apply:

A. "**Billing Information**" means any data that enables any person to access a customer's account, such as a credit card, checking, savings, share or similar account, utility bill, mortgage loan account, or debit card.

B. "**CBD Product**" means any Dietary Supplement, Food, or Drug containing cannabidiol.

C. "**Charge**," "**Charged**," or "**Charging**" means any attempt to collect money or other consideration from a consumer, including causing Billing Information to be submitted for payment, including against the consumer's credit card, debit card, bank account, telephone bill, or other account.

D. "**Clear(ly) and Conspicuous(ly)**" means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be

presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means.

2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.

5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.

6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.

7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.

8. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

E. "**Covered Product(s)**" means any Dietary Supplement, Food, or Drug, including but not limited to CBD Products sold or marketed by Respondents.

F. "**Respondents**" means all of the Individual Respondents and the Corporate Respondents, individually, collectively, or in any combination.

1. "**Corporate Respondents**" means Bionatrol Health, LLC, and its successors and assigns, and Isle Revive, LLC, doing business as Isle Revive CBD, and their successors and assigns.

2. "**Individual Respondent**" means Marcelo Torre and Anthony McCabe.

G. "**Dietary Supplement**" means (1) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more

ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional Food or as a sole item of a meal or the diet.

H. "**Drug**" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than Food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

I. "**Essentially Equivalent Product**" means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients) in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

J. "**Food**" means (1) any article used for Food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

PROVISIONS

I. PROHIBITED REPRESENTATIONS: REGARDING HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, or assist others in making, expressly or by implication, any representation that such product:

A. treats, alleviates, or cures age-related cognitive decline;

B. prevents age-related cognitive decline; pain, including arthritis pain; hypertension; or migraines;

C. treats, alleviates, or cures any disease, including but not limited to bipolar disorder; pain, including arthritis pain; depression; heart disease; hypertension; and migraines;

D. replaces the need for prescription painkillers like oxycontin; or

E. is safe for all consumers,

unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Provision, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product must not make, or assist others in making, expressly or by implication, any representation, other than representations covered under the Provision of this Order entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product,

or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. all protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. all documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. all documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. all documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Corporate Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

IV. PROHIBITED MISREPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not misrepresent, in any manner, expressly or by implication:

A. that any Covered Product is clinically proven to:

   1. improve alertness, focus, or memory recall;

   2. treat, alleviate, or cure age-related cognitive decline; anxiety; bipolar disorder; pain, including arthritis pain; depression; heart disease; hypertension; inflammation; insomnia; or migraines; or

   3. prevent age-related cognitive decline; anxiety; , including arthritis pain; heart disease; hypertension; inflammation; insomnia; or migraines;

B. that the performance or benefits of a Covered Product are scientifically or clinically proven or otherwise established; or

C. the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V. PROHIBITED MISREPRESENTATIONS ABOUT THE COST OF A GOOD OR SERVICE

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not misrepresent, in any manner, expressly or by implication:

A. any cost to the consumer to purchase, receive, use, or return the initial good or service;

B. that the consumer will not be Charged for any good or service;

C. that a good or service is offered on a "free," "trial," "sample," "bonus," "gift," "no obligation," "discounted" basis, or words of similar import, denoting or implying the absence of an obligation on the part of the recipient of the offer to affirmatively act in order to avoid Charges, including where a Charge will be assessed pursuant to the offer unless the consumer takes affirmative steps to prevent or stop such a Charge;

D. that the consumer can obtain a good or service for a processing, service, shipping, handling, or administrative fee with no further obligation;

E. any purpose for which the consumer's Billing Information will be used;

F. that a transaction has been authorized by the consumer;

G. any material aspect of the nature or terms of a refund, cancellation, exchange, or repurchase policy for the good or service; or

H. any other material fact.

VI. PROHIBITIONS AGAINST UNAUTHORIZED CHARGES

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not Charge, causing to be Charged, assist others in Charging, or attempt to Charge any consumer, without obtaining the consumer's express informed consent to the Charge and having created and maintained a record of such consent.

VII. FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them from:

A. for any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. for any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VIII. MONETARY RELIEF

IT IS FURTHER ORDERED that:

A. Corporate Respondents must pay to the Commission $20,000.00, which Respondents stipulate their undersigned counsel holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

IX. ADDITIONAL MONETARY PROVISIONS

IT IS FURTHER ORDERED that:

A. Corporate Respondents and Individual Respondent Torre relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Corporate Respondents

and Individual Respondent Torre have no right to challenge any activities pursuant to this Provision.

E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that payment is due, the entire amount will immediately become due and payable.

F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.

G. Corporate Respondents and Individual Respondent Torre acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers), which those Respondents have previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

X. NOTICES TO CUSTOMERS

IT IS FURTHER ORDERED that Corporate Respondents and Individual Respondent Torre ("They") must notify customers as follows:

A. They must identify all consumers who purchased CBD Products on or after June 10, 2019 ("eligible customers").

1. Such eligible customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody or control, including from third parties such as resellers;

2. Eligible customers include those identified at any time, including after Respondents' execution of the Agreement through the eligibility period, which runs for 1 year after the issuance date of the Order.

B. They must send a notice via electronic mail to all identified eligible customers:

1. The notice must be in the form shown in Attachment A.

2. The subject line of the email notice must state, "About Your Purchase of Bionatrol CBD Oil."

3. The email of the notice must not include any other attachments.

C. They must notify all eligible customers within 45 days after the issuance date of this Order and any eligible customers identified thereafter within 30 days of their identification.

D. They must report on their notification program under penalty of perjury:

1. They must submit a report within 90 days after the issuance date of this Order summarizing their compliance to date, including the total number of eligible customers identified and notified.

2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, they must submit it within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

XI. ACKNOWLEDGMENTS OF THE ORDER

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 10 years after the issuance date of this Order, each Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is the majority owner or controls directly or indirectly, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for labeling, manufacturing, advertising, marketing, promotion, distribution, offering for sale, or sale of any Covered Product and all agents and representatives who participate in labeling, manufacturing, advertising, marketing, promotion, distribution, offering for sale, or sale of any Covered Product; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

XII. COMPLIANCE REPORTS AND NOTICES

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. Sixty days after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondents must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, each Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 10 years after the issuance date of this Order, each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, each Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Bionatrol Health, LLC, FTC File No. 202-31144.

XIII. RECORDKEEPING

IT IS FURTHER ORDERED that Respondents must create certain records for 10 years after the issuance date of the Order, and retain each such record for 5 years, unless otherwise specified below. Specifically, Corporate Respondents and each Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. a copy of each unique advertisement or other marketing material making a representation subject to this Order;

F. for 5 years from the date of the last dissemination of any representation covered by this Order:

1. all materials that were relied upon in making the representation; and

2. all tests, studies, analysis, other research, or other such evidence in Respondents' possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations;

G. for 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communications relate to Respondents' compliance with this Order; and

H. for 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents, that tend to show any lack of compliance by Respondents with this Order.

XIV. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the

Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Respondents, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XV. ORDER EFFECTIVE DATES

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. any Provision in this Order that terminates in less than 20 years;

B. this Order's application to any Respondent that is not named as a defendant in such complaint; and

C. this Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ATTACHMENT A TO THE ORDER

CLAIMS ABOUT PRODUCTS CONTAINING CBD
In re Bionatrol Health, LLC

Dear <Name of customer>:

Our records show that you bought Bionatrol Full-Spectrum CBD Oil from bionatrolcbd.com. We are writing to tell you that the Federal Trade Commission (FTC), the nation's consumer protection agency, has sued us for making misleading claims that our CBD oil can effectively prevent, cure, treat, or ease serious diseases and health conditions, including the following: age-related cognitive decline, arthritis pain, bipolar disorder, depression, heart disease, hypertension, and migraines.

To settle the FTC's lawsuit, we're contacting our customers to tell them that we don't have proof that our CBD products will effectively prevent, cure, treat, or improve the serious diseases and health conditions listed above. If you have other questions about this lawsuit, visit [add URL].

CBD oil and other alternative treatments might be harmful to your medical care, and could interfere with your prescriptions. CBD products could also be dangerous if you take them with other medicines or at a high dose. Talk to your doctor before you take any treatments or stop any prescriptions. For more information about protecting yourself from bogus health product claims visit ftc.gov/health.

Sincerely,

[Signature]

Marcelo Torre, Manager
Anthony McCabe, Former Manager
Bionatrol Health, LLC

Concurring Statement

STATEMENT OF COMMISSIONER ROHIT CHOPRA

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.

- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.

- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish – and unlawful – claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine "a competitor's ability to compete" on honest attributes.[1]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID-19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[2] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer

1 *In re Pfizer, Inc.*, 81 F.T.C. 23, 62 (1972).

2 *See, e.g.*, Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL STREET J. (Sept. 8, 2020), https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; *Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic*, AMERICAN MEDICAL ASSOCIATION (last updated on Oct. 31, 2020), https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.

Americans into high-cost, subpar treatment centers, and some even hire intermediaries – so-called "body brokers" – who collect kickbacks from this harmful practice.[3]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[4] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[5]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[6] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[7] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[8] Under the Penalty Offense

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3 For example, recent reporting describes the "Florida Shuffle," where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America*, VOX (Mar. 2, 2020), https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-brijayne. *See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), https://www ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid (calling on the FTC to do more to tackle this problem).

4 Pub. L. No. 115-271 §§ 8021-8023 (codified in 15 U.S.C. § 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

5 Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.

6 Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.

7 In one of these matters, the respondents are paying nothing.

8 15 U.S.C. § 45(m)(1)(b).

Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[9] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[10] and apprising firms of these findings – along with a warning that noncompliance can result in penalties – makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a "high level of voluntary compliance achieved quickly and at a low cost."[11] Going forward, we should pursue this strategy.[12]

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.

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9 *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256. Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

10 This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that "[f]airness to the consumer, as well as fairness to competitors" compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.*, 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that "a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act." *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.*, 155 F.T.C. 1, 6 (2013).

11 Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an "extremely effective and efficient way to enforce the law." Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.

12 My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

CONCURRING STATEMENT OF COMMISSIONER CHRISTINE S. WILSON

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication.

The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters[1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo- controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain

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1 Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions*, Oct. 22, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims; Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis*, Sept. 10, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused; Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases*, Apr. 2, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.

2 Press Release, *FTC Order Stops the Marketer of "Thrive" Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID-19*, July 10, 2020, available at https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.

3 *See, e.g.*, Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

conditions – specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that "[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes."[6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

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4 *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.

5 *See, e.g.*, Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC v. Avrom Boris Lasarow, et al.* (Feb. 2015), https://www ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health; Statement of Commissioner Joshua D. Wright, *FTC v. Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin; Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), https://www ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru; Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part; Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC v. Springtech 77376, et al.* (July 2013), https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; *see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12-49 (May 2012), available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.

6 *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order with Bionatrol Health, LLC ("Bionatrol"); Isle Revive, LLC also doing business as Isle Revive CBD ("Isle Revive"); Marcelo Torre, individually and as a manager of Bionatrol and Isle Revive; and Anthony McCabe, individually (collectively, "Respondents").

The proposed consent order ("order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves Respondents' advertising for products containing cannabidiol ("CBD Products), including Bionatrol Full-Spectrum CBD Oil Extract. The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that their CBD Products, among other things: are safe for all users; treat pain better than prescription medicine like OxyContin; prevent and treat age-related cognitive decline, chronic pain, including arthritis pain, heart disease, hypertension, and migraines; and are "medically proven" to (a) improve anxiety, insomnia, chronic pain, hypertension, and cardiovascular health; (b) treat depression and bipolar disorder; (c) reduce age-related cognitive decline; (d) improve memory recall; and (e) reduce arthritis pain, migraines, and headaches. The complaint further alleges that Respondents misrepresented the cost to purchase one bottle of their CBD Oil Extract and unfairly charged consumers' credit cards for the additional cost without their express informed consent.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food that Respondents sell or market, including CBD Products.

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product:

A. treats, alleviates, or cures age-related cognitive decline;

B. prevents age-related cognitive decline; pain, including arthritis pain; hypertension; or migraines;

C. treats, alleviates, or cures any disease, including but not limited to bipolar disorder; pain, including arthritis pain; depression; heart disease; hypertension; and migraines;

D. replaces the need for prescription painkillers like oxycontin; or

E. is safe for all consumers,

unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety, or side effects of any covered product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III requires that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by the order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits Respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research or that any benefit of any covered product is scientifically or clinically proven.

Part V prohibits Respondents from misrepresenting, among other things, any cost to the consumer to purchase, receive, use, or return the initial good or service; that a good or service is offered on a "free," "trial," "sample," "bonus," "gift," "no obligation," "discounted" basis, or words of similar import; and any material aspect of the nature or terms of a refund, cancellation, exchange, or repurchase policy for the good or service.

Analysis to Aid Public Comment

Part VI prohibits Respondents from charging any consumer without obtaining the consumer's express informed consent to the charge and having created and maintained a record of such consent.

Part VII provides Respondents a safe harbor for making claims approved by the Food and Drug Administration ("FDA").

Parts VIII and IX require Respondents Bionatrol and Isle Revive to pay the Commission $20,000.00 and describes the procedures and legal rights related that payment.

Part X requires Respondents Bionatrol, Isle Revive, and Torre to send email notices to consumers who purchased Bionatrol Full-Spectrum CBD Oil Extract informing them about the settlement.

Parts XI requires Respondents to submit an acknowledgement of receipt of the order, to serve the order on certain individuals, including all officers or directors of any business Respondents control and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which Respondents have delivered a copy of the order.

Part XII requires Respondents to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. **Part XIII** contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance or non-compliance with the order. **Part XIV** contains other requirements related to the Commission's monitoring of Respondents' order compliance. **Part XV** provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

Complaint

IN THE MATTER OF

EASYBUTTER, LLC.
AND
MICHAEL SOLOMON

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4734; File No. 202 3047
Complaint, February 1, 2021 – Decision, February 1, 2021

This consent order addresses EasyButter, LLC's advertising of products containing cannabidiol. The complaint alleges that Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by disseminating false and unsubstantiated advertisements claiming that: (1) their CBD Products prevent diabetes and treat acne, AIDS, autism, bipolar disorder, cancer, depression, epilepsy, PTSD, seizures, and substance abuse; (2) tests or studies prove that their CBD products treat autism; and (3) doctors recommend CBD over prescription medications for depression and PTSD. The consent order prohibits Respondents from making any representation about the efficacy of any covered product, including that such product will: (1) alleviate or cure seizures; or (2) cure, mitigate, or treat any disease, including but not limited to acne, AIDS, autism, bipolar disorder, cancer, depression, diabetes, epilepsy, post-traumatic stress disorder, and substance abuse, unless the representation is non-misleading, including that, at the time such representation is made, he possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true.

Participants

For the *Commission*: *Gideon Sinasohn.*

For the *Respondents*: *Jessica Shraybman, Shraybman Law, PLLC.*

COMPLAINT

The Federal Trade Commission, having reason to believe that EasyButter, LLC., a limited liability company, and Michael Solomon, individually and as officer and owner of EasyButter, LLC (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent EASYBUTTER, LLC ("EasyButter") is a Florida limited liability company with its principal place of business at 1289 Clint Moore Rd, Boca Raton, FL 33487.

2. Respondent MICHAEL SOLOMON ("Solomon") is an owner and President of EasyButter and is the owner. Individually or in concert with others, Michael Solomon controlled or had the authority to control, or participated in the acts and practices of EasyButter, including the acts and practices set forth in this Complaint. His principal office or place of business is the same as that of EasyButter.

3. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Respondents' Marketing of CBD Products

4. Cannabidiol ("CBD") is a substance naturally occurring in, and that can be extracted from, the hemp plant, *cannabis sativa*. Respondents have advertised, promoted, offered for sale, sold, and distributed products containing CBD ("CBD Products") that are intended for human use. These CBD Products are "food" and/or "drugs," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

5. Consumers can purchase Respondents' CBD products by calling (833) 743-6763 or by ordering online at www.hempmeCBD.com.

6. Respondents' CBD products are offered for human and animal consumption and topical application in a variety of products, including oils, creams, hemp shea butter, bath bombs, lip balms, gummies, hemp tabs, honey sticks, lozenges, and assorted pet products.

7. These products are sold to consumers under the names: "Hempme Hemp Shea Butter;" "Hempme Facial Moisturizer;" "Hempme Hemp Repair RX Pain;" "Hempme CBD Gummy Bears;" "Hempme Hemp Gummies;" "Hempme CBD Tablets;" "Hempme CBD Organic Gummy;" "Hempme CBD Sugarfree Gummy;" "Hempme Gummy Worms;" "Hempme Energy Lemon Haze Terpene Hemp Lozenges;" "Hempme Relax Grape/Grand Daddy Purp Terpene Hemp Lozenges;" "Hempme CBD Honey Sticks;" "Hempme Hemp Oil;" "Hempme Roll On Menthol Temple Massage;" "Hempme CBD Massage Oil;" "Hempme Cinnamon Hemp Oil;" "Hempme Blueberry Hemp Oil;" "Hempme Peppermint Hemp Oil;" "Hempme Peach Hemp Oil;" " Hempme Strawberry Hemp Oil;" "Hempme Citrus Skin Care Pump;" Hempme Pre-Rolled Tube (Strawberry);" "Hempme Pre-Rolled Tube (Pineapple);" "Hempme Pre-Rolled Tube (Kush);" "Hempme Strawberry CBD Oil Cartridge;" "Hempme Blueberry CBD Oil Cartridge;" "CBD Disposable Vapor Pen (Relax);" "CBD Disposable Vapor Pen (Energy);" "Hempme Bubble Gum CBD Oil Cartridge;" "Hempme Watermelon CBD Oil Cartridge;" "Hempme Fruit Punch CBD Oil Cartridge;" and "Hempme Pineapple CBD Oil Cartridge."

8. Respondents represent, directly or indirectly, expressly or by implication through their websites and in product labels depicted on their websites that Respondents' CBD products prevent diabetes or treat or cure a variety of ailments, including AIDS, acne, autism, bipolar disease, cancer, depression, epilepsy, post-traumatic stress disorder (PTSD), and seizures.

9. Respondents charge consumers $12.95 to $305.95 for Respondents' CBD products, plus shipping and handling.

Respondents' Advertising and Marketing

10. Since at least January 2018, to induce consumers to purchase their products, Respondents have disseminated or caused to be disseminated advertisements and promotional

materials. Respondents have promoted CBD products through the website www.hempmeCBD.com and social media. These advertisements and promotional materials have contained the following representations or statements, among others:

a. From Respondents' website, www.HempMeCBD.com, captured on January 6, 2020:

i. "**A Real Life-Saver**

Doctors have just recently been able to truly study [CBD's] effects on the human bod (sic), and its ability to alleviate the symptoms of conditions ranging from AIDS to seizures is showing incredible results. CBD's anti-psychotic properties can help with people's mental health issues. People suffering from PTSD, Anxiety & Depression have seen major improvements from consistent doses of the compound, and Doctors around the world are beginning to recommend CBD over prescription medications."

ii. "Also, in a recent study, Israeli research has shown an 80% success rate in reducing problematic behavior in children with Autism using CBD."

iii. "It is theorized that the reason CBD has such a positive effect could be because of its impact on cannabinoid receptors inside the brain of someone with Autism. CBD appears to 'open' these receptors' pathways to allow molecules to act on them. These pathways were previously closed off by the condition."

iv. "Depression is an emotional cause of sleeping challenges. Also, lack of enough sleep can cause depression. Sleep deprivation also makes one agitated, tense and irritable and the effects can be overwhelming. Since depression is rooted in the nervous system, it's often caused by chemical imbalance. According to Dr. Charles Raison, CNN's mental health expert, CBD oil can restore the chemical imbalance and help in dealing with depression, leading to improved sleep."

v. "Some of the top health benefits of CBD oil has been known to cure are seizures, anxiety, depression, and cancer-related symptoms. It has even been proven to aid in substance abuse treatment and diabetes prevention."

vi. "Also it has a profound effect on helping people dealing with: Acne, Stomach illness, Even cancer symptoms."

vii. "CBD has a profound effect on helping people dealing with . . . cancer symptoms"

viii. "CBD is commonly known to alleviate ailments related to mental diseases such as: Epilepsy Depression Bipolar."

Count I
False or Unsubstantiated Efficacy Claims

11. In connection with the advertising, marketing, promotion, offering for sale, or sale of CBD products, including through the means described in Paragraph 10, Respondents have represented, directly or indirectly, expressly or by implication, that their CBD products prevent diabetes and treat acne, AIDS, autism, bipolar disorder, cancer, depression, epilepsy, PTSD, seizures, and substance abuse.

12. The representations set forth in Paragraph 11 are false or misleading or were not substantiated at the time the representations were made.

Count II
False Establishment Claims

13. In connection with the advertising, marketing, promotion, offering for sale, or sale of CBD products, including through the means described in Paragraph 10, Respondents have represented, directly or indirectly, expressly or by implication, that:

a. tests or studies prove that their CBD products treat autism; and

b. doctors recommend CBD over prescription medications for depression and PTSD.

14. In fact, tests or studies do not prove that CBD treats autism, and doctors do not recommend CBD over prescription medications for depression and PTSD. Therefore, the making of the representations set forth in Paragraph 13 are false or misleading.

Violations of Sections 5 and 12

15. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this first day of February, 2021, has issued this Complaint against Respondents.

By the Commission.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

    a. EasyButter, LLC, is a Florida Limited Liability Company with its principal place of business at 1289 Clint Moore Rd, Boca Raton, FL 33487.

    b. Michael Solomon is an owner and President of EasyButter, LLC. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of EasyButter, LLC. His principal office or place of business is the same as that of EasyButter, LLC.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions apply:

A. "CBD Product" means any Dietary Supplement, Food, or Drug containing cannabidiol.

B. "Covered Product" or "Covered Products" means any Dietary Supplement, Food, or Drug, including but not limited to CBD Products sold or marketed by Respondents.

C. "Dietary Supplement" means: (1) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

D. "Drug" means: (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

E. "Essentially Equivalent Product" means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive binders, colors, fillers, excipients) in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

F. "Food" means: (1) any article used for food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

G. "Respondents" means the Corporate Respondent and the Individual Respondent, individually, collectively, or in any combination.

1. "Corporate Respondent" means EasyButter, LLC, a limited liability company, and its successors and assigns.

2. "Individual Respondent" means Michael Solomon.

PROVISIONS

I. PROHIBITED REPRESENTATIONS: REGARDING HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, or assist others in making, expressly or by implication, any representation that such product:

A. alleviates or cures seizures; or

B. cures, mitigates, or treats any disease, including but not limited to acne, AIDS, autism, bipolar disorder, cancer, depression, diabetes, epilepsy, post-traumatic stress disorder, and substance abuse,

unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Provision, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product must not make, or assist others in making, expressly or by implication, any

representation, other than representations covered under the Provision of this Order entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product for humans or animals, including that such product prevents diabetes, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Corporate Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

IV. PROHIBITED MISREPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not misrepresent, in any manner, expressly or by implication that:

A. Any Covered Product is clinically proven to treat autism;

B. Doctors recommend any Covered Product over prescription medications for depression, and PTSD;

C. The performance or benefits of any product are scientifically or clinically proven or otherwise established; or

D. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V. FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them from:

A. For any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. For any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI. MONETARY RELIEF

IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $36,254.37, which Respondents stipulate their undersigned counsel holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

VII. ADDITIONAL MONETARY PROVISIONS

IT IS FURTHER ORDERED that:

A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondents have no right to challenge any activities pursuant to this Provision.

E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that payment is due, the entire amount will immediately become due and payable.

F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.

G. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers), which Respondents have previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

VIII. NOTICES TO CUSTOMERS

IT IS FURTHER ORDERED that Respondents must notify customers as follows:

A. Respondents must identify all consumers who purchased CBD Products on or after January 1, 2018 and through September 1, 2020 ("eligible customers").

1. Such eligible customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody or control, including from third parties such as resellers;

2. Eligible customers include those identified at any time, including after Respondents' execution of the Agreement through the eligibility period, which runs for 1 year after the issuance date of the Order.

B. Respondents must notify all identified eligible customers by mailing each a notice:

1. The letter must be in the form shown in Attachment A.

2. The envelope containing the letter must be in the form shown in Attachment B.

3. The mailing of the notification letter must not include any other enclosures.

4. The mailing must be sent by first-class mail, postage prepaid, address correction service requested with forwarding and return postage guaranteed. For any mailings returned as undeliverable, Respondents must use standard address search methodologies such as re-checking Respondents' records and the Postal Service's National Change of Address database and re-mailing to the corrected address within 8 days.

C. Respondents must notify all eligible customers within 180 days after the issuance date of this Order and any eligible customers identified thereafter within 30 days of their identification.

D. Respondents must provide a notice on all of their social media accounts (including any Facebook, Twitter, Instagram, or YouTube accounts) and on the first page of their websites. Such notice must link to a copy of the Order, along with a toll-free telephone number and an email address for the redress administrator. The notice must be posted not later than 3 days after the effective date of the Order and for at least 1 year after the redress period ends.

E. Respondents must report on their notification program under penalty of perjury:

1. Respondents must submit a report annually and at the conclusion of the program summarizing its compliance to date, including the total number of eligible customers identified and notified.

2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Respondents must submit it within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

IX. ACKNOWLEDGMENTS OF THE ORDER

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 20 years after the issuance date of this Order, each Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is the majority owner or controls directly or indirectly, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for labeling, manufacturing, advertising, marketing, promotion, distribution, offering for sale, or sale of CBD Products and all agents and representatives who participate in labeling, manufacturing, , advertising, marketing, promotion, distribution, offering for sale, or sale of CBD Products; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within [30] days, a signed and dated acknowledgment of receipt of this Order.

X. COMPLIANCE REPORTS AND NOTICES

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. Sixty days after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondents must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, each Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such

Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. Each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, each Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re HempmeCBD, FTC File No. 2023047.

XI. RECORDKEEPING

IT IS FURTHER ORDERED that Respondents must create certain records for 20 years after the issuance date of the Order, and retain each such record for 5 years, unless otherwise

specified below. Specifically, Corporate Respondents and each Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. Personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. Copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. A copy of each unique advertisement or other marketing material making a representation subject to this Order;

F. For 5 years from the date of the last dissemination of any representation covered by this Order:

1. All materials that were relied upon in making the representation; and

2. All tests, studies, analysis, other research, or other such evidence in Respondents' possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations;

G. For 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communications relate to Respondents' compliance with this Order; and

H. For 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents that tend to show any lack of compliance by Respondents with this Order.

XII. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Respondents, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XIII. ORDER EFFECTIVE DATES

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such

complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ATTACHMENT A TO THE ORDER – LETTER TEMPLATE

CLAIMS ABOUT PRODUCTS CONTAINING CBD

Federal Trade Commission v. EasyButter, LLC, et. al.

<Date>

Subject: [*Insert name of product customer will recognize*]

<Name of customer>
<mailing address of customer
including zip code>

Dear <Name of customer>:

Our records show that you bought [names of products] from [our company *or other name consumers will recognize – the retailer, perhaps*]. We are writing to tell you that the Federal Trade Commission, the nation's consumer protection agency, has [charged us with *or* sued us for] deceptive or false advertising.

The Federal Trade Commission (FTC), the nation's consumer protection agency, sued [our company *or other name consumers will recognize – the retailer, perhaps*] for making misleading claims that our CBD products can effectively prevent, cure, treat, or mitigate serious diseases and health conditions, including the following:

> acne; AIDS; autism; bipolar disorder; cancer; depression; diabetes; epilepsy; PTSD; seizures; and substance abuse.

We're writing to inform you that, contrary to our claims, there is no scientific proof that our CBD products will effectively prevent, cure, treat, or mitigate the serious diseases and health conditions listed above.

CBD products and other alternative treatments might be harmful to your medical care, and could interfere with your prescriptions. CBD products could also be dangerous if you take

them with other medicines or at a high dose. Talk to your doctor before you take any treatments or stop any prescriptions.

As a part of this lawsuit, you may be entitled to a refund. Please visit [URL] for more information about refunds. If you have other questions about this lawsuit, visit [add URL]. For more information about protecting yourself from bogus health product claims visit ftc.gov/health.

Sincerely,

[signature]

[*identify Respondent/Defendant or other person responsible for signing the notification letter*]

ATTACHMENT B to the Order – Envelope Template:

The envelope for the notification letter must be in the following form, with the underlined text completed as directed:

[*Identify Respondent*
Street Address
City, State and Zip Code]

FORWARDING AND RETURN POSTAGE GUARANTEED ADDRESS CORRECTION SERVICE REQUESTED

[name and
mailing address of customer,
including zip code]

Concurring Statement

STATEMENT OF COMMISSIONER ROHIT CHOPRA

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish – and unlawful – claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine "a competitor's ability to compete" on honest attributes.[1]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID-19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[2] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer

1 *In re Pfizer, Inc.*, 81 F.T.C. 23, 62 (1972).

2 *See, e.g.*, Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL STREET J. (Sept. 8, 2020), https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; *Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic*, AMERICAN MEDICAL ASSOCIATION (last updated on Oct. 31, 2020), https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.

Americans into high-cost, subpar treatment centers, and some even hire intermediaries – so-called "body brokers" – who collect kickbacks from this harmful practice.[3]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[4] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[5]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[6] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[7] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[8] Under the Penalty Offense

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3 For example, recent reporting describes the "Florida Shuffle," where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America*, VOX (Mar. 2, 2020), https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-brijayne. *See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), https://www ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid (calling on the FTC to do more to tackle this problem).

4 Pub. L. No. 115-271 §§ 8021-8023 (codified in 15 U.S.C. § 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

5 Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.

6 Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.

7 In one of these matters, the respondents are paying nothing.

8 15 U.S.C. § 45(m)(1)(b).

Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[9] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[10] and apprising firms of these findings – along with a warning that noncompliance can result in penalties – makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a "high level of voluntary compliance achieved quickly and at a low cost."[11] Going forward, we should pursue this strategy.[12]

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.

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9 *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256. Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

10 This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc.*, *supra* note 2 (finding that "[f]airness to the consumer, as well as fairness to competitors" compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.*, 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that "a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act." *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.*, 155 F.T.C. 1, 6 (2013).

11 Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an "extremely effective and efficient way to enforce the law." Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.

12 My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

CONCURRING STATEMENT OF COMMISSIONER CHRISTINE S. WILSON

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication.

The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters[1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo- controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain

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1 Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions*, Oct. 22, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims; Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis*, Sept. 10, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused; Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases*, Apr. 2, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.

2 Press Release, *FTC Order Stops the Marketer of "Thrive" Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID-19*, July 10, 2020, available at https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.

3 *See, e.g.*, Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

conditions – specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that "[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes."[6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

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4 *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.

5 *See, e.g.*, Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC v. Avrom Boris Lasarow, et al.* (Feb. 2015), https://www ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health; Statement of Commissioner Joshua D. Wright, *FTC v. Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin; Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), https://www ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru; Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part; Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC v. Springtech 77376, et al.* (July 2013), https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; *see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12-49 (May 2012), available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.

6 *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order with EASYBUTTER, LLC, ("EasyButter") and Michael Solomon, individually and as an officer and owner of EASYBUTTER, LLC. ("Respondents").

The proposed consent order ("order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the Respondents' advertising of products containing cannabidiol ("CBD Products). The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) their CBD Products prevent diabetes and treat acne, AIDS, autism, bipolar disorder, cancer, depression, epilepsy, PTSD, seizures, and substance abuse; (2) tests or studies prove that their CBD products treat autism; and (3) doctors recommend CBD over prescription medications for depression and PTSD.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food the Respondents sell, market, promote, or advertise, including CBD Products

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product will: (1) alleviate or cure seizures; or (2) cure, mitigate, or treat any disease, including but not limited to acne, AIDS, autism, bipolar disorder, cancer, depression, diabetes, epilepsy, post-traumatic stress disorder, and substance abuse, unless the representation is non-misleading, including that, at the time such representation is made, he possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, "competent and reliable scientific evidence" must consist of human clinical testing of the covered product or of an essentially equivalent product that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety or side effects of any covered product, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the

relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III requires that with regard to any human clinical test or study ("test") upon which the Respondents rely to substantiate any claim covered by the order, the Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits Respondents from misrepresenting: (1) that any covered product is scientifically proven to treat autism; (2) that doctors recommend any covered product over prescription medications for depression, and PTSD; (3) that the performance or benefits of any product are scientifically or clinically proven; or (4) the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research; are scientifically or clinically proven.

Part V provides Respondents a safe harbor for making claims approved by the Food and Drug Administration ("FDA").

Part VI requires Respondents to pay the Commission $36,254.37 within 8 days of the effective date of the order.

Part VII requires Respondents to relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to the order.

Part VIII requires Respondents to send notices to consumers who purchased their CBD products informing them about the settlement.

Parts IX requires Respondents to submit an acknowledgement of receipt of the order, and for the individual Respondent to serve the order on certain individuals, including all officers or directors of any business the individual Respondent controls and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which a Respondent has delivered a copy of the order.

Part X requires Respondents to file compliance reports with the Commission, and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. **Part XI** contains recordkeeping requirements for accounting records,

personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance or non-compliance with the order. **Part XII** contains other requirements related to the Commission's monitoring of the Respondents' order compliance. **Part XIII** provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

Complaint

IN THE MATTER OF

CBD MEDS, INC.,
G2 HEMP, INC.,
AND
LAWRENCE MOSES
A/K/A
LAWRENCE D. MOSES, JR.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4735; File No. 202 3080
Complaint, February 2, 2021 – Decision, February 2, 2021

This consent order addresses CBD Meds, Inc.'s advertising of products containing cannabidiol. The complaint alleges that Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by disseminating false and unsubstantiated advertisements claiming that: (1) CBD treats, prevents, or reduces the risk of artery blockage, dementia, blood sugar levels, seizures and convulsions, psoriasis, HIV dementia, cancer, age-related bone disease, arthritis, blood pressure conditions, diabetes, gastrointestinal disorders, glaucoma, strokes, Alzheimer's disease, multiple sclerosis, Parkinson's disease, epilepsy, autism, post traumatic stress disorder, bipolar disorders, and schizophrenia; (2) clinical trials, studies, or scientific research prove that CBD treats or prevents seizures, cancer, strokes, Alzheimer's disease, Parkinson's disease, and HIV dementia, and may make chemotherapy more effective; (3) a U.S. government study has shown that CBD may make chemotherapy more effective; and (4) the U.S. government has stated that CBD is scientifically proven to have antioxidant and neuroprotectant properties. The consent order prohibits Respondents from making any representation about the efficacy of any covered product, including that such product will: (1) treat blood pressure conditions or gastrointestinal disorders; (2) reduce seizures and convulsions; (3) reduce blood sugar levels; or (4) cure, mitigate or treat any disease in humans, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

Participants

For the *Commission*: *Barbara Chun.*

For the *Respondents*: *Lawrence Moses, CEO and Owner, pro se.*

COMPLAINT

The Federal Trade Commission, having reason to believe that CBD Meds, Inc., a corporation, G2 Hemp, Inc., a corporation, and Lawrence Moses, individually and as an officer of CBD Meds, Inc. and G2 Hemp, Inc. (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent CBD Meds, Inc. ("CBD Meds") is a California nonprofit mutual benefit corporation. Pursuant to California law, a nonprofit mutual benefit corporation is set up for the benefit of its members and may conduct business at a profit. Cal. Corp. Code §§ 7110

cmt., 7140(l). Thus, CBD Meds is a corporation organized to carry on business for its own profit or the profit of its members within the meaning of Section 4 of the FTC Act. 15 U.S.C. § 44. Its principal office or place of business is in Winchester, California 92596.

2. Respondent G2 Hemp, Inc. ("G2 Hemp") is a California corporation. Its principal office or place of business is in Winchester, California 92596.

3. Respondent Lawrence Moses ("Moses"), also known as Lawrence D. Moses, Jr., is the owner and CEO of CBD Meds and G2 Hemp. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices of CBD Meds and G2 Hemp, including the acts and practices alleged in this Complaint. His principal office or place of business is the same as that of CBD Meds and G2 Hemp.

4. Respondents CBD Meds and G2 Hemp (collectively, "Corporate Respondents") have operated as a common enterprise while engaging in the unlawful acts and practices alleged below. Corporate Respondents have conducted the business practices described below through interrelated companies that have common ownership, officers, managers, business functions, and office locations. Because these Corporate Respondents have operated as a common enterprise, each of them is jointly and severally liable for the acts and practices alleged below. Respondent Moses has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of the common enterprise alleged in this Complaint.

5. Cannabidiol ("CBD") is a substance naturally occurring in, and that can be extracted from, the hemp plant, *cannabis sativa*. Respondents have advertised, promoted, offered for sale, sold and distributed products intended for human and animal consumption or use containing CBD. Consumers have been able to purchase Respondents' CBD products by ordering online at G2Hemp.com. Respondents' CBD products are offered in the form of capsules for both humans and pets, droppers, chewing gum, and skin cream. According to the product labels, dosages vary. For the capsules and pet meds, for example, each capsule contains either 10 or 25 mg of CBD. Respondents' CBD products are "food" and/or "drugs," within the meaning of Sections 12 and 15(b) and (c) of the Federal Trade Commission Act.

6. The acts and practices of Respondents alleged in this Complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Respondents' Advertising and Marketing of CBD Products

7. To induce consumers to purchase their products, Respondents have disseminated or have caused to be disseminated advertisements for their CBD products. Respondents promoted CBD products through the websites CBDMEDS.org and G2Hemp.com, and through social media such as YouTube. These advertisements have contained the following representations or statements, among others, that CBD can treat, prevent or mitigate various serious medical conditions or diseases:

a. From CBDMeds.org, captured April 17, 2020 (Ex. A ("What is CBD and what are its benefits" page)) and G2Hemp.com, captured January 30, 2020 (Ex. B (same)).

What is CBD and what are its benefits?

by Lawrence | Mar 9, 2017 | Latest News | 0 comments

Research on the benefits of cannabidiol (CBD) is well documented by the U.S. government via the NCBI (National Center for Biotechnology Information) and the U.S. National Library of Medicine. We have compiled six (6) therapeutic properties of CBD with links below. Our government explains in great detail the scientific explanation for each of the following therapeutic properties of cannabidiol:

1. Analgesic (Pain Relief) – https://www.ncbi.nlm.nih.gov/pubmed/11164622
2. Anti-Emetic (Nausea Relief) – https://www.ncbi.nlm.nih.gov/pubmed/10575283
3. Anti-Inflammatory – https://www.ncbi.nlm.nih.gov/pubmed/10575283
4. Anti-Psychotic – https://www.ncbi.nlm.nih.gov/pubmed/22716160
5. Anti-Seizure – https://www.ncbi.nlm.nih.gov/pubmed/10863546
6. Anti-Anxiety – https://www.ncbi.nlm.nih.gov/pubmed/6285406

b. From CBDMeds.org, captured April 17, 2020 (Ex. C ("Home" page)) and G2Hemp.com, captured March 2, 2020 (Ex. D ("Home" page)).

> Later, [the federal government] even patented "cannabinoids as antioxidants and neuroprotectants". US Patent 6630507(2) outlines specific potential for stroke, brain trauma, Alzheimer's and other conditions. Here's a copy of the actual patent:
> [Image of patent heading].
>
> ***
>
> 'Cannabis and Cannabinoids' by the United States Federal Government
> [Image of National Cancer Institute trademark]
>
> Let's help educate ourselves! The following information comes straight from our United States Federal government from one of its websites Cancer.gov! Please share so that all people can read about what our government is saying about cannabis as a treatment for cancer and other serious chronic conditions. The information provided is very objective, as it is based on the results of clinical trials our government has conducted on mice and rats.

c. From CBDMeds.org, captured April 17, 2020 (Ex. C (Home page)).

> Latest News . . .
> National Cancer Institutes' [sic] Clinical Studies on CBD
> Feb 5, 2016

The United States Federal Government performed a laboratory study of cannabidiol (CBD) in human glioma cells showed [sic] that when given along with chemotherapy, CBD may make chemotherapy more effective and increase cancer cell death without harming normal cells.

d. From CBDMeds.org, captured April 17, 2020 (Ex. E (United States Patent on CBD page)) and G2Hemp.com, captured January 30, 2020 (Ex. F (same)):

United States Patent on CBD (Patent #6630507)
by Lawrence | Sep 7, 2016 | Latest News | 0 comments

Cannabinoids as antioxidants and neuroprotectants – straight from the horse's mouth! Another [sic] words, straight from our federal government!!!

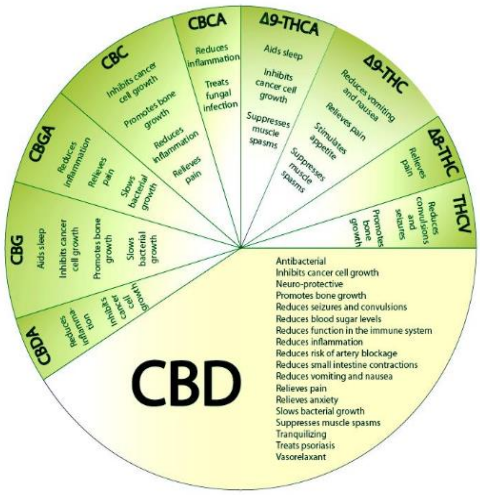
According to our own United States Federal Government, Cannabinoids such as CBD have been found to have antioxidant and neuroprotectant properties. . .The cannabinoids are found to have particular application as neuroprotectants, for example in limiting neurological damage following ischemic insults, such as stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia.

Still don't believe us that our federal government took out a patent on CBD and other cannabinoids? Click the following link and please share this with any of your friends who may be skeptical about the positive medicinal benefits of medical cannabis!

e. From CBDMeds.org, captured April 17, 2020 ("About" page):

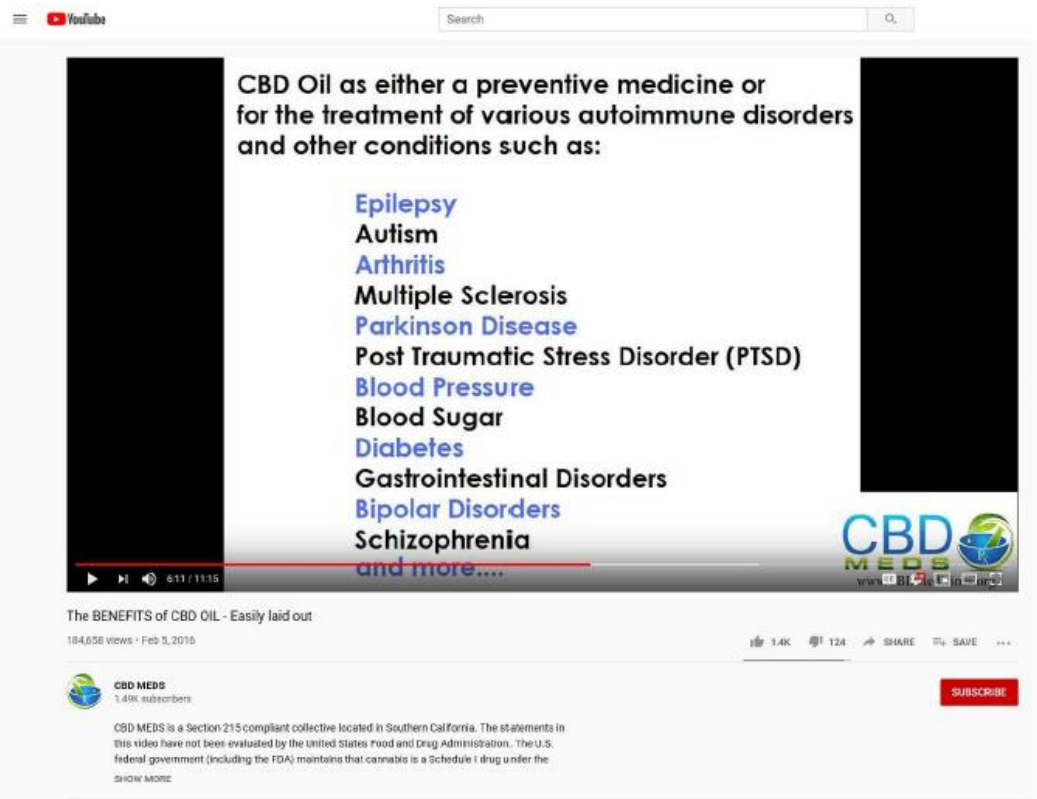
About our CBD Medicines

It is our belief that cannabidiol (CBD) offers the most therapeutic and medicinal benefits found in any cannabinoid from the cannabis plant. We also believe that the medicinal benefits of an enriched CBD cannabis plant are superior to an enriched CBD hemp plant. Our reasoning is that a CBD hemp plant contains zero amounts of THC, and we believe that THC plays a vital role in CBD's efficiency, and here is why. CBD and THC are the two biggest cannabinoids found in the cannabis plant, with CBD alone accounting up to 40% of the plant's extract. Based on the medical results from our patients who have taken CBD oils from both the cannabis plant and the hemp plant, we firmly believe that the two most significant cannabinoids (CBD & THC) were meant to work together. Therefore, until the science is available to prove us wrong, we have decided to not supply, offer, or endorse any CBD products which come from a CBD hemp plant. Instead, we have cloned our own CBD strain called Geneis I, which has very low amounts of THC in it, with the objective that it will not disrupt or interfere with a patient's daily life. A good analogy we can use to help support our theory goes like this. If THC was a vehicle's alternator and CBD was the engine, then anyone could turn the ignition, but if the alternator is not present, one cannot fire up the engine!



f. From CBD Meds' YouTube video, "The BENEFITS of CBD OIL – Easily laid out," captured February 27, 2020 (screenshot at 6 minutes, 3 to 24 seconds):

ON-SCREEN



VOICE-OVER BY NARRATOR, LAWRENCE MOSES:

"Your doctor may recommend CBD oil as either preventative medicine or for the treatment of various autoimmune disorders and other conditions such as epilepsy, autism, arthritis, multiple sclerosis, Parkinson's disease, post traumatic stress disorder, blood pressure, blood sugar, diabetes, gastrointestinal disorders, bipolar disorders, schizophrenia, and more."

g. From G2Hemp.com, captured January 30, 2020 (Ex. G ("Benefits from CBD for Seniors" page)):

Benefits from CBD for Seniors
. . .
Cardiovascular Improvement . . . [CBD oil's] anti-inflammatory effects can help with heart diseases and may even help prevent strokes.

> Improves Bone Health . . . Research is showing that CBD oil may help delay bone decay and prevent age-related bone disease. It can even help heal fractures and stimulate bone growth and collagen production.
>
> Protects Against Alzheimers [sic] and Dementia . . . CBD oil may help prevent the onset of [Alzheimer's disease and dementia] thanks to its neuroprotectant properties.
>
> Parkinson's Disease Prevention . . . CBD oil could play a role in managing the symptoms of and even preventing Parkinson's disease.
>
> Relief from Glaucoma . . . CBD oil could provide some relief and possibly even prevention, thanks to its promotion of neural health.

Count I
False or Unsubstantiated Efficacy Claims

8. In connection with the advertising, marketing, promotion, offering for sale, or sale of CBD products, including through the means described in Paragraph 7, Respondents have represented, directly or indirectly, expressly or by implication, that CBD:

a. reduces risk of artery blockage;

b. prevents dementia;

c. reduces blood sugar levels;

d. prevents or reduces seizures and convulsions;

e. treats psoriasis and HIV dementia; and

f. treats or prevents cancer, age-related bone disease, arthritis, blood pressure conditions, diabetes, gastrointestinal disorders, glaucoma, strokes, Alzheimer's disease, multiple sclerosis, Parkinson's disease, epilepsy, autism, post traumatic stress disorder, bipolar disorders, and schizophrenia.

9. The representations set forth in Paragraph 8 are false or misleading, or were not substantiated at the time the representations were made.

Count II
False Establishment Claims

10. In connection with the advertising, marketing, promotion, offering for sale, or sale of CBD products, including through the means described in Paragraph 7, Respondents have represented, directly or indirectly, expressly or by implication, that:

a. clinical trials, studies, or scientific research prove that CBD:

1. prevents seizures;

2. treats cancer;

3. treats or prevents strokes, Alzheimer's disease, Parkinson's disease, and HIV dementia; and

4. may make chemotherapy more effective and increase cancer cell death without harming normal cells;

b. a U.S. government laboratory study showed that CBD may make chemotherapy more effective and increase cancer cell death without harming normal cells; and

c. the U.S. government has stated that CBD is scientifically proven to have antioxidant and neuroprotectant properties, limit neurological damage following ischemic insults, such as stroke and trauma, and treat neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia.

11. In fact:

a. clinical trials, studies, or scientific research do not prove that CBD:

1. prevents seizures;

2. treats cancer;

3. treats or prevents strokes, Alzheimer's disease, Parkinson's disease, and dementia; and

4. may make chemotherapy more effective and increase cancer cell death without harming normal cells;

b. a U.S. government laboratory study has not shown that CBD may make chemotherapy more effective and increase cancer cell death without harming normal cells; and

c. the U.S. government has not stated that CBD is scientifically proven to have antioxidant and neuroprotectant properties, limit neurological damage following ischemic insults, such as stroke and trauma, and treat neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia.

12. Therefore, the representations set forth in Paragraph 10 are false and misleading.

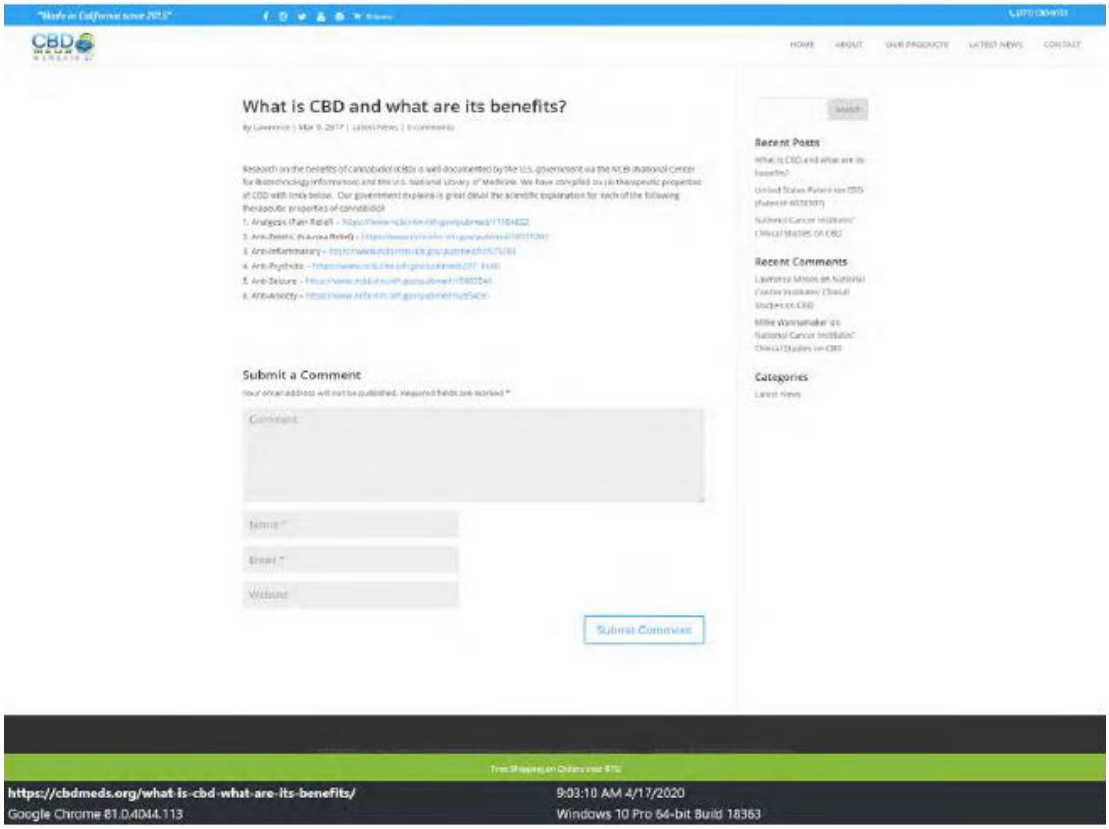
Violations of Sections 5 and 12

13. The acts and practices of Respondents as alleged in this Complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this second day of February, 2021, has issued this Complaint against Respondents.

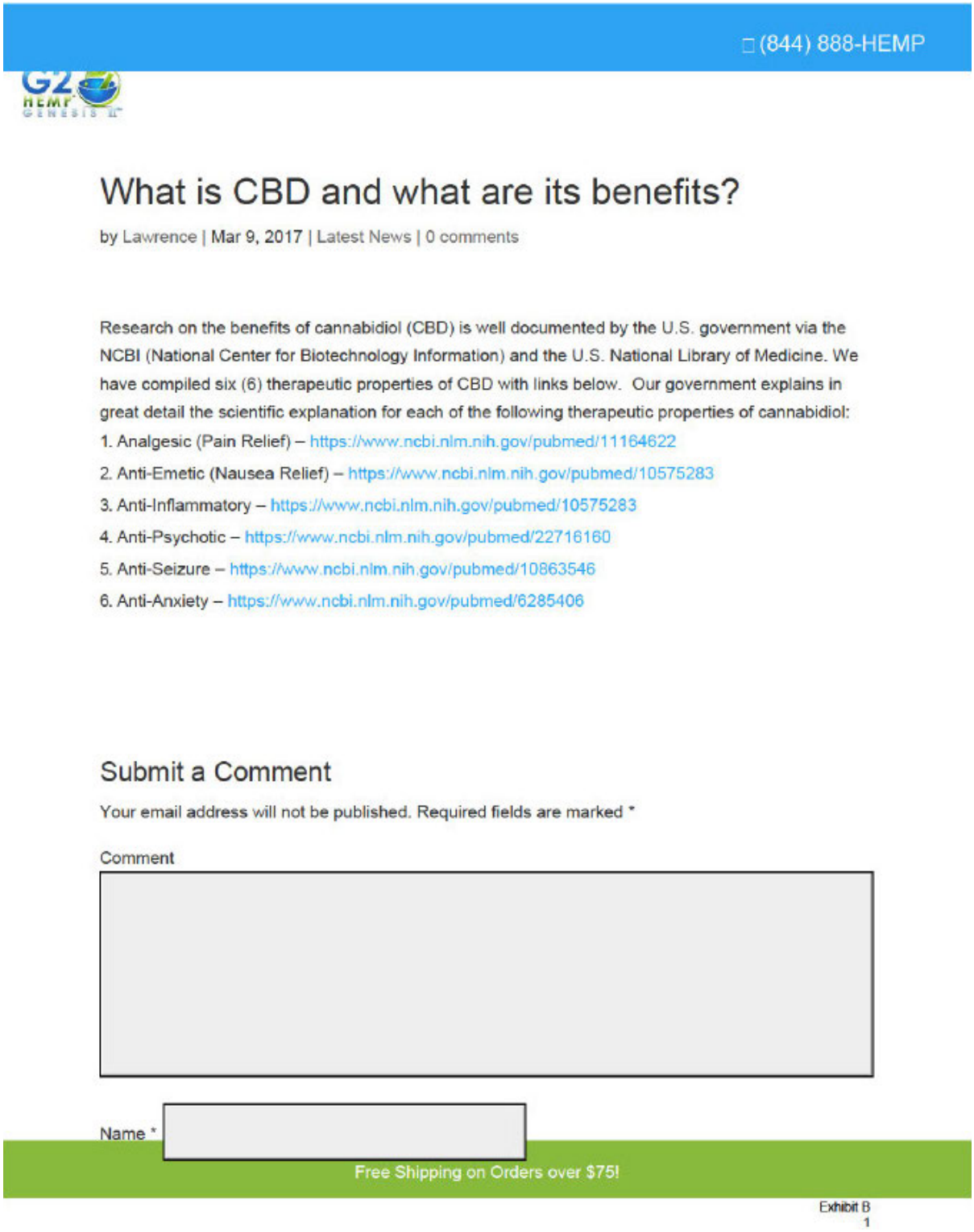
By the Commission.

Exhibit A


What is CBD and what are its benefits?
Recent Posts
Recent Comments
Categories
Submit a Comment
Comment
Name *
Email *
Website
Submit Comment
https://cbdmeds.org/what-is-cbd-what-are-its-benefits/
Google Chrome 81.0.4044.113
9:03:10 AM 4/17/2020
Windows 10 Pro 64-bit Build 18363

Complaint

Exhibit B



□ (844) 888-HEMP

G2 HEMP GENESIS II

What is CBD and what are its benefits?

by Lawrence | Mar 9, 2017 | Latest News | 0 comments

Research on the benefits of cannabidiol (CBD) is well documented by the U.S. government via the NCBI (National Center for Biotechnology Information) and the U.S. National Library of Medicine. We have compiled six (6) therapeutic properties of CBD with links below. Our government explains in great detail the scientific explanation for each of the following therapeutic properties of cannabidiol:

1. Analgesic (Pain Relief) – https://www.ncbi.nlm.nih.gov/pubmed/11164622
2. Anti-Emetic (Nausea Relief) – https://www.ncbi.nlm.nih.gov/pubmed/10575283
3. Anti-Inflammatory – https://www.ncbi.nlm.nih.gov/pubmed/10575283
4. Anti-Psychotic – https://www.ncbi.nlm.nih.gov/pubmed/22716160
5. Anti-Seizure – https://www.ncbi.nlm.nih.gov/pubmed/10863546
6. Anti-Anxiety – https://www.ncbi.nlm.nih.gov/pubmed/6285406

Submit a Comment

Your email address will not be published. Required fields are marked *

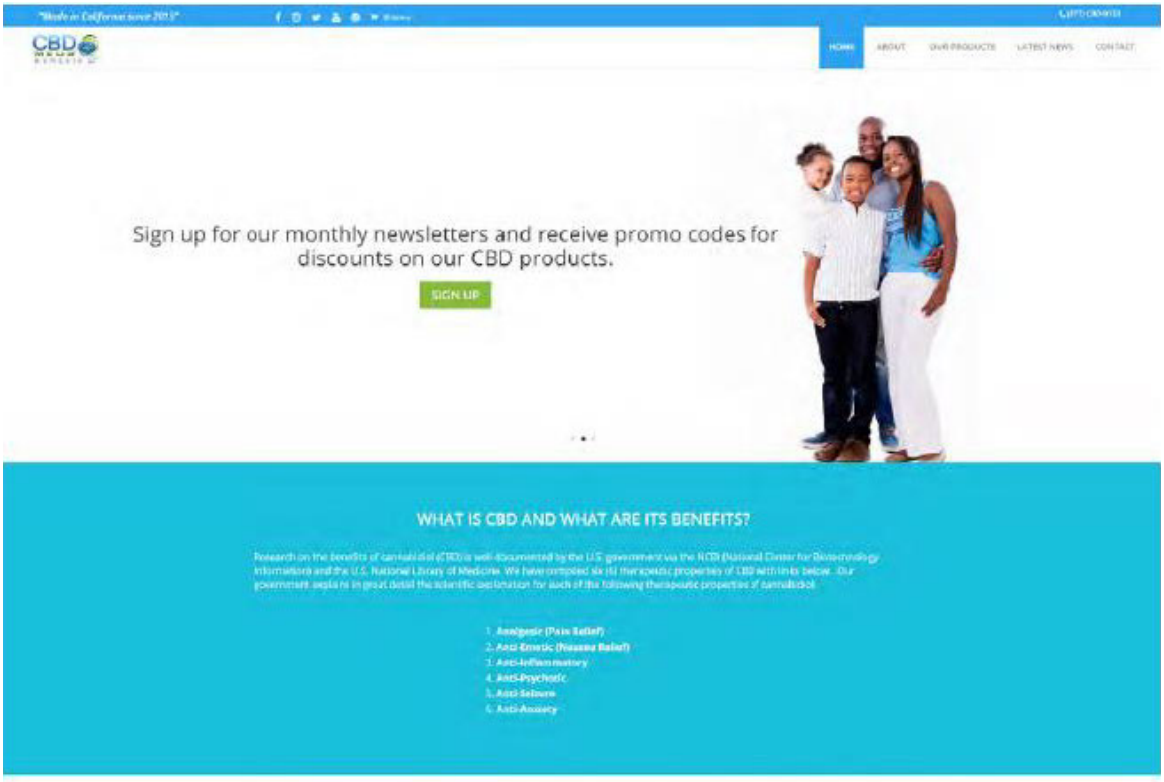
Comment

Name *

Free Shipping on Orders over $75!

Exhibit B
1

Exhibit C



My name is Lawrence Moses, and I am the founder of CBD MEDS™. I have always tried my best to dedicate a part of my life towards servitude, whenever and wherever possible. When I was introduced to the medicinal benefits of Cannabidiol (CBD) in 2013, I realized that the cannabis plant was presenting an opportunity for me to continue on that idealistic path.

For the last five years, we have been producing high-quality, whole plant enriched CBD extracts which contain a full spectrum of U.S. government patented cannabinoids. During that time, we developed our own CBD hemp strain using proprietary genetics drawn from across the world. We patented those genetics under the strain name GENESIS II™, and all of our products produced by that CBD hemp strain are all-natural and do not contain any herbicides, pesticides, chemical fertilizers, toxins, preservatives, GMO, or gluten.

It's my sincere hope that those seeking an alternative solution to synthetic medications may experience relief when using our CBD products. Based on the research conducted by the federal government, I am convinced that CBD and many other cannabinoids will one day prove to outperform many of the synthetic medications we've been consuming over the last 100 years.

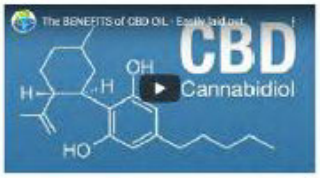
May Love bless and in good faith!

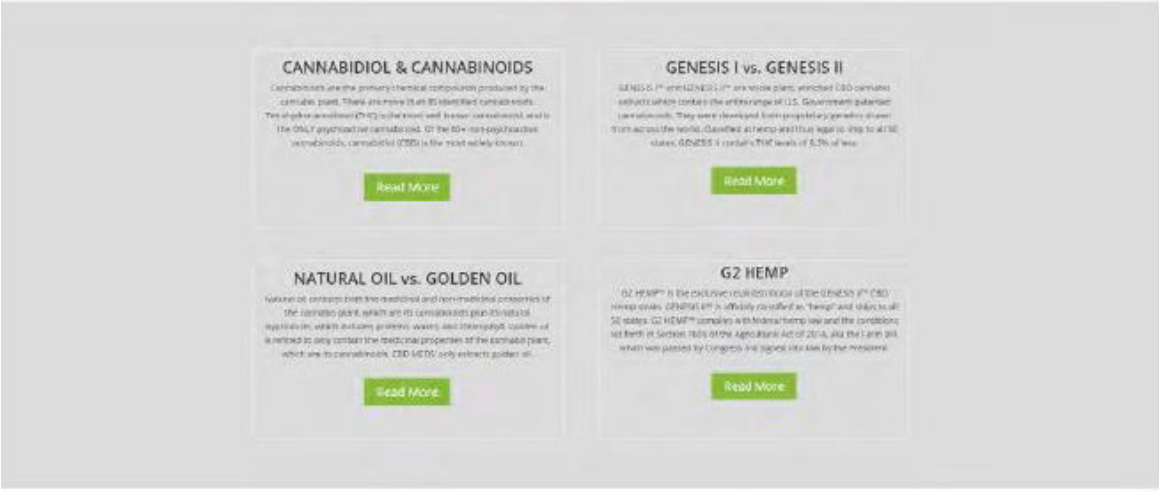
Lawrence Moses

ALL ABOUT CBD

FAQ ABOUT CBD

Complaint





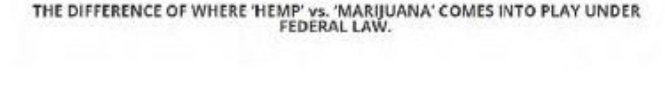


Exhibit C
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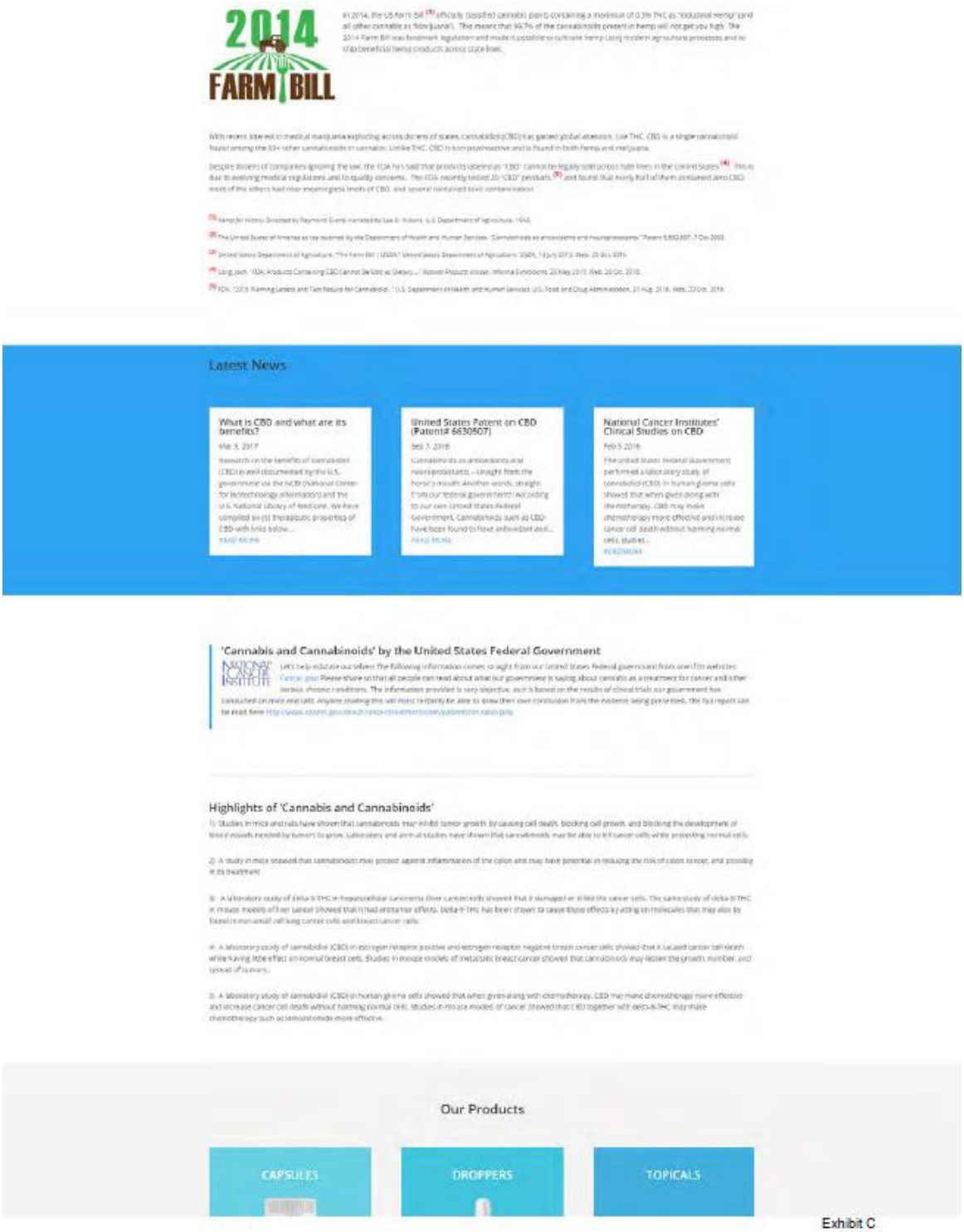
2014
FARM BILL
Latest News
What is CBD and what are its benefits?
United States Patent on CBD (Patent# 6630507)
National Cancer Institutes' Clinical Studies on CBD
'Cannabis and Cannabinoids' by the United States Federal Government
Highlights of 'Cannabis and Cannabinoids'
Our Products
CAPSULES
DROPPERS
TOPICALS

Exhibit C
3

Complaint

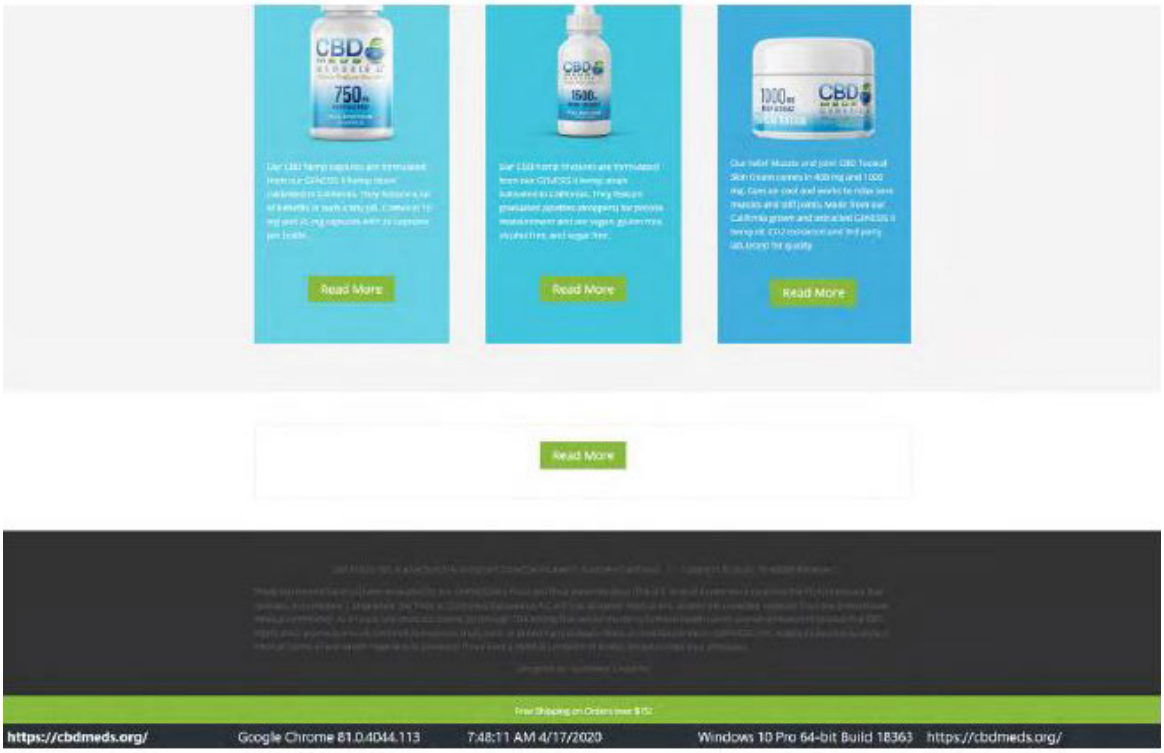

Exhibit C
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Exhibit D

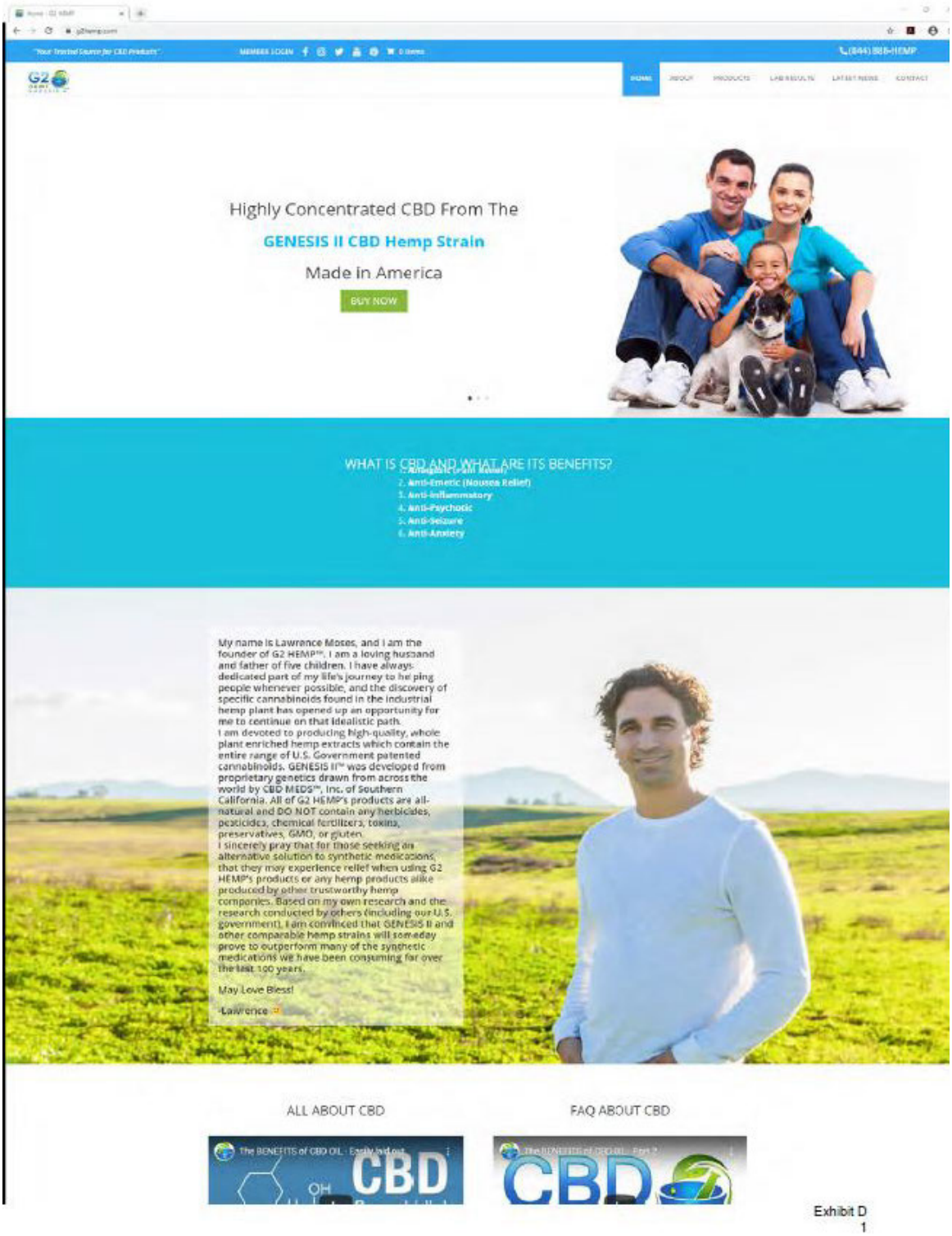

Exhibit D
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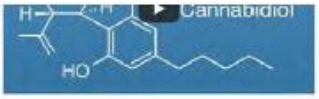
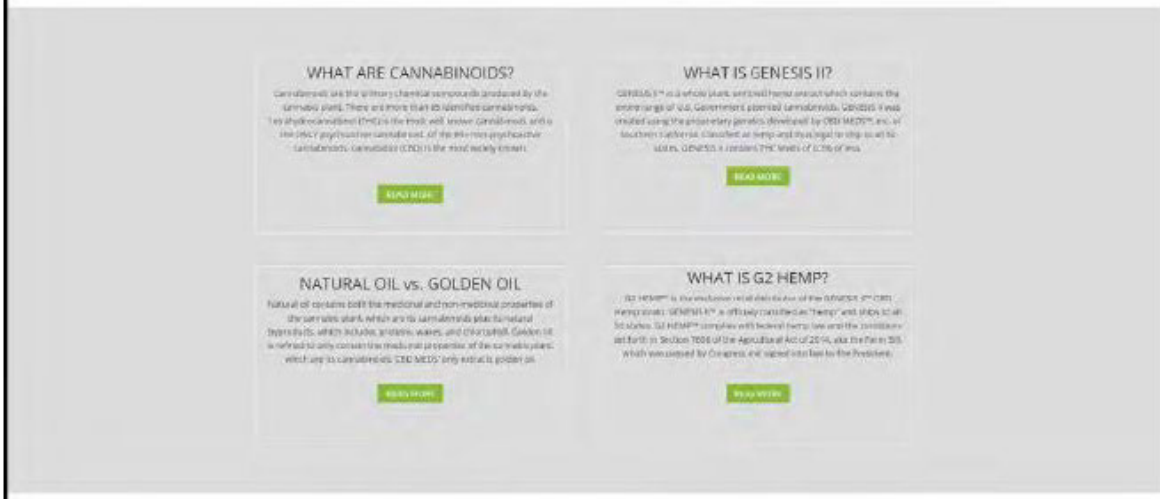
Complaint





THE DIFFERENCE BETWEEN CANNABIS, MARIJUANA, HEMP, GENESIS I, AND GENESIS II (SHORT VERSION)

THE DIFFERENCE BETWEEN CANNABIS, MARIJUANA, HEMP, GENESIS I, AND GENESIS II (LONG VERSION)

US006630507B1

(12) **United States Patent**
Hampson et al.

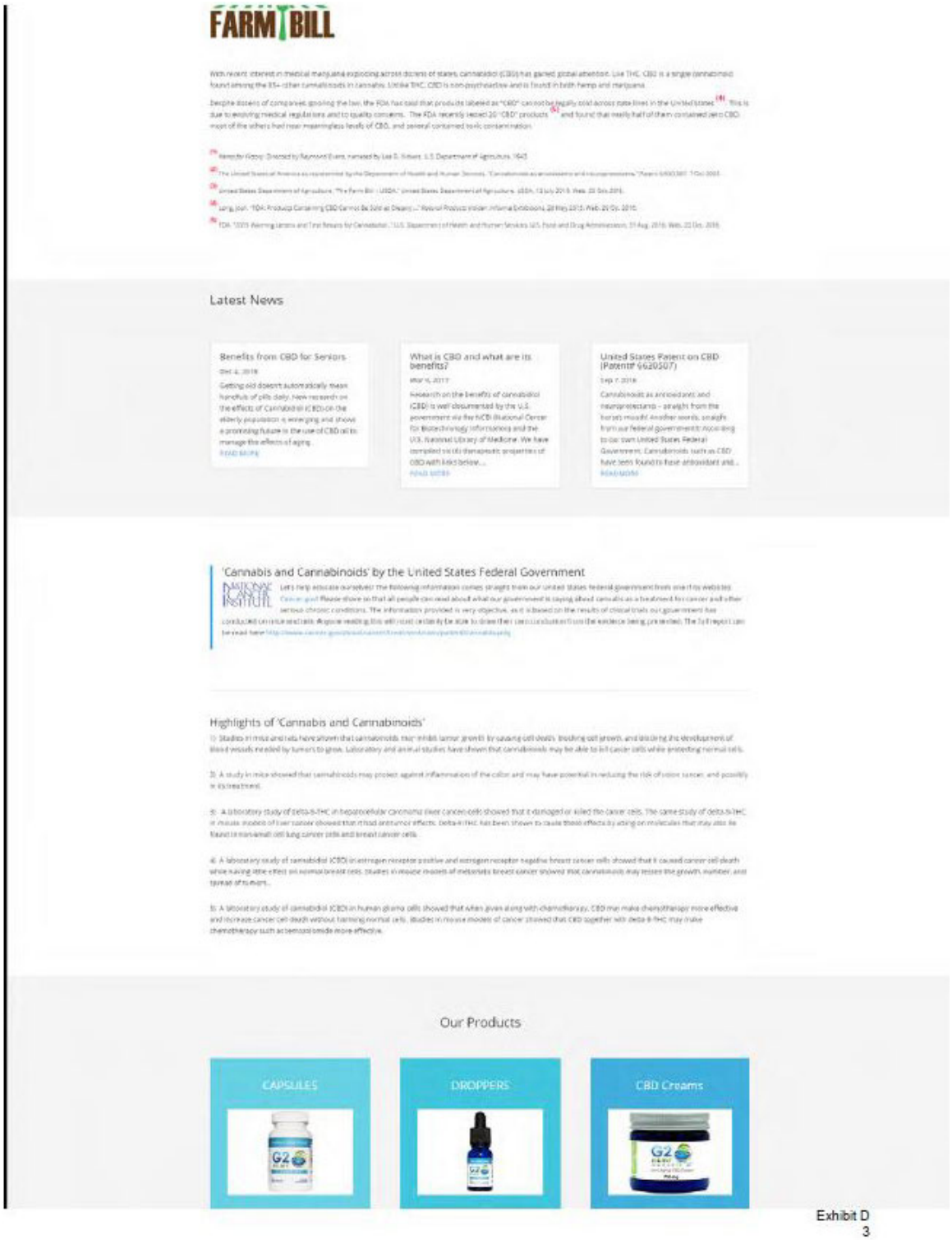
(10) **Patent No.: US 6,630,507 B1**
(45) **Date of Patent: Oct. 7, 2003**

(54) **CANNABINOIDS AS ANTIOXIDANTS AND NEUROPROTECTANTS**

OTHER PUBLICATIONS
Windholz et al., The Merck Index, Tenth Edition (1983) p.

THE DIFFERENCE OF WHERE 'HEMP' vs. 'MARIJUANA' COMES INTO PLAY UNDER FEDERAL LAW.

Exhibit D
2


FARM BILL
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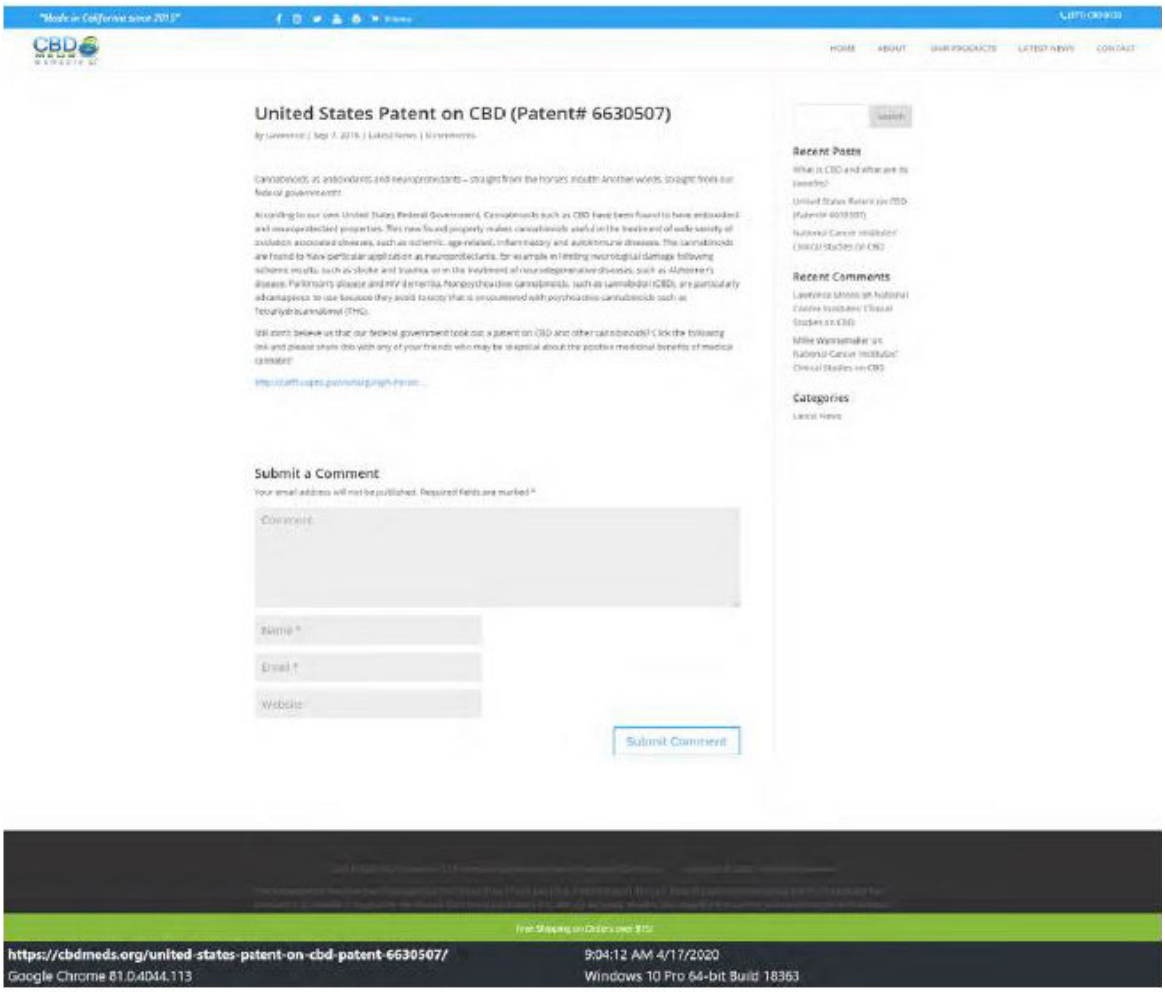
DROPPERS
CBD Creams

Exhibit D
3

Complaint

Exhibit D
4

Exhibit E


United States Patent on CBD (Patent# 6630507)
Recent Posts
Recent Comments
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Name *
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Google Chrome 81.0.4044.113
9:04:12 AM 4/17/2020
Windows 10 Pro 64-bit Build 18363

Complaint

Exhibit F

(844) 888-HEMP

G2 HEMP GENESIS LLC

United States Patent on CBD (Patent# 6630507)

by Lawrence | Sep 7, 2016 | Latest News | 0 comments

Cannabinoids as antioxidants and neuroprotectants – straight from the horse's mouth! Another words, straight from our federal government!!!

According to our own United States Federal Government, Cannabinoids such as CBD have been found to have antioxidant and neuroprotectant properties. This new found property makes cannabinoids useful in the treatment of wide variety of oxidation associated diseases, such as ischemic, age-related, inflammatory and autoimmune diseases. The cannabinoids are found to have particular application as neuroprotectants, for example in limiting neurological damage following ischemic insults, such as stroke and trauma, or in the treatment of neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia. Nonpsychoactive cannabinoids, such as cannabidoil (CBD), are particularly advantageous to use because they avoid toxicity that is encountered with psychoactive cannabinoids such as Tetrahydrocannabinol (THC).

Still don't believe us that our federal government took out a patent on CBD and other cannibinoids? Click the following link and please share this with any of your friends who may be skeptical about the positive medicinal benefits of medical cannabis!

http://patft.uspto.gov/netacgi/nph-Parser...

Submit a Comment

Your email address will not be published. Required fields are marked *

Comment

Free Shipping on Orders over $75!

Exh bit F
1

Exhibit G

(844) 888-HEMP

Benefits from CBD for Seniors

by cbdmedicines | Dec 4, 2018 | Latest News | 0 comments

Getting old doesn't automatically mean handfuls of pills daily. New research on the effects of Cannabidiol (CBD) on the elderly population is emerging and shows a promising future in the use of CBD oil to manage the effects of aging.

Natural Pain Relief

There are many remedies for pain relief, but there are also many side effects of pain relievers, such as organ damage. CBD oil can provide more natural pain relief. Clinical studies have shown cannabidiol (CBD) to be very effective in decreasing arthritis and nerve pain due to its anti-inflammatory properties.

Free Shipping on Orders over $75!

As you age, sleep becomes more elusive, possibly due to stress and anxiety or because various body pains may keep you from reaching deep sleep. CBD oil is thought to reduce both. Studies indicate that cannabidiol (CBD) may reduce the amount of time it takes you to fall asleep, and may also help you sleep more deeply for longer, which is important in staving off neurodegenerative diseases.

Cardiovascular Improvement

Heart disease is the predominant cause of death in the elderly. It therefore makes sense that you want to find a way to keep your cardiovascular system healthy. CBD oil can help to reduce stress and control blood pressure by relaxing the blood vessels. Its anti-inflammatory effects can help with heart diseases and may even help prevent strokes.

Learn About Genesis II CBD

Improves Bone Health

As you age, so do your bones, and they become more fragile than they once were; almost half of people over the age of 65 have reported arthritis diagnoses. Research is showing that CBD oil may help delay bone decay and prevent age-related bone disease. It can even help heal fractures and stimulate bone growth and collagen production.

Protects Against Alzheimers and Dementia

It may be a "senior moment," or it may be an indication of something more serious: the neurodegeneration that accompanies diseases such as Alzheimers or dementia. CBD oil may help prevent the onset of these diseases thanks to its neuroprotectant properties. Cannabidiol (CBD) may enhance the birth of new brain cells and assist the brain in repairing itself, which could help resist various types of dementia. It also plays a role in preventing nerve inflammation which may cause dementia.

Parkinson's Disease Prevention

Due to those neuroprotectant, anti-oxidant, and anti-inflammatory properties, CBD oil could play a role in managing the symptoms of and even preventing Parkinson's disease. The better sleep you get with cannabis helps delay age-related neurodegenerative diseases, and some people have indicated improvement of the symptoms of Parkinson's disease, including tremor and dyskinesias.

Relief from Glaucoma

Glaucoma is a common affliction amongst the elderly population, but the cannabidiol (CBD) and the other cannabinoids found in CBD oil could provide some relief and possibly even prevention, thanks to its promotion of neural health. Not only does glaucoma fall under the umbrella of neurodegenerative diseases for which C BD oil could help provide relief and even prevent, but its pain-relieving effects apply to your eyes, as well. There is even evidence that it could reduce

intraocular pressure by as much as 25%.

https://www.ncbi.nlm.nih.gov/pubmed/10920191
https://www.cdc.gov/arthritis/data_statistics/arthritis-related-stats.htm
https://www.zamnesia.com/blog-how-cannabis-can-improve-life-for-the-elderly-n1212
https://seniordirectory.com/articles/info/benefits-of-cbd-for-senior-citizens
https://echoconnection.org/5-ways-cannabinoids-can-help-elderly-community/
https://www.projectcbd.org/science/cannabis-pharmacology/cbd-and-parkinsons-disease
https://www.royalqueenseeds.com/blog-cbd-a-potential-therapeutic-for-cardiovascular-diseases-n958
https://heart.bmj.com/content/84/5/560

BUY GENESIS II CBD NOW

Submit a Comment

Your email address will not be published. Required fields are marked *

Comment

Name *

Email *

Website

Complaint

Submit Comment

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- Our Lab Results
- About
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- Contact Us

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Designed by: Sunflower Creatives

Exhibit G
4

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

    a. Respondent CBD Meds, Inc., ("CBD Meds") is a California nonprofit mutual benefit corporation. Pursuant to California law, a nonprofit mutual benefit corporation is set up for the benefit of its members and may conduct business at a profit. Cal. Corp. Code §§ 7110 cmt., 7140(1). Thus, CBD Meds is organized to carry on business for its own profit or the profit of its members within the meaning of Section 4 of the FTC Act. 15 U.S.C. § 44. Its principal office or place of business is in Winchester, California 92596.

    b. Respondent G2 Hemp, Inc. ("G2 Hemp") is a California corporation. At times relevant to this Complaint, G2 Hemp operated a website that advertised and sold cannabidiol products. Its principal office or place of business is in Winchester, California 92596.

    c. Respondent Lawrence Moses, also known as Lawrence D. Moses, Jr., is the owner and CEO of CBD Meds and G2 Hemp. Individually or in concert with others, he controlled or had the authority to control, or

participated in the acts and practices of CBD Meds and G2 Hemp, including the acts and practices alleged in the Complaint. His principal office or place of business is the same as that of CBD Meds and G2 Hemp.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "**CBD Product**" means any Dietary Supplement, Food, or Drug containing cannabidiol.

B. "**Covered Product**" means any Dietary Supplement, Food, or Drug, including but not limited to CBD Products.

C. "**Dietary Supplement**" means: (1) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

D. "**Drug**" means: (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

E. "**Essentially Equivalent Product**" means a product that contains the identical ingredients, except for inactive ingredients (e.g. binders, colors, fillers, excipients) in the same form and dosage, and with the same route of administration (e.g.orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

F. "**Food**" means: (1) any article used for food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

G. "**Respondents**" means all of the Corporate Respondents and the Individual Respondent, individually, collectively, or in any combination.

1. "**Corporate Respondents**" means CBD Meds, Inc., a corporation, and G2 Hemp, Inc., a corporation, and their successors and assigns.

2. "**Individual Respondent**" means Lawrence Moses, a/k/a Lawrence D. Moses, Jr.

Provisions

I. Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation

IT IS ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, or assist others in making, expressly or by implication, any representation that such product:

A. treats blood pressure conditions or gastrointestinal disorders; reduces seizures and convulsions; or reduces blood sugar levels; or

B. cures, mitigates, or treats any disease, including but not limited to cancer, age-related bone disease, arthritis, diabetes, glaucoma, strokes, Alzheimer's disease, multiple sclerosis, Parkinson's disease, epilepsy, autism, post traumatic stress disorder, bipolar disorders, schizophrenia, psoriasis, or HIV dementia,

unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Section, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by

this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. Prohibited Representations: Other Health-Related Claims

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, or assist others in making, expressly or by implication, any representation, other than representations covered under the Section of this Order entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, including that such product prevents artery blockage, dementia, seizures and convulsions, cancer, age-related bone disease, arthritis, blood pressure conditions, diabetes, gastrointestinal disorders, glaucoma, Alzheimer's disease, multiple sclerosis, Parkinson's disease, epilepsy, autism, post traumatic stress disorder, bipolar disorders, or schizophrenia, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by (1) any Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

IV. Prohibited Misrepresentations Regarding Tests, Studies, or Other Research

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection

with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not misrepresent, in any manner, expressly or by implication:

A. that any Covered Product is scientifically proven to prevent seizures; treat cancer; treat or prevent strokes, Alzheimer's disease, Parkinson's disease, or HIV dementia; or make chemotherapy more effective and increase cancer cell death without harming normal cells;

B. that the performance or benefits of any product are scientifically or clinically proven or otherwise established;

C. the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research;

D. that a U.S. government laboratory study showed that any Covered Product may make chemotherapy more effective and increase cancer cell death without harming normal cells; or

E. that the U.S. government has stated that any Covered Product is scientifically proven to have antioxidant and neuroprotectant properties, limit neurological damage following ischemic insults, such as stroke and trauma, and treat neurogenerative diseases, such as Alzheimer's disease, Parkinson's disease and HIV dementia.

V. FDA Approved Claims

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, Respondents' officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them, from:

A. for any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration ("FDA"), or under any new drug application approved by the FDA; and

B. for any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI. Notices to Customers

IT IS FURTHER ORDERED that Respondents must notify customers as follows:

A. Respondents must identify all consumers who purchased the CBD Products on or after January 9, 2017 and through the Order's effective date ("eligible customers").

1. Such eligible customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody or control;

2. Eligible customers include those identified at any time including after Respondents' execution of the Agreement through the eligibility period, which runs for 1 year after the issuance date of the Order.

B. Respondents must notify all identified eligible customers by mailing each a notice:

1. The letter must be in the form shown in Attachment A.

2. The envelope containing the letter must be in the form shown in Attachment B.

3. The mailing of the notification letter must not include any other enclosures.

4. The mailing must be sent by first-class mail, postage prepaid, address correction service requested with forwarding and return postage guaranteed. For any mailings returned as undeliverable, Respondents must use standard address search methodologies such as re-checking Respondents' records and the Postal Service's National Change of Address database and re-mailing to the corrected address within 8 days.

C. Respondents must notify all eligible customers within 180 days after the issuance date of this Order and any eligible customers identified thereafter within 30 days of their identification.

D. Respondents must provide a notice on their websites' landing pages. Such notice must link to a copy of the Order. The notice must be posted not later than 3 days after the effective date of the Order and for at least 1 year after the Order's effective date.

E. Respondents must report on their notification program under penalty of perjury:

1. Respondents must submit a report at the conclusion of the notification program summarizing their compliance, including the total number of notices sent or re-sent, the dates sent, and eligible customers identified.

2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Respondents must submit it within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

VII. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 20 years after the issuance date of this Order, the Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is the majority owner or controls directly or indirectly, unless such business cannot violate the Order, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Report and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

VIII. Compliance Report and Notices

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. Sixty days after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondents must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, the Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. Each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, the Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re CBD Meds, Inc.

IX. Recordkeeping

IT IS FURTHER ORDERED that Respondents must create certain records for 20 years after the issuance date of the Order, and retain each such record for 5 years, unless otherwise specified below. Specifically, Corporate Respondents and the Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. copies or records of all consumer complaints and refund requests concerning the subject matter of the Order, whether received directly or indirectly, such as through a third party, and any response;

D. a copy of each unique advertisement or other marketing material making a representation subject to this Order.

E. For 5 years from the date of the last dissemination of any representation covered by this Order:

1. all materials that were relied upon in making the representation; and

2. all tests, studies, analysis, other research or other such evidence in Respondent's possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

F. for 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communication relate to Respondents' compliance with this Order.

G. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission.

X. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Respondents, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XI. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ATTACHMENT A TO THE ORDER

CLAIMS ABOUT PRODUCTS CONTAINING CBD
In the Matter of CBD Meds, Inc., et al.

<Date>

<Name of customer>
<mailing address of customer
including zip code>

Subject: CBD Products sold by CBD Meds and G2 Hemp

Dear <Name of customer>:

Our records show that you bought CBD products from CBD Meds and G2 Hemp. We are writing to tell you that the Federal Trade Commission, (FTC), the nation's consumer protection agency, has charged us with deceptive or false advertising.

The FTC brought a lawsuit against our companies for making misleading claims that our CBD products can effectively prevent, treat, or ease serious diseases or health conditions, including the following:

> Artery blockage; dementia; blood sugar levels; seizures and convulsions; psoriasis; HIV dementia; cancer; age-related bone disease; arthritis; blood pressure conditions; diabetes; gastrointestinal disorders; glaucoma; strokes; Alzheimer's disease; multiple sclerosis; Parkinson's disease; epilepsy; autism; post traumatic stress disorder; bipolar disorders; and schizophrenia.

To settle the FTC's lawsuit, we're contacting our customers to tell them that we don't have proof that our CBD products will effectively prevent, treat, or improve the serious diseases and health conditions listed above. In addition, the U.S. government has not validated those claims.

If you have other questions about this lawsuit, visit [add URL].

CBD oil and other alternative treatments might be harmful to your medical care, and could interfere with your prescriptions. CBD products could also be dangerous if you take them with other medicines or at a high dose. Talk to your doctor before you take any treatments or stop any prescriptions. For more information about protecting yourself from bogus health product claims visit ftc.gov/health.

Sincerely,

[signature]
Lawrence Moses
CEO, CBD Meds, Inc. and G2 Hemp, Inc.

ATTACHMENT B to the Order – Envelope Template:

The envelope for the notification letter must be in the following form, with the underlined text completed as directed:

CBD MEDS, INC. AND G2 HEMP, INC.
Street Address
City, State and Zip Code

FORWARDING AND RETURN POSTAGE GUARANTEED ADDRESS CORRECTION SERVICE REQUESTED

[name and
mailing address of customer,
including zip code]

ABOUT YOUR PURCHASE FROM CBD MEDS, INC. AND G2 HEMP, INC.

STATEMENT OF COMMISSIONER ROHIT CHOPRA

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish – and unlawful – claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine "a competitor's ability to compete" on honest attributes.[1]

1 *In re Pfizer, Inc.*, 81 F.T.C. 23, 62 (1972).

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID-19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[2] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer Americans into high-cost, subpar treatment centers, and some even hire intermediaries – so-called "body brokers" – who collect kickbacks from this harmful practice.[3]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[4] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[5]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous

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2 *See, e.g.*, Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL STREET J. (Sept. 8, 2020), https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; *Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic*, AMERICAN MEDICAL ASSOCIATION (last updated on Oct. 31, 2020), https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.

3 For example, recent reporting describes the "Florida Shuffle," where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America*, VOX (Mar. 2, 2020), https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-brijayne. *See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), https://www ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid (calling on the FTC to do more to tackle this problem).

4 Pub. L. No. 115-271 §§ 8021-8023 (codified in 15 U.S.C. § 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

5 Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.

actions charging that pain relief devices and similar products were sold deceptively,[6] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[7] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[8] Under the Penalty Offense Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[9] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[10] and apprising firms of these findings – along with a warning that noncompliance can result in penalties – makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a "high

6 Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.

7 In one of these matters, the respondents are paying nothing.

8 15 U.S.C. § 45(m)(1)(b).

9 *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256. Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

10 This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc.*, *supra* note 2 (finding that "[f]airness to the consumer, as well as fairness to competitors" compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.*, 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that "a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act." *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.*, 155 F.T.C. 1, 6 (2013).

level of voluntary compliance achieved quickly and at a low cost."[11] Going forward, we should pursue this strategy.[12]

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.

11 Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an "extremely effective and efficient way to enforce the law." Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.

12 My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

CONCURRING STATEMENT OF COMMISSIONER CHRISTINE S. WILSON

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication.

The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters[1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo- controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain

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1 Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions*, Oct. 22, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims; Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis*, Sept. 10, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused; Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases*, Apr. 2, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.

2 Press Release, *FTC Order Stops the Marketer of "Thrive" Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID-19*, July 10, 2020, available at https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.

3 *See, e.g.*, Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

conditions – specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that "[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes."[6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

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4 *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.

5 *See, e.g.*, Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC v. Avrom Boris Lasarow, et al.* (Feb. 2015), https://www ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health; Statement of Commissioner Joshua D. Wright, *FTC v. Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin; Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), https://www ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru; Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part; Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC v. Springtech 77376, et al.* (July 2013), https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; *see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12-49 (May 2012), available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.

6 *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order with CBD Meds, Inc., G2 Hemp, Inc. and Lawrence Moses, a/k/a Lawrence D. Moses, Jr., individually and as an officer of CBD Meds, Inc. and G2 Hemp, Inc. ("Respondents").

The proposed consent order ("order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the Respondents' advertising of products containing cannabidiol ("CBD Products). The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) CBD treats, prevents, or reduces the risk of artery blockage, dementia, blood sugar levels, seizures and convulsions, psoriasis, HIV dementia, cancer, age-related bone disease, arthritis, blood pressure conditions, diabetes, gastrointestinal disorders, glaucoma, strokes, Alzheimer's disease, multiple sclerosis, Parkinson's disease, epilepsy, autism, post traumatic stress disorder, bipolar disorders, and schizophrenia; (2) clinical trials, studies, or scientific research prove that CBD treats or prevents seizures, cancer, strokes, Alzheimer's disease, Parkinson's disease, and HIV dementia, and may make chemotherapy more effective; (3) a U.S. government study has shown that CBD may make chemotherapy more effective; and (4) the U.S. government has stated that CBD is scientifically proven to have antioxidant and neuroprotectant properties.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food Respondents sell or market, including CBD Products.

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product will: (1) treat blood pressure conditions or gastrointestinal disorders; (2) reduce seizures and convulsions; (3) reduce blood sugar levels; or (4) cure, mitigate or treat any disease in humans, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety or side effects of

any covered product, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III requires that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by the order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits Respondents from misrepresenting: (1) that any covered product is scientifically proven to (a) prevent seizures; (b) treat cancer; (c) treat or prevent strokes, Alzheimer's disease, Parkinson's disease, or HIV dementia; or (d) make chemotherapy more effective and increase cancer cell death without harming normal cells; (2) that the performance or benefits of any covered product is scientifically or clinically proven; (3) the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research; (4) that a U.S. government study showed that any covered product makes chemotherapy more effective, or (5) that the U.S. government has stated that any covered product is scientifically proven to have antioxidant and neuroprotectant properties, limit neurological damage following ischemic insults, and treat neurogenerative diseases;

Part V provides Respondents a safe harbor for making claims approved by the Food and Drug Administration ("FDA").

Part VI requires Respondents to send notices to consumers who purchased their CBD products informing them about the settlement.

Parts VII requires Respondents to submit an acknowledgement of receipt of the order, and for the individual Respondent to serve the order on certain individuals, including all officers or directors of any business the individual Respondent controls and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which a Respondent has delivered a copy of the order.

Part VIII requires Respondents to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect

compliance obligations. **Part IX** contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance with the order. **Part X** contains other requirements related to the Commission's monitoring of Respondents' order compliance. **Part XI** provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

Complaint

IN THE MATTER OF

EPICHOUSE, LLC
D/B/A
FIRST CLASS HERBALIST CBD, COBALT SERUM, COBALT ENHANCE,
AND
COBALT CREAM,
AND
JOHN LE

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4736; File No. 202 3094
Complaint, February 2, 2021 – Decision, February 2, 2021

This consent order addresses Epichouse, LLC's advertising for products containing cannabidiol, including First Class Herbalist CBD oil. The complaint alleges that Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by disseminating false and unsubstantiated advertisements claiming that their CBD Products, among other things: are safe for all users; treat pain better than prescription medicine like OxyContin; prevent and treat numerous serious health conditions, including age-related cognitive decline, cancer, chronic pain, diabetes, heart disease, hypertension, and migraines; and are scientifically proven to improve many serious health conditions. The consent order prohibits Respondents from making any representation about the efficacy of any covered product, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

Participants

For the *Commission*: *Keith Fentonmiller* and *Brady Williams.*

For the *Respondents*: *Karl Kronenberger, Kronenberger Rosenfeld, LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Epichouse, LLC, a corporation, also doing business as First Class Herbalist CBD, Cobalt Serum, Cobalt Enhance, and Cobalt Cream, and John Le, individually and as an owner and officer of Epichouse, LLC (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Epichouse, LLC ("Epichouse"), also doing business as First Class Herbalist CBD, Cobalt Serum, Cobalt Enhance, and Cobalt Cream, is a Utah corporation with its principal place of business at 3370 Brock St., West Valley City, Utah 84119-2902.

2. Respondent John Le is the sole owner and officer of Epichouse. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices alleged in this complaint. He resides in Midvale, Utah.

3. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as "commerce" as defined in Section 4 of the Federal Trade Commission Act.

Respondents' Marketing of CBD Products

4. Cannabidiol ("CBD") is a substance naturally occurring in, and that can be extracted from, the hemp plant, *cannabis sativa*. Respondents advertised, promoted, offered for sale, sold, and distributed products containing CBD ("CBD Products") that are intended for human use. These CBD Products are "food" and/or "drugs," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

5. Through the website firstclassherbalistcbd.com, Respondents sold CBD Products in the form of oils, coffee, and edible "gummies," and as a topical cream. Respondents sold their CBD Products to consumers throughout the United States under some or all of the following names: "CBD Oil;" "CBD Hemp Oil Drops;" "Herbalist Oils CBD Hemp Oil Drops;" "Pure Herbal CBD Hemp Oil Drops;" "CBD Coffee;" "CBD Gummies;" "Pure Herbal CBD Gummies;" "Full Spectrum CBD;" "CBD Pain Rub;" "Herbalist Oils CBD Pain Rub;" "CBD + Turmeric Drops;" "Pure Isolate CBD;" and "100% Pure CBD Oil." Respondents charged consumers $39.99 to $79.95 for their CBD Products.

6. From approximately September 2019 through April 2020, Respondents disseminated or caused to be disseminated advertisements for CBD Products, including but not necessarily limited to the attached Exhibits A through E. Respondents promoted CBD Products through a variety of means, including through their website firstclassherbalistcbd.com. These advertisements contained the following statements and depictions:

a. CBD Oil:

# # #

NATURAL, FAST RELIEF

Your results with CBD Hemp Oil Drops will improve with continued use. CBD is 100% non-habit forming and is completely safe. It can be taken daily, has NO psychoactive properties, and will not harm you in any way. Plus, your satisfaction is 100% guaranteed.

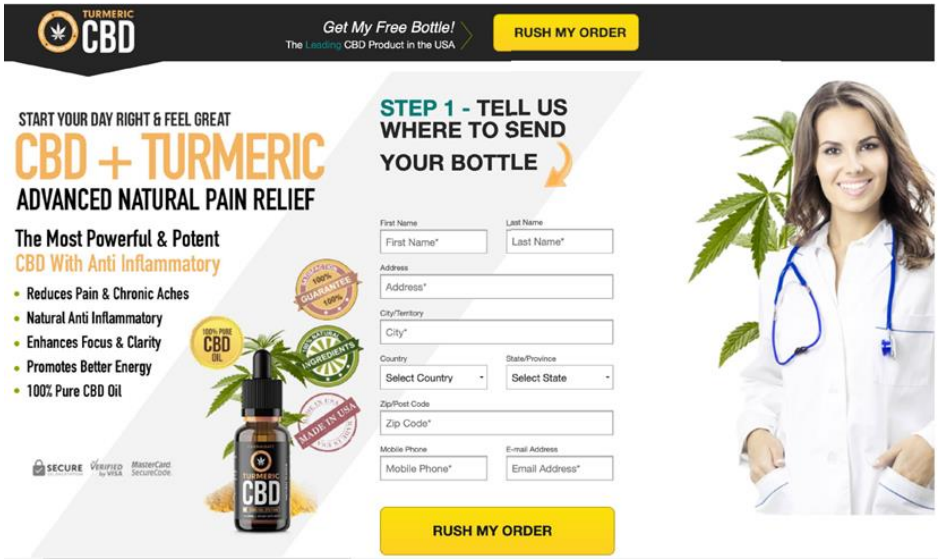
# # #

THE SCIENCE OF
CBD (CANNABIDOIL) [sic]

…CBD Oil has been medically proven to positively regulate your ECS [endocannabinoid system] affecting issues such as anxiety, insomnia, chronic pain, hypertension and even cardiovascular issues.
…
Psychological Benefits: CBD is commonly used to address anxiety, and for patients who suffer through the misery of insomnia, studies suggest that CBD may help with both falling asleep and staying asleep….

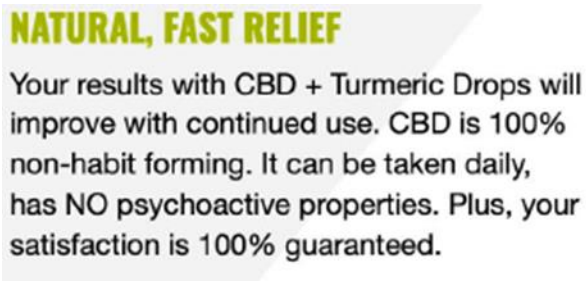
[Exhibit A (www.firstclassherbalistcbd.com, identified by Respondents as EPIC00674)].

b. CBD + Turmeric Oil:



Complaint

# # #



# # #

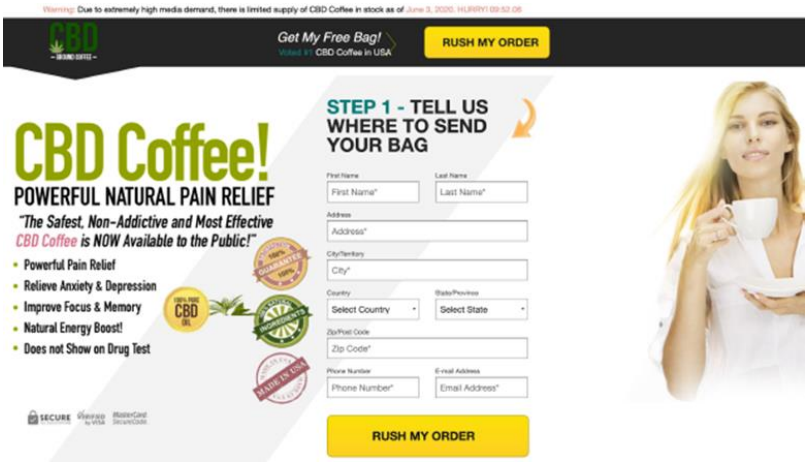
THE SCIENCE OF
CBD (CANNABIDOIL) [sic]

CBD Oil has been shown to positively regulate your ECS addressing issues such as anxiety, insomnia, chronic pain, and inflammation. Here is what the ECS system is known to do:

- **Body:** Stimulates an anti-inflammatory response which helps reduce all forms of chronic aches and pains. . . .
- **Brain**: Helps positively regulate mood patterns which help reduce anxiety and stress. It also promotes better sleep cycles and in some cases may offer a safe remedy for depression and bipolar disorders.
- **Age**: Inflammation is a natural killer responsible for all sorts of disease such as diabetes, heart disease, cancer, and more. . . .

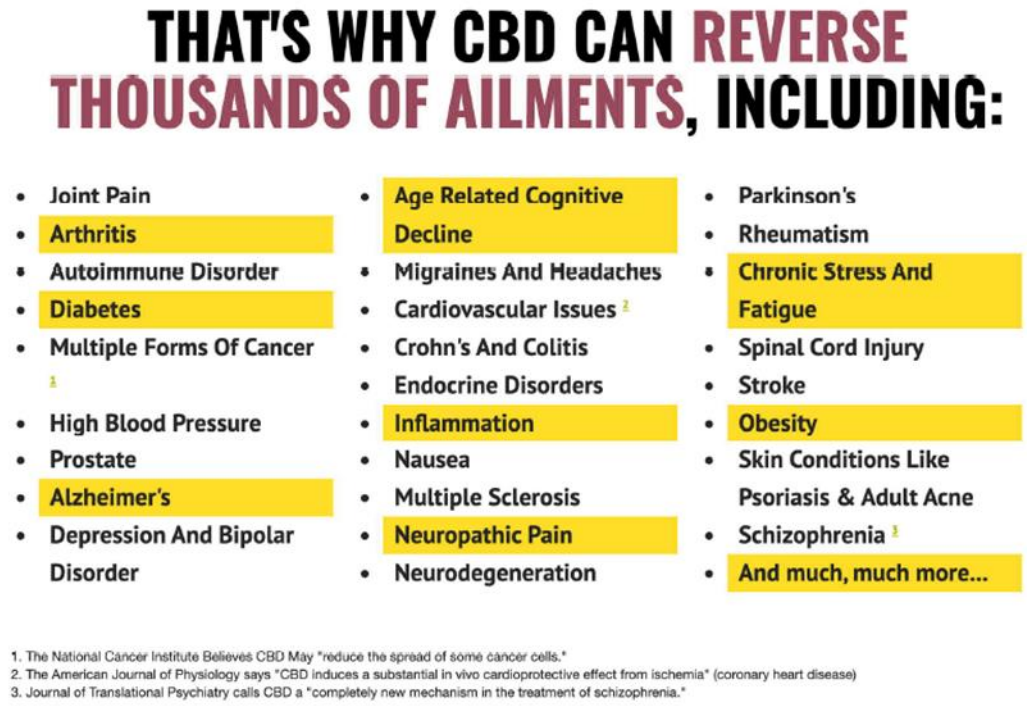
[Exhibit B (www.firstclassherbalistcbd.com, identified by Respondents as EPIC00682)].

c. CBD Coffee Products:

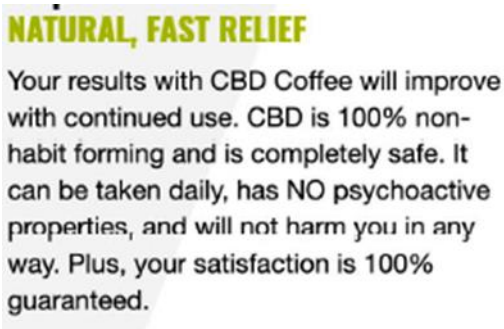


# # #

CBD Oil Coffee works WITH your body to ELIMINATE YOUR PAIN FROM WITHIN. And it goes to work quickly. After over 20,000 clinical studies, it has been proven over and over again… arthritis pain… eliminated….



# # #



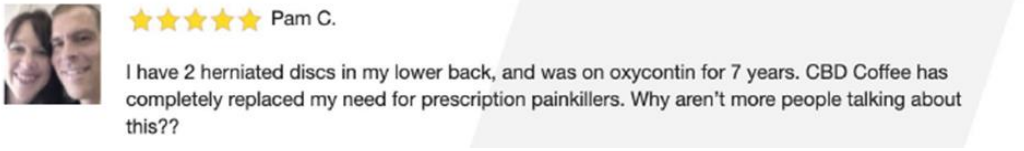
# # #

THE SCIENCE OF
CBD (CANNABIDOIL) [sic]

… CBD Oil has been medically proven to positively regulate your ECS addressing issues such as anxiety, insomnia, chronic pain, hypertension, and even cardiovascular issues.

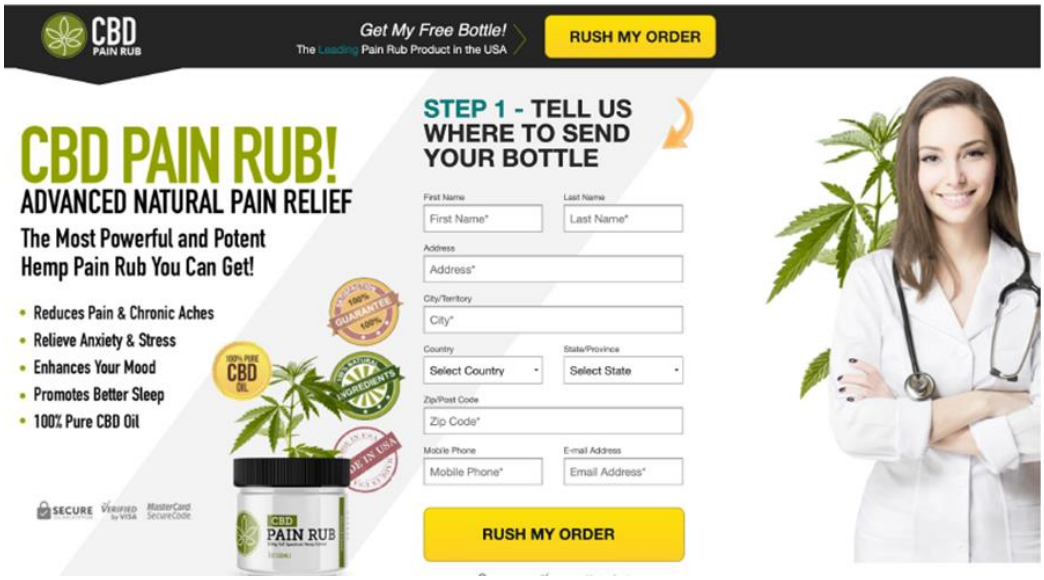
- **Physical Benefits:** Stimulates an anti-inflammatory response which helps reduce all forms of chronic aches and pains. . . .
- **Psychological Benefits**: Helps positively regulate mood patterns which help reduce anxiety and stress. It also promotes better sleep cycles and in some cases may offer a safe remedy for depression and bipolar disorders.
- **Neurological Benefits**: Our CBD Oil's positive impact on the neural system helps reduce age-related cognitive decline. It also helps support focus, alertness & memory recall while reducing the frequency of migraines and headaches.

# # #



[Exhibit C (www.firstclassherbalistcbd.com, identified by Respondents as EPIC00662)].

d. CBD Pain Rub Products:



…Another study also indicated that when used topically, CBD could lower pain and inflammation due to arthritis. . . .

# # #

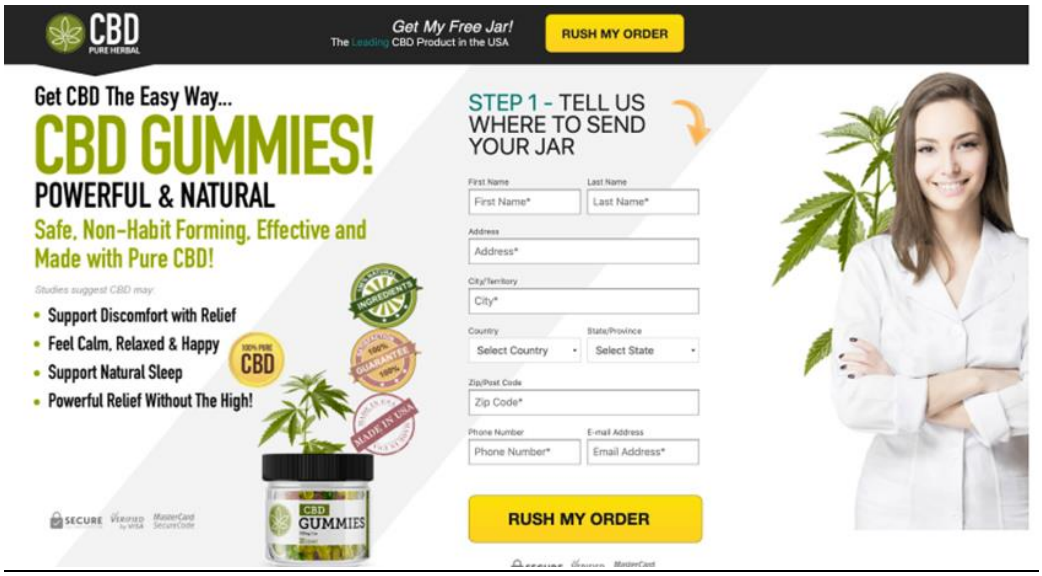
THE SCIENCE OF
CBD (CANNABIDOIL) [sic]

… CBD Rub has been shown to positively regulate your ECS addressing issues such as anxiety, insomnia, chronic pain, and inflammation. Here is what the ECS system is known to do:

- **Body:** Stimulates an anti-inflammatory response which helps reduce all forms of chronic aches and pains. . . .
- **Brain**: Helps positively regulate mood patters which help reduce anxiety and stress. It also promotes better sleep cycles and in some cases may offer a safe remedy for depression and bipolar disorders.
- **Age**: Inflammation is a natural killer responsible for all sorts of disease such as diabetes, heart disease, cancer, and more….

[Exhibit D (www.firstclassherbalistcbd.com, identified by Respondents as EPIC00680)].

e. CBD Gummy Products:



# # #

THE SCIENCE OF
CBD (CANNABIDOIL) [sic]

CBD Oil has been shown to positively regulate your ECS addressing issues such as anxiety, insomnia, chronic pain and inflammation. Here is what the ECS system is known to do:

- **Body:** Stimulates an anti-inflammatory response which helps reduce all forms of chronic aches and pains. . . .

- **Brain**: Helps positively regulate mood patters which help reduce anxiety and stress. It also promotes better sleep cycles and in some cases may offer a safe remedy for depression and bipolar disorders.
- **Age**: Inflammation is a natural killer responsible for all sorts of disease such as diabetes, heart disease, cancer, and more….

[Exhibit E (www.firstclassherbalistcbd.com, identified by Respondents as EPIC00667)].

7. Respondents have not conducted any studies demonstrating that their CBD Products cure, treat, alleviate, or prevent diseases or health conditions. There are no competent and reliable human clinical studies in the scientific literature to substantiate that these products or their ingredients cure, treat, alleviate, or prevent the diseases or health conditions mentioned in the advertising excerpts set forth in Paragraph 6.

Count I
False or Unsubstantiated Efficacy Claims

8. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBD Products, including through the means described in Paragraph 6 of this Complaint, Respondents have represented, directly or indirectly, expressly or by implication, that CBD Products:

a. treat, alleviate, or cure age-related cognitive decline; chronic pain, including neuropathic pain, pain from spinal cord injuries, and pain from diseases like arthritis; adult acne; Alzheimer's disease; arthritis; autoimmune disorder; bipolar disorder; cancer; colitis; Crohn's disease; depression; diabetes; endocrine disorders; heart disease; high blood pressure; migraines; multiple sclerosis; neurodegeneration; obesity; Parkinson's disease; prostate problems; psoriasis; rheumatism; schizophrenia; and stroke;

b. prevent age-related cognitive decline, cancer, chronic pain, diabetes, heart disease, hypertension, and migraines;

c. can replace the need for prescription painkillers like oxycontin; and

d. are safe for all consumers.

9. The representations set forth in Paragraph 8 are false or misleading, or were not substantiated at the time the representations were made.

Count II
False Establishment Claims

10. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBD Products, including through the means described in Paragraph 6 of this Complaint, Respondents have represented, directly or indirectly, expressly or by implication, that studies or scientific research prove that CBD Products:

a. improve alertness, focus, and memory recall;

b. treat, alleviate, or cure age-related cognitive decline; anxiety; bipolar disorder; cancer; chronic pain, including arthritis pain; depression; diabetes; heart disease; high blood pressure; inflammation; insomnia; and migraines; and

c. prevent age-related cognitive decline; anxiety; chronic pain, including arthritis pain; cancer; diabetes; heart disease; hypertension; inflammation; insomnia; and migraines.

11. In fact, studies or scientific research do not prove that their CBD Products:

a. improve alertness, focus, and memory recall;

b. treat, alleviate, or cure age-related cognitive decline; anxiety; bipolar disorder; cancer; chronic pain, including arthritis pain; depression; diabetes; heart disease; high blood pressure; inflammation; insomnia; and migraines; and

c. prevent age-related cognitive decline; anxiety; chronic pain, including arthritis pain; cancer; diabetes; heart disease; hypertension; inflammation; insomnia; and migraines.

Therefore, the representations set forth in Paragraph 10 are false or misleading.

Violations of Section 5 and 12

12. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this second day of February, 2021, has issued this Complaint against Respondents.

By the Commission.

Complaint

Exhibit A

FTC Cmplt. Exh. A-1

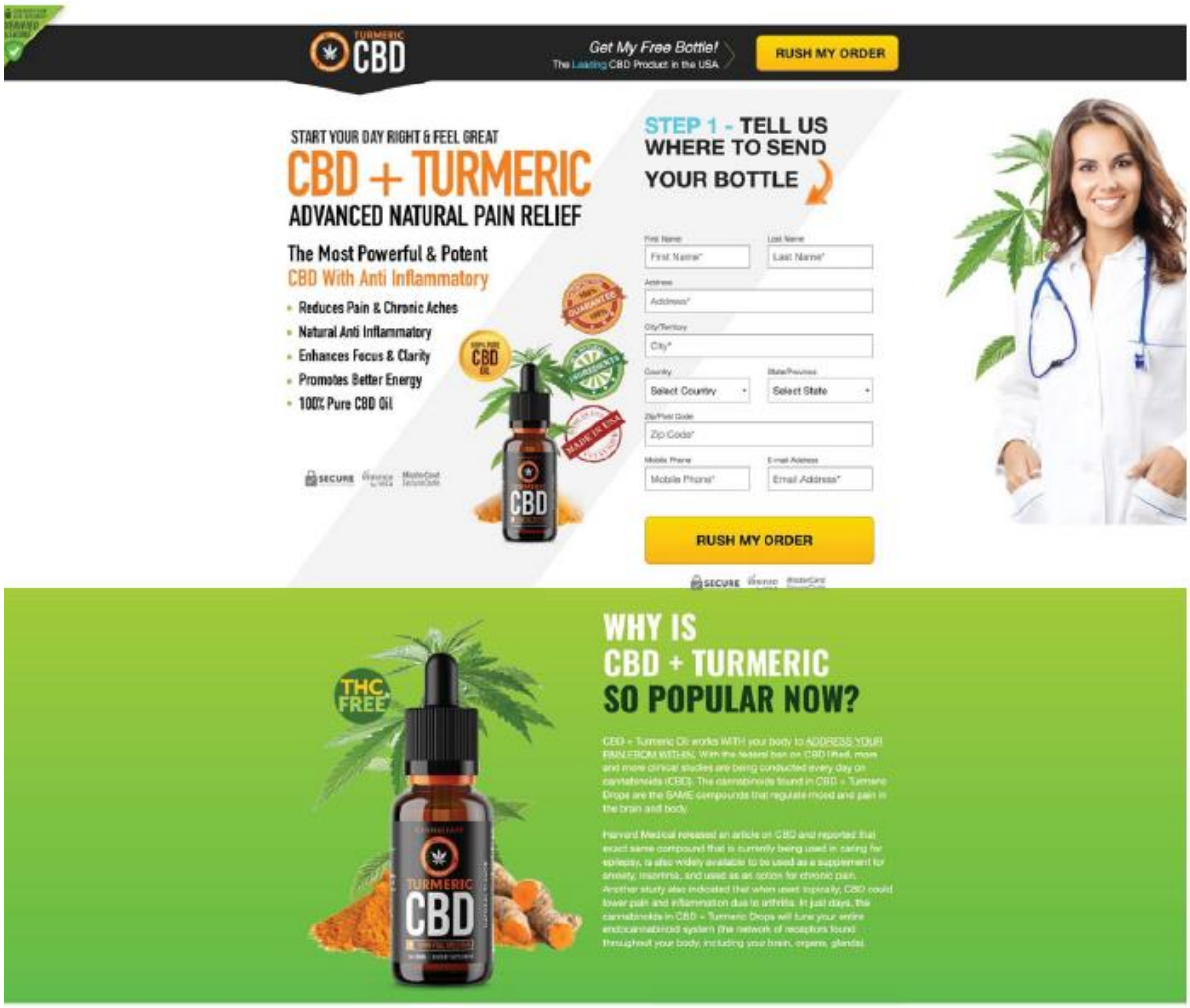
FTC Cmplt. Exh. A-2

Complaint

FTC Cmplt. Exh. A-3

Complaint

Exhibit B



FTC Cmplt. Exh. B-1

Complaint

FTC Cmplt. Exh. B-2

FTC Cmplt. Exh. B-3

Complaint

Exhibit C

FTC Cmplt. Exh. C-1

THAT'S WHY CBD CAN REVERSE THOUSANDS OF AILMENTS, INCLUDING:

- Joint Pain
- Arthritis
- Autoimmune Disorder
- Diabetes
- Multiple Forms Of Cancer [1]
- High Blood Pressure
- Prostate
- Alzheimer's
- Depression And Bipolar Disorder
- Age Related Cognitive Decline
- Migraines And Headaches
- Cardiovascular Issues [2]
- Crohn's And Colitis
- Endocrine Disorders
- Inflammation
- Nausea
- Multiple Sclerosis
- Neuropathic Pain
- Neurodegeneration
- Parkinson's
- Rheumatism
- Chronic Stress And Fatigue
- Spinal Cord Injury
- Stroke
- Obesity
- Skin Conditions Like Psoriasis & Adult Acne
- Schizophrenia [3]
- And much, much more...

1. The National Cancer Institute Believes CBD May "reduce the spread of some cancer cells."
2. The American Journal of Physiology says "CBD induces a substantial in-vivo cardioprotective effect from ischemia" (coronary heart disease).
3. Journal of Translational Psychiatry calls CBD a "completely new mechanism in the treatment of schizophrenia."

HOW TO USE CBD COFFEE TO GET RESULTS

Step 1
DAILY DOSE OF CBD

From the minute you take your first sip of our CBD Coffee - cannabinoids will flood your system - acting as natural neuro transmitters to stop pain, end anxiety, ensure a good night's sleep, and promote complete body balance.

Step 2
NATURAL, FAST RELIEF

Your results with CBD Coffee will improve with continued use. CBD is 100% non-habit forming and is completely safe. It can be taken daily, has NO psychoactive properties, and will not harm you in any way. Plus, your satisfaction is 100% guaranteed.

Step 3
TRANSFORM YOUR HEALTH

With our Full Spectrum CBD Coffee, you always get the proper dose in your body, so you feel good all day long. And it gives you superior absorption compared to all other CBD oil on the market.

FTC Cmplt. Exh. C-2

Complaint

FTC Cmplt. Exh. C-3

Complaint

Exhibit D

FTC Cmplt. Exh. D-1

Complaint

FTC Cmplt. Exh. D-2

FTC Cmplt. Exh. D-3

Complaint

Exhibit E

FTC Cmplt. Exh. E-1

FTC Cmplt. Exh. E-2

Complaint

FTC Cmplt. Exh. E-3

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

    a. Respondent Epichouse, LLC ("Epichouse"), also doing business as First Class Herbalist CBD, Cobalt Serum, Cobalt Enhance, and Cobalt Cream, a Utah corporation with its principal office or place of business at 3370 Brock St., West Valley City, Utah 84119-2902.

    b. Respondent John Le, the sole owner and officer of Epichouse. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices alleged in this complaint. He resides in Midvale, Utah.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For the purpose of this Order, the following definitions apply:

A. "**CBD Product**" means any Dietary Supplement, Food, or Drug containing cannabidiol.

B. "**Covered Product(s)**" means any Dietary Supplement, Food, or Drug, including but not limited to CBD Products sold or marketed by Respondents.

C. "**Dietary Supplement**" means (1) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional Food or as a sole item of a meal or the diet.

D. "**Drug**" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than Food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

E. "**Essentially Equivalent Product**" means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients) in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

F. "**Food**" means (1) any article used for food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

G. "**Respondent**" means the Individual Respondent and the Corporate Respondent, individually, collectively, or in any combination.

1. "**Corporate Respondent**" means Epichouse, LLC, a limited liability company, also doing business as First Class Herbalist CBD, Cobalt Serum, Cobalt Enhance, and Cobalt Cream, and its successors and assigns.

2. "**Individual Respondent**" means John Le.

PROVISIONS

I. PROHIBITED REPRESENTATIONS: HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, or assist others in making, expressly or by implication, any representation that such product:

A. treats, alleviates, or cures age-related cognitive decline, neurodegeneration, or prostate problems;

B. prevents age-related cognitive decline, pain, hypertension, or migraines;

C. treats, alleviates, or cures any disease, including but not limited to adult acne; Alzheimer's disease; arthritis, autoimmune disorder; bipolar disorder; cancer; pain, including neuropathic pain, pain from spinal cord injuries, and pain from diseases like arthritis; colitis; Crohn's disease; depression; diabetes; endocrine disorders; heart disease; high blood pressure; migraines; multiple sclerosis; obesity; Parkinson's disease; psoriasis; rheumatism; strokes; or schizophrenia;

D. replaces the need for prescription painkillers like oxycontin; or

E. is safe for all consumers;

unless the representation is non-misleading, and, at the time of making such representation, Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Section, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such

testing as described in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product must not make, or assist others in making, expressly or by implication, any representation, other than representations covered under the Provision of this Order entitled Prohibited Representations: Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. all protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. all documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. all documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. all documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Corporate Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

IV. PROHIBITED REPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection

with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not misrepresent, in any manner, expressly or by implication:

A. that any Covered Product is clinically proven to:

1. improve alertness, focus, or memory recall;

2. treat, alleviate, or cure age-related cognitive decline; anxiety; bipolar disorder; cancer; pain, including arthritis pain; depression; diabetes; heart disease; high blood pressure; inflammation; insomnia; and migraines; or

3. prevent age-related cognitive decline; anxiety; pain, including arthritis pain; cancer; diabetes; heart disease; hypertension; inflammation; insomnia; or migraines;

B. that the performance or benefits of a Covered Product are scientifically or clinically proven or otherwise established; or

C. the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V. FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, Respondents' officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them from:

A. for any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. for any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI. MONETARY RELIEF

IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $30,000.00, which Respondents stipulate their undersigned counsel holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

VII. ADDITIONAL MONETARY PROVISIONS

IT IS FURTHER ORDERED that:

A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the Complaint. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Respondents have no right to challenge any actions pursuant to this Provision.

VIII. NOTICES TO CUSTOMERS

IT IS FURTHER ORDERED that Respondents must notify customers as follows:

E. Respondents must identify all consumers who purchased CBD Products on or after September 1, 2019 ("eligible customers").

1. Such eligible customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody or control, including from third parties such as resellers;

2. Eligible customers include those identified at any time, including after Respondents' execution of the Agreement through the eligibility period, which runs for 1 year after the issuance date of the Order.

F. Respondents must send a notice via electronic mail to all identified eligible customers:

1. The notice must be in the form shown in Attachment A.

2. The subject line of the email notice must state, "About Your Purchase from First Class Herbalist CBD."

3. The email of the notice must not include any other attachments.

G. Respondents must notify all eligible customers within 45 days after the issuance date of this Order and any eligible customers identified thereafter within 30 days of their identification.

H. Respondents must report on their notification program under penalty of perjury:

1. Respondents must submit a report within 90 days after the issuance date of this Order summarizing their compliance to date, including the total number of eligible customers identified and notified.

2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Respondents must submit it within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

IX. ACKNOWLEDGMENTS OF THE ORDER

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 10 years after the issuance date of this Order, the Individual Respondent for any business that such Respondent, individually or collectively with any other Respondent, is the majority owner or controls directly or indirectly, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for labeling, manufacturing, advertising, marketing,

promotion, distribution, offering for sale, or sale of any Covered Product and all agents and representatives who participate in labeling, manufacturing, advertising, marketing, promotion, distribution, offering for sale, or sale of any Covered Product; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From the individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

X. COMPLIANCE REPORTS AND NOTICES

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. Sixty days after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondent must describe if he knows or should know due to his own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, the Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 10 years after the issuance date of this Order, each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must report any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, the Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: ___" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Epichouse, LLC.

XI. RECORDKEEPING

IT IS FURTHER ORDERED that Respondents must create certain records for 10 years after the issuance date of the Order, and retain each such record for 5 years, unless otherwise specified below. Specifically, Corporate Respondents and the Individual Respondent for any

business that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. a copy of each unique advertisement or other marketing material making a representation subject to this Order; and

F. for 5 years from the date of the last dissemination of any representation covered by this Order:

1. all materials that were relied upon in making the representation; and

2. all tests, studies, analysis, other research, or other such evidence in Respondents' possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations;

I. for 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communications relate to Respondents' compliance with this Order; and

J. for 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents, that tend to show any lack of compliance by Respondents with this Order.

XII. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order: suspended and any failure to transfer any assets as required by this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Respondents, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XIII. ORDER EFFECTIVE DATES

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. any Provision in this Order that terminates in less than 20 years;

B. this Order's application to any Respondent that is not named as a defendant in such complaint; and

C. this Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such

complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ATTACHMENT A TO THE ORDER

CLAIMS ABOUT PRODUCTS CONTAINING CBD
In re Epichouse, LLC – First Class Herbalist CBD

Dear <Name of customer>:

Our records show that you bought CBD Oil, CBD + Turmeric Oil, CBD Coffee, CBD Pain Rub, or CBD Gummies from www.firstclassherbalistcbd.com. We are writing to tell you that the Federal Trade Commission (FTC), the nation's consumer protection agency, has sued us for making misleading claims that our CBD oil can effectively prevent, cure, treat, or ease serious diseases and health conditions, including the following:

age-related cognitive decline, Alzheimer's disease, arthritis, autoimmune disorder, bipolar disorder, cancer, colitis, Crohn's disease, depression, diabetes, endocrine disorders, heart disease, high blood pressure, migraines, multiple sclerosis, neurodegeneration, obesity, Parkinson's disease, prostate problems, psoriasis, rheumatism, schizophrenia, spinal cord injury, and stroke.

To settle the FTC's lawsuit, we're contacting our customers to tell them that we don't have proof that our CBD products will effectively prevent, cure, treat, or improve the serious diseases and health conditions listed above. If you have other questions about this lawsuit, visit [add URL].

CBD oil and other alternative treatments might be harmful to your medical care and could interfere with your prescriptions. CBD products could also be dangerous if you take them with other medicines or at a high dose. Talk to your doctor before you take any treatments or stop any prescriptions. For more information about protecting yourself from bogus health product claims visit ftc.gov/health.

Sincerely,

[Signature]
John Le
Owner
Epichouse, LLC

Concurring Statement

STATEMENT OF COMMISSIONER ROHIT CHOPRA

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.

- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.

- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish – and unlawful – claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine "a competitor's ability to compete" on honest attributes.[1]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID-19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[2] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer

1 *In re Pfizer, Inc.*, 81 F.T.C. 23, 62 (1972).

2 *See, e.g.*, Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL STREET J. (Sept. 8, 2020), https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; *Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic*, AMERICAN MEDICAL ASSOCIATION (last updated on Oct. 31, 2020), https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.

Americans into high-cost, subpar treatment centers, and some even hire intermediaries – so-called "body brokers" – who collect kickbacks from this harmful practice.[3]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[4] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[5]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[6] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[7] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[8] Under the Penalty Offense

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3 For example, recent reporting describes the "Florida Shuffle," where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America*, VOX (Mar. 2, 2020), https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-brijayne. *See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), https://www ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid (calling on the FTC to do more to tackle this problem).

4 Pub. L. No. 115-271 §§ 8021-8023 (codified in 15 U.S.C. § 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

5 Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.

6 Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.

7 In one of these matters, the respondents are paying nothing.

8 15 U.S.C. § 45(m)(1)(b).

Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[9] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[10] and apprising firms of these findings – along with a warning that noncompliance can result in penalties – makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a "high level of voluntary compliance achieved quickly and at a low cost."[11] Going forward, we should pursue this strategy.[12]

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.

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9 *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256. Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

10 This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that "[f]airness to the consumer, as well as fairness to competitors" compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.*, 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that "a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act." *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.*, 155 F.T.C. 1, 6 (2013).

11 Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an "extremely effective and efficient way to enforce the law." Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.

12 My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

CONCURRING STATEMENT OF COMMISSIONER CHRISTINE S. WILSON

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication.

The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters[1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo- controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions – specifically, the FDA has approved a drug containing CBD as an active ingredient

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1 Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions*, Oct. 22, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims; Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis*, Sept. 10, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused; Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases*, Apr. 2, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.

2 Press Release, *FTC Order Stops the Marketer of "Thrive" Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID-19*, July 10, 2020, available at https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.

3 *See, e.g.*, Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that "[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes."[6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

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4 *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.

5 *See, e.g.*, Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC v. Avrom Boris Lasarow, et al.* (Feb. 2015), https://www ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health; Statement of Commissioner Joshua D. Wright, *FTC v. Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin; Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), https://www ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru; Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part; Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC v. Springtech 77376, et al.* (July 2013), https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; *see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12-49 (May 2012), available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.

6 *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order with Epichouse, LLC ("Epichouse"), also doing business as First Class Herbalist CBD, Cobalt Serum, Cobalt Enhance, and Cobalt Cream, and John Le, individually and as an officer of Epichouse (collectively, "Respondents").

The proposed consent order ("order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves Respondents' advertising for products containing cannabidiol ("CBD Products"), including First Class Herbalist CBD oil. The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that their CBD Products, among other things: are safe for all users; treat pain better than prescription medicine like OxyContin; prevent and treat numerous serious health conditions, including age-related cognitive decline, cancer, chronic pain, diabetes, heart disease, hypertension, and migraines; and are scientifically proven to improve many serious health conditions.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food that Respondents sell or market, including CBD Products.

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product:

A. treats, alleviates, or cures age-related cognitive decline, neurodegeneration, or prostate problems;

B. prevents age-related cognitive decline, pain, hypertension, or migraines;

C. treats, alleviates, or cures any disease, including but not limited to adult acne; Alzheimer's disease; arthritis, autoimmune disorder; bipolar disorder; cancer; pain, including neuropathic pain, pain from spinal cord injuries, and pain from diseases like arthritis; colitis; Crohn's disease; depression; diabetes; endocrine disorders; heart disease; high blood pressure; migraines; multiple sclerosis; obesity; Parkinson's disease; psoriasis; rheumatism; strokes; or schizophrenia;

D. replaces the need for prescription painkillers like oxycontin; or

E. is safe for all consumers,

unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety, or side effects of any covered product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III requires that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by the order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits Respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research or that any benefit of any covered product is scientifically or clinically proven.

Part V provides Respondents a safe harbor for making claims approved by the Food and Drug Administration ("FDA").

Parts VI and VII require Respondents to pay the Commission $30,000.00 and describes the procedures and legal rights related that payment.

Part VIII requires Respondents to send email notices to consumers who purchased First Class Herbalist Relief CBD oil informing them about the settlement.

Parts IX requires Respondents to submit an acknowledgement of receipt of the order, to serve the order on certain individuals, including all officers or directors of any business Respondents control and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which Respondents have delivered a copy of the order.

Part X requires Respondents to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. **Part XI** contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance or non-compliance with the order. **Part XII** contains other requirements related to the Commission's monitoring of Respondents' order compliance. **Part XIII** provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

Complaint

IN THE MATTER OF

REEF INDUSTRIES, INC.
D/B/A
REEFCBD.COM AND REEF WELLNESS,
CANNATERA, INC.,
ANDHEMP, LTD.,
ANDREW M. BOUCHIE,
JOHN R. CAVANAUGH,
AND
SHAUN PAQUETTE

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4737; File No. 202 3064
Complaint, February 4, 2021 – Decision, February 4, 2021

This consent order addresses Reef Industries, Inc.'s advertising of cannabidiol (CBD), a cannabinoid compound found in hemp and cannabis. The complaint alleges that respondent violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) CBD products can effectively prevent, cure, treat, or mitigate multiple diseases and other health conditions; and (2) studies or scientific research prove that CBD products effectively prevent, cure, treat, or mitigate multiple diseases and other health conditions. The consent order requires requires randomized, double-blind, placebo-controlled clinical testing for the challenged claims or any disease treatment, mitigation, or cure claim for a Covered Product, and prohibits other misleading or unsubstantiated representations about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or essentially equivalent product.

Participants

For the *Commission*: *Nick Coates* and *Laura Fremont.*

For the *Respondents*: *Robert Hindin, Robert Hindin & Associates.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Reef Industries, Inc., a corporation, Cannatera, Inc., a corporation, AndHemp, Ltd., a limited company, and Andrew M. Bouchie, John R. Cavanaugh, and Shaun Paquette, individually and as officers and/or owners of Reef Industries, Inc., Cannatera, Inc., and/or AndHemp, Ltd. (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Reef Industries, Inc. ("Reef"), also doing business as Reefcbd.com and Reef Wellness, is a California corporation with its principal office or place of business at 3033 Bristol Street #G, Costa Mesa, California 92626.

2. Respondent Cannatera, Inc., ("Cannatera") is a California corporation with its principal office or place of business at 1235 E. Francis Street Suite M, Ontario, California 91761.

3. Respondent AndHemp, Ltd., ("AndHemp") is a United Kingdom limited company with its principal office or place of business at 1235 E. Francis Street, Ontario, California 91761.

4. Respondent Andrew M. Bouchie ("Bouchie") is an officer, director, and principal shareholder of Reef, an officer of Cannatera, and President and co-owner of AndHemp. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Reef.

5. Respondent John R. Cavanaugh ("Cavanaugh") is an officer, director, and principal shareholder of Reef. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Reef.

6. Respondent Shaun Paquette ("Paquette") is an officer and director of Reef, officer of Cannatera, and co-owner of AndHemp. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Reef.

7. Respondents Reef, Cannatera, and AndHemp (collectively, "Corporate Respondents") have operated as a common enterprise while engaging in the unlawful acts and practices alleged below. Corporate Respondents have conducted the business practices described below through an interrelated network of companies that have common ownership, officers, business functions, business and mailing addresses, and unified advertising and marketing. Because these Corporate Respondents have operated as a common enterprise, each of them is jointly and severally liable for the acts and practices alleged below. Respondents Bouchie, Cavanaugh, and Paquette formulated, directed, controlled, had the authority to control, or participated in the acts and practices of the common enterprise alleged in this Complaint.

8. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Respondents' Marketing of CBD Products

9. Cannabidiol ("CBD") is a substance naturally occurring in, and that can be extracted from, the hemp plant, *cannabis sativa*. Respondents have advertised, promoted, offered for sale, sold, and distributed products containing CBD ("CBD Products") that are intended for human use. According to the product labels and Respondents' websites, dosages vary. These CBD Products are "food" and/or "drugs," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act. For example:

a. Reef has sold a variety of CBD Products, including tinctures, gummies, gel caps, salves, gels, sprays, lotions, serums, moisturizers, and vape oils. These products contained, for example, between 9.884 to 644.700 mg of CBD per unit. Until approximately January 2020, consumers could purchase these CBD Products from Respondents by ordering online at reefcbd.com, or at a brick and mortar store called Reef Wellness located at 3033 Bristol Street #G, Costa Mesa, California 92626.

b. Cannatera has sold a variety of CBD Products containing different amounts of CBD. Cannatera's Refresh (Cleanser), for example, contained 83.520 mg of CBD per unit. Cannatera's Revive (Serum) contained 94.191 mg of CBD per unit. Cannatera's Renew (Moisturizer) contained 187.920 mg of CBD per unit. Until approximately January 2020, consumers could purchase Cannatera CBD Products from Respondents by ordering online at reefcbd.com.

c. AndHemp has sold a variety of CBD Products containing different amounts of CBD. For example, AndHemp's lavender lotion contained 183.372 mg of CBD per unit. AndHemp's muscle gel contained 138.600 mg of CBD per unit. AndHemp's pain oil spray contained 359.100 mg of CBD per unit. Until approximately January 2020, consumers could purchase AndHemp CBD Products from Respondents by ordering online at andhemp.com or reefcbd.com.

10. Respondents have disseminated or have caused to be disseminated advertisements for CBD Products, including but not necessarily limited to the attached Exhibits A through Q. Respondents promoted CBD Products through a variety of means, including through their websites reefcbd.com and cannatera.com, and through social media platforms such as Twitter, Facebook, YouTube, and Instagram. These advertisements contained the following statements:

a. What Are Some Potential CBD Benefits?

. . .

CBD hemp oil has a huge range of potential health benefits and uses, including . . . fighting cancer, . . . eliminating depression, [and] preventing inflammatory arthritis . . . .

. . .

Reduces Anxiety and Depression

According to the Anxiety and Depression Association of America, depression affects 6% and anxiety affects 18% of the U.S. population each year. Research shows that CBD oil can help with both.

CBD has been shown to reduce levels of stress and anxiety in those suffering from conditions such as PTSD, social anxiety disorder, and obsessive-compulsive disorder. . . .

Though a B12 deficiency may also be to blame, CBD has been shown to reduce depression by enhancing both serotonergic and glutamate cortical signaling (both are lacking in those with depression).

Calms Childhood Epilepsy

CBD has anti-seizure properties that have been shown to successfully treat drug-resistant children who have neurological disorders like epilepsy (with no side effects!). In one study published in the New England Journal of Medicine, CBD decreased frequency of seizures by 23 percentage points more than those taking a placebo.

Relief for Chronic Pain

Those suffering from chronic pain from diseases like fibromyalgia are finding relief with CBD. Taking CBD can offer pain relief and can even prevent nervous system degeneration. In fact, it has been approved in Canada for multiple sclerosis and cancer rain [sic].

. . .

Reduces Inflammation

Chronic inflammation is a huge problem in our society that contributes to many non-infectious diseases including heart disease, cancer, Alzheimer's, autoimmune disease, and more, according to the National Center for Biotechnology Information.

Diet and lifestyle play a huge part in chronic inflammation but when folks are already eating a healthy, nutrient dense diet and optimizing their lifestyle (getting enough sleep and exercise for example), CBD oil can help. Research also shows that CBD oil can reduce chronic inflammation that leads to disease.

. . .

Improves Heart Health

Heart disease is a growing problem today. In fact, it's the leading cause of death in the U.S. A healthy diet and lifestyle are a tor [sic] priority for heart health, but CBD oil can also help. According to research cannabidiol reduces artery blockage, reduces stress induced cardiovascular

response, and san [sic] reduce blood pressure. It may also reduce cholesterol.

As mentioned earlier, CBD oil is helpful in preventing oxidative stress and inflammation. Both of these are often precursors to heart disease.

(Exhibit A, blog post by Reef, *What Are Some Potential CBD Benefits?* (January 1, 2019), www.reefcbd.com).

b. **Nature's Medicine: Top 5 Health Benefits of CBD Oil**

If you suffer from chronic pain, anxiety, seizures, or any number of other maladies, finding relief can feel impossible. But did you know there's a natural treatment that can help?

It's true! CBD oil is an effective treatment or supplemental treatment for tons of issues, from everyday aches and pains to complex diseases like cancer.

. . .

Cancer-Fighting

Although the research about hemp oil as a treatment for cancer is still new, it's very promising. Preliminary studies have shown that CBD slows the growth of certain kinds of cancer cells, or kills them entirely (https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternativemedicine/marijuana-and-cancer.html). Although CBD should not be used as a cancer treatment on its own, it's a great addition to professionally supervised medical care.

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Anti-Seizure

When the electrical activity of the brain fluctuates, seizures occur. Thankfully, CBD oil can help control seizures. One study showed a 38.9 percent drop (https://www.nejm.org/doi/full/10.1056/NEJMoa1611618#t=article) in seizure activity in people who regularly took CBD.

Fights Diabetes

If you or someone you love suffers from diabetes, try using CBD oil to treat it. Not only is it safer than the most common diabetes medications, but it's also more effective. CBD oil can prevent diabetes and obesity,

treat insulin resistance, and help with the chronic skin sensitivity that often accompanies diabetes.

Be Well!

As you can see, CBD is a safe and effective treatment for many ailments and diseases. It works with our bodies' natural processes and rhythms to restore balance and health.

If you suffer from anxiety, pain, diabetes, seizures, or even cancer, try adding CBD oil into your treatment regimen.

It could change your life!

(Exhibit B, blog post by Reef, *Nature's Medicine: Top 5 Health Benefits of CBD Oil* (Jan. 22, 2019), www.reefcbd.com).

c. **Ryan Smith Trains Hard With Reef CBD**

. . .

Reef CBD has a huge range of potential health benefits and uses, including . . . fighting cancer . . . [and] preventing inflammatory arthritis . . . .

. . .

Not only does Reef CBD interact with receptors in the brain, but it also works with the immune system. Reef CBD oil for pain will reduce inflammation and relieve pain at the same time. Chronic inflammation is a huge problem in our society that contributes to many non-infectious diseases including heart disease, cancer, Alzheimer's, autoimmune disease, and more, according to the National Center for Biotechnology Information. Diet and lifestyle play a huge part in chronic inflammation but when folks are already eating a healthy, nutrient-dense diet and optimizing their lifestyle (getting enough sleep and exercise for example), Reef CBD can help. Research also shows that CBD can reduce chronic inflammation that leads to disease.

. . .

CBD has been shown to reduce levels of stress and anxiety in those suffering from conditions such as PTSD, social anxiety disorder, and obsessive-compulsive disorder. . . . CBD has been shown to reduce depression by enhancing both serotonergic and glutamate cortical signaling (both are lacking in those with depression).

(Exhibit C, blog post by Reef, *Ryan Smith Trains Hard with Reef CBD* (May 29, 2019), www.reefcbd.com).

d. **7 CBD Benefits Strongly Backed by Science**

. . .

Protect Nerves

Studies have shown that CBD may protect the nerve endings and dampen overactive messages traveling through the nervous system. A seizure is an overwhelming of the brain with too many messages at once. But this protection may go beyond seizures.

- A 2018 professional review of existing studies found that nerve protection may help those with Parkinson's and Multiple Sclerosis.

- A 2018 study found that for those with Parkinson's early, [sic] intervention is vital because the damage that Parkinson's does to the nerves happens quickly and is irreversible, making CBD's effects limited.

- A study conducted by Maryland researchers way back in 2000 had already determined that CBD was able to protect nerves from damage. While we have scientific rigor for a reason, it also means that sometimes scientists spend decades studying something before we see practical application in therapeutics or medicine.

Has CBD's day finally come? We hope so. And with each new study confirming the findings of the last, that looks to be the case.

Many scientists believe that CBD benefits may extend to other conditions that damage nerves like celiac, the disease that causes gluten intolerance as well as multiple sclerosis (MS), lupus and rheumatoid arthritis. But it's still too early in the studies. You might choose to use to see if it helps you with conditions of the nervous system. But the jury is still out on these CBD benefits.

But seizures and nerve protection aren't the only areas where the science is strong.

. . .

Reduce inflammation

The benefits of CBD on inflammation are something anyone can get excited about, even the chillest dude you know. A lot of the chronic diseases that exist today wouldn't exist without inflammation. For example, irritable bowel syndrome (IBS), colitis, arthritis, dermatitis, autoimmune diseases. Inflammation is important. It's how your body fights infection. But when it sticks around after last call, it becomes that belligerent drunk who's flipping the tables and making those unwanted advances.

The benefits of CBD for inflammation are promising. But it may be some time though before we can say that it can treat a specific disease. More studies are needed to find the right doses. But until then, many people are experimenting and reporting positive results.

- In 2016, researchers found that a high dose of CBD could significantly reduce colon inflammation when given via a suppository.

- A 2017 study showed that CBD reduced joint inflammation[.] They found the most effective dose to be 300 µg, which is approximately 1/3 of a milligram. It reduced inflammation response by nearly 23%.

- In 2016, researchers used CBD to reduce gum inflammation in those with gingivitis.

And we're only scratching the surface here.

. . .

Reduce anxiety symptoms

. . .

Multiple studies support the anti-anxiety effects of CBD. Researchers are particularly interested in its ability to help people with:

- Panic disorder

- Obsessive-compulsive disorder (OCD)

- Social anxiety disorder

- Post-traumatic stress disorders

. . .

Reduce intestinal distress

Irritable Bowel Syndrome is an inflammatory condition, but it deserves its own section. Common IBS diseases include ulcerative colitis and Crohn's.

- A 2013 study on those with IBS found that CBD is a "very promising compound since it shares the typical cannabinoid beneficial effects on gut lacking any psychotropic effects[.]"

- A 2011 study showed a reduction in TNF-α expression as well as the presence of cleaved caspase-3 in the intestines of those with colitis. Both of these markers represent a scientifically measurable reduction in bowel inflammation.

- A 2009 study found that CBD reduced damage to the colon caused by toxins, such as chemo.

(Exhibit D, blog post by Reef, *7 CBD Benefits Strongly Backed by Science* (June 7, 2019), www.reefcbd.com).

e. **Reef CBD Body Rubs Not Your Typical Topical**

. . .

Chronic inflammation is a huge problem in our society that contributes to many non-infectious diseases including heart disease, cancer, Alzheimer's, autoimmune disease, and more, according to the National Center for Biotechnology Information. Diet and lifestyle play a huge part in chronic inflammation but when folks are already eating a healthy, nutrient-dense diet and optimizing their lifestyle (getting enough sleep and exercise for example), Reef CBD body rub can help. Research also shows that CBD oil can reduce chronic inflammation that leads to disease.

The benefits of CBD on inflammation are something anyone can get excited about, even the chillest dude you know. A lot of the chronic diseases that exist today wouldn't exist without inflammation. For example, irritable bowel syndrome (IBS), colitis, arthritis, dermatitis, autoimmune diseases. Inflammation is important. It's how your body fights infection. But when it sticks around after last call, it becomes that belligerent drunk who's flipping the tables and making those unwanted advances.

The benefits of Reef CBD for inflammation are promising. Many people are experimenting and reporting positive results.

- In 2016, researchers found that a high dose of CBD could significantly reduce colon inflammation when given via suppository.

- A 2017 study showed that CBD reduced joint inflammation. They found the most effective dose to be 300 μg, which is approximately 1/3 of a milligram. It reduced inflammation response by nearly 23%.

- In 2016, researchers used CBD to reduce gum inflammation in those with gingivitis.

. . .

- A 2018 study on HIV patients showed the CBD reduced nerve pain by 30%. This can likely be attributed to the anti-inflammation and neuroprotective properties.

(Exhibit E, blog post by Reef, *Reef CBD Body Rubs Not Your Typical Topical* (June 18, 2019), www.reefcbd.com).

f. **ReefCBD**

@ReefCBD_

Heart disease is a growing problem today. In fact, it's the leading cause of death in the U.S. A healthy diet and lifestyle is a top priority for heart health, but CBD oil can also help. #FridayFeeling

ACCODRING [SIC] TO RESEARCH CANNABIDIOL REDUCES ARTERY BLOCKAGE, REDUCES STRESS INDUCED CARIOVASCULAR [SIC] RESPONSE, AND CAN REDUCE BLOOD PRESSURE.

FOR MORE INFORMATION GO TO WWW.REEFCBD.COM.

*THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE, OR PREVENT ANY DISEASE.

(Exhibit F, Tweet by @reefcbd (Nov. 9, 2018), https://twitter.com/ReefCBD/status/1060932604910723072).

g. **CANNABINOID AND CANNATERA: THE BENEFITS OF CBD ON THE SKIN**

. . .

It Soothes Inflammation

If you suffer from eczema, rosacea or psoriasis, you're familiar with the scaly, red bumps that arise due to inflammation. This is where CBD skin care benefits shine.

Applied topically, the oil interacts with our body's own endocannabinoid receptors. In turn, inflammation decreases, along with painful itching.

In fact, one study of 21 patients found that, after three weeks of applying CBD lotion twice a day, eight were able to permanently eliminate their severe skin itching.

. . .

One study revealed that CBD is also a neurological protectant, helping to treat age-related disorders including cerebral ischemia, which occurs when blood flow to the brain is compromised.

(Exhibit G, web ad by Andrew M. Bouchie, *Cannabinoid and Cannatera: The Benefits of CBD on the Skin* (Mar. 25, 2019), https://medium.com/@andy_67985/cannabinoid-and-cannatera-the-benefits-of-cbd-on-the-skin-b0db6b215175).

h. HOW CBD PRODUCTS ARE BENEFICIAL TO YOUR BODY

. . .

ECZEMA

All of CBD lotion, CBD salve, and even CBD cream [sic] can help to treat eczema. However, at this point, it is necessary to point out that they work to different degrees for different people because people have different skin composition. CBD helps some people to get eczema off their skin completely but it only works partially for others.

This is normal as there is no single drug that works for everyone.

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PAIN

This is the most popular benefit of CBD on the body. Nevertheless, it is necessary to mention it here too. A lot of studies and clinical trials have confirmed it and many people who have used it have also confirmed the efficacy of CBD on chronic pain.

(Exhibit H, blog post by Cannatera, *How CBD Products Are Beneficial to Your Body* (June 13, 2019), https://cannatera.com/blogs/news/how-cbd-products-are-beneficial-to-your-body).

i. ACNE, INFLAMMATION AND CBD

. . .

Scientific Research

Science supports its efficacy in this capacity: research shows that CBD may treat all kinds of skin problems, including chronic conditions. A study finding that CBD slows overproduction of skin cells signals promise for psoriasis; According [sic] to the National Center for Biotechnology Information, chronic inflammation is a consistent problem in the United States, contributing to numerous non-infectious diseases like heart disease and autoimmune disease. Although diet and lifestyle play a significant role in chronic inflammation, CBD oil can encourage improvement.

(Exhibit I, blog post by Cannatera, *Acne, Inflammation and CBD* (July 19, 2019), https://cannatera.com/blogs/news/acne-inflammation-and-cbd).

j. UV RAYS: WHY ARE THEY HARMFUL?

. . .

Exposure to UVA rays contributes to premature aging factors such as wrinkles and fine lines. On the other hand, UVB exposure is linked to sunburns and skin cancers. Although UVC rays do not penetrate the Earth, they can come from tanning beds and lights fixtures which can ultimately lead to skin cancer. People that are overexposed to UV radiation have a higher risk of developing skin cancer.

. . .

One of the key ingredients in our moisturizer is Cannabidiol. Studies suggest that CBD may prevent premature aging, inflammation, and UV ray damage when applied to the skin.

(Exhibit J, blog post by Cannatera, *UV Rays: Why Are they Harmful?* (Aug. 19, 2019), https://cannatera.com/blogs/news/uv-rays-why-are-they-harmful).

k. CBD OIL FOR ACNE: IS IT EFFECTIVE?

. . .

Another study in 2016 revealed that the cannabis plant has antibacterial and anti-fungal effects. These characteristics help reduce infections from dirt and other pollutants on the skin.

(Exhibit K, blog post by Cannatera, *CBD Oil for Acne: Is it Effective?* (June 9, 2019), https://cannatera.com/blogs/news/cbd-oil-for-acne-is-it-effective).

l. REASONS WHY CBD SHOULD BE IN YOUR SKINCARE REGIMEN

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Hence, CBD may help deal with a wide range of skin conditions such as eczema, psoriasis, and pesky breakouts.

(Exhibit L, blog post by Cannatera, *Reasons Why CBD Should be in Your Skincare Regimen* (May 26, 2019), https://cannatera.com/blogs/news/reasons-why-cbd-should-be-in-your-skincare-regimen).

m. CAN CBD REALLY HELP ACNE?

. . .

Other research shows that CBD can be effective in reducing stress levels, which, in turn, can alleviate skin conditions like acne. CBD might be particularly effective for people who suffer from social anxiety.

"A small 2010 study found that cannabidiol could reduce symptoms of social anxiety in people with a social anxiety disorder (SAD). Brain scans of participants revealed changes in blood flow to the regions of the brain linked to feelings of anxiety," says Medical News Today.

(Exhibit M, blog post by Cannatera, *Can CBD Really Help Acne?* (May 22, 2019), https://cannatera.com/blogs/news/can-cbd-really-help-acne).

n. HEMP OIL SKIN CARE: HOW HEMP OIL BENEFITS YOUR SKIN

. . .

With sales of CBD products projected to hit $22 billion by 2022, it's important to know why people are using it so much.

From helping diabetics, to preventing heart disease and anxiety, the benefits seem to be endless.

. . .

LOWERS BLOOD SUGAR

CBD is commonly used by diabetics for its regulating effects on blood sugar, but how does that affect your skin?

Hyperglycemia, high blood sugar, is believed to be a common cause of acne. CBD, even when absorbed through the skin, can help regulate that, lowering your risk of pesky pimples.

(Exhibit N, blog post by Cannatera, *Hemp Oil Skin Care: How Hemp Oil Benefits Your Skin* (Apr. 18, 2019), https://cannatera.com/blogs/news/how-does-hemp-oil-benefit-your-skin).

o. INFLAMMATORY CONDITIONS LEAD TO MANY SKIN PROBLEMS

. . .

Inflammation causes an itchy rash that can often be treated and dealt with easily. Other times, inflammation leads to chronic conditions like eczema, psoriasis, rosacea, and seborrheic dermatitis that require ongoing treatment to keep under control.

. . .

When skin inflammation is severe, medical interventions are often sought to fight it. However, in many cases, mild to severe inflammation can be kept in check by using the proper skincare products on a daily basis. This would include those offered by Cannatera. Our products contain CBD, a compound found in the hemp plant. You've probably heard of it. CBD has been garnering a lot of attention over the last few years in the health and beauty world for its anti-inflammatory and anti-aging properties.

According to recent research on the subject, by regularly using products containing CBD, such as Cannatera skincare products, you'll be applying

the anti-inflammatory power of CBD oil and the powerful anti-oxidants it contains directly to the source of your inflammation, and relief can be achieved quickly.

(Exhibit O, blog post by Cannatera, *Inflammatory Conditions Lead to Many Skin Problems* (Jan. 23, 2019), https://cannatera.com/blogs/news/inflammatory-conditions-lead-to-many-skin-problems).

p. Studies show that the endocannabinoid system may be critical for regulating sleep and sleep stability, as it promotes harmony throughout the body. When CBD interacts with this system, those who suffer may be able to achieve longer periods and overall quality of sleep. CBD may also provide relief for insomnia sufferers who struggle to achieve REM sleep due to anxiety.

. . .

CBD for Insomnia

Nearly 40 million people in America suffer from chronic insomnia.

Source: National Center for Biotechnology Information

(Exhibit P, Facebook post by @AndHemp (Nov. 3, 2019), https://www.facebook.com/andhemp/photos/a.557224958418793/560463798094909/?type=3&theater).

q. **CBD Benefits: A Look at CBD as a Potential Digestive Aid**

. . .

To date, the most effective methods of treatment for people with these debilitating conditions has been to offer some kind of medication to help combat symptoms. The cannabinoid cannabidiol (CBD) which is one of over a hundred cannabinoids found in the cannabis plant, could bring new levels of relief to people who have issues with things like irritable bowel syndrome or Chron's [sic] disease.

. . .

Scientists have stated:

"Pharmacological modulation of the endogenous cannabinoid system could provide a new therapeutic target for the treatment of a number of gastrointestinal diseases…"

> This is exciting news for people who deal with GI issues on a daily basis, especially when so many other prescription medication alternatives come along with side effects that can be just as troubling as the condition alone.
>
> There have been a few small formal studies to help solidify this abstract assumption that scientists have made about CBD. One small study of 46 people who had moderately severe Chron's [sic] disease showed that 65 percent of participants saw a full remission of their symptoms. There was a review published in 2008 by a neurologist that stated IBS could be a result of a clinical endocannabinoid deficiency. In 2011, one study found that CBD helped create a reduction in inflammation in the bowels caused by a pesky bacterium called bacterial lipopolysaccharides (LPS), which just happens to be a major thing in the bodies of people with have IBS.
>
> . . .
>
> Even though there is no definitive dosing guidelines or proof that CBD is a cure-all for digestive issues, it is an alternative treatment that could be worth a shot if you are suffering from GI issues. Check out the CBD oil for sale on AndHemp.
>
> (Exhibit Q, blog post by AndHemp, *CBD Benefits: A Look at CBD as a Potential Digestive Aid* (July 8, 2019), www.andhemp.com).

Count I
False or Unsubstantiated Efficacy Claims

11. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBD Products, Respondents have represented, directly or indirectly, expressly or by implication, that CBD Products effectively prevent, cure, treat, or mitigate multiple diseases and other health conditions, including: acne, Alzheimer's disease, arthritis, autoimmune disease, cancer, celiac disease, childhood epilepsy, chronic inflammation, chronic insomnia, chronic pain (including chronic pain from fibromyalgia, multiple sclerosis, and cancer), colitis, Crohn's disease, damage to the colon due to chemotherapy, depression, diabetes, eczema, epilepsy, gingivitis, heart disease, insulin resistance, irritable bowel syndrome ("IBS"), lupus, multiple sclerosis, neurodegenerative disorders, neurological and age-related disorders (including cerebral ischemia), obsessive-compulsive disorder ("OCD"), panic disorder, Parkinson's disease, post-traumatic stress disorder ("PTSD"), psoriasis, rosacea, seizures, seizure disorders, skin cancer, skin infections, social anxiety disorder, and strokes.

12. The representations set forth in Paragraph 11 are false or misleading, or were not substantiated at the time the representations were made.

Count II
False Establishment Claims

13. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBD Products, Respondents have represented, directly or indirectly, expressly or by implication, that studies or scientific research prove that CBD Products effectively prevent, cure, treat, or mitigate multiple diseases and other health conditions, including: arthritis, autoimmune disease, cancer, childhood epilepsy, chronic inflammation, chronic insomnia, chronic pain (including chronic pain from fibromyalgia, multiple sclerosis, and cancer), colitis, Crohn's disease, damage to the colon due to chemotherapy, depression, epilepsy, gingivitis, heart disease, irritable bowel syndrome ("IBS"), multiple sclerosis, neurological and age-related disorders (including cerebral ischemia), obsessive-compulsive disorder ("OCD"), panic disorder, Parkinson's disease, post-traumatic stress disorder ("PTSD"), psoriasis, seizures, seizure disorders, skin cancer, skin infections, social anxiety disorder, and strokes.

14. In fact, studies or scientific research do not prove that CBD Products effectively prevent, cure, treat, or mitigate multiple diseases and other health conditions, including: arthritis, autoimmune disease, cancer, childhood epilepsy, chronic inflammation, chronic insomnia, chronic pain (including chronic pain from fibromyalgia, multiple sclerosis, and cancer), colitis, Crohn's disease, damage to the colon due to chemotherapy, depression, epilepsy, gingivitis, heart disease, irritable bowel syndrome ("IBS"), multiple sclerosis, neurological and age-related disorders (including cerebral ischemia), obsessive-compulsive disorder ("OCD"), panic disorder, Parkinson's disease, post-traumatic stress disorder ("PTSD"), psoriasis, seizures, seizure disorders, skin cancer, skin infections, social anxiety disorder, and strokes. Therefore, the representations set forth in Paragraph 13 are false or misleading.

Violations of Sections 5 and 12

15. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this fourth day of February, 2021, has issued this Complaint against Respondents.

By the Commission.

Exhibit A

Exhibit A

MENU (/) (/cart)

Reef CBD Blog

HOME / REEF CBD BLOG (/BLOGS/CBD-BLOG)

REEF CBD BLOG (/BLOGS/CBD-BLOG)

What Are Some Potential CBD Benefits? (/blogs/cbd-blog/what-are-some-potential-cbd-benefits)

Posted by Reef Naturals (Javascrip:void())

CBD hemp oil has a huge range of potential health benefits and uses, including reducing rain, soothing anxiety, fighting cancer, improving mood, eliminating depression, preventing inflammatory arthritis, protecting the immune system, balancing the metabolism, aiding sleep disorders, and healing the skin, among others. CBD oil can also be used in many ways and has a variety of applications for natural health.

It may have side effects such as low blood pressure, light-headedness, fatigue, dry mouth, and slowed motor functions. However, these side effects have been found to be mild according to various studies. Use of CBD oil is recommended if you live in a country or region where the possession, use, and distribution of marijuana is legal.

Reduces Anxiety and Depression

According to the Anxiety and Depression Association of America, depression affects 6% and anxiety affects 18% of the U.S. population each year. Research shows that CBD oil can help with both.

CBD has been shown to reduce levels of stress and anxiety in those suffering from conditions such as PTSD, social anxiety disorder, and obsessive-compulsive disorder. CBD even reduced the stress and discomfort surrounding public speaking.

Though a B12 deficiency may also be to blame, CBD has been shown to reduce depression by enhancing both serotonergic and glutamate cortical signaling (both are lacking in those with depression).

Calms Childhood Epilepsy

CBD has anti-seizure properties that have been shown to successfully treat drug-resistant children who have neurological disorders like epilepsy (with no side effects!). In one study published in the New England Journal of Medicine, CBD decreased frequency of seizures by 23 percentage points more than those taking a placebo.

Relief for Chronic Pain

Those suffering from chronic pain from diseases like fibromyalgia are finding relief with CBD. Taking CBD can offer pain relief and can even prevent nervous system degeneration. In fact, it has been approved in Canada for multiple sclerosis and cancer rain.

What's amazing is that CBD doesn't cause dependence or tolerance, so it's a great choice for those trying to stay away from opioids.

Promotes Healthy Weight

Cannabidiol can help maintain healthy blood sugar, stimulates genes and proteins that helps break down fat, and increase mitochondria that helps burn calories.

CBD also encourages the body to convert white fat to brown fat. White fat is the kind of fat we typically think of when we think about body fat. Brown fat is fat that is in small deposits that behaves differently than white fat. Brown fat is said to improve health by enhancing the bodies ability to burn white fat, create heat, and even regulate blood sugar.

Fights Multi-Drug Resistant Bacteria

Researchers discovered that cannabinoids (including CBD) have an unusual ability to destroy bacteria (especially drug-resistant strains). More research is needed to find out how and why it works.

A 2011 study found that CBD can also slow the progression of tuberculosis in rats. Researchers concluded that CBD likely does this by inhibiting T-sell proliferation, rather than possessing antibacterial properties.

Whatever the mechanism is for destroying bacteria, CBD seems to be a potent weapon against the antibiotic resistant "superbugs" that are becoming more and more of a problem today.

Reduces Oxidative Stress

Oxidative stress is responsible for many ailments today. Oxidative stress is when the body has too many free radicals and can't keep up with neutralizing them (with antioxidants). This is more of a problem now than in the past because our environment is zo mush more toxic than it once was. A 2010 study shows that CBD oil acts as an antioxidant and another study found CBD has neuroprotective qualities. So, CBD can reduce neurological damage caused by free radicals.

Fights Cancer

CBD oil's role in cancer treatment still needs more research, but what is available is looking promising. According to the American Cancer Society, CBD oil can slow growth and spread of some kinds of cancer (in animals). Because it fights oxidative stress and inflammation, (and both are linked to cancer) it makes sense that CBD oil could help fight cancer cells.

Reduces Inflammation

Chronic inflammation is a huge problem in our society that contributes to many non-infectious diseases including heart disease, cancer, Alzheimer's, autoimmune disease, and more, according to the National Center for Biotechnology Information.

Diet and lifestyle play a huge part in chronic inflammation but when folks are already eating a healthy, nutrient-dense diet and optimizing their lifestyle (getting enough sleep and exercise for example), CBD oil can help. Research also shows that CBD oil can reduce chronic inflammation that leads to disease.

Help for Schizophrenia

Schizophrenia is a complicated and serious disease that is typically managed through therapy and pharmaceutical drugs (that carry hefty side effects). Anecdotally, many folks have found that CBD oil has helped reduce hallucinations. Research is beginning to catch up too. A March 2015 review of available research found that CBD was a safe, effective, and well tolerated treatment for psychosis. But more research is needed to bring CBD into clinical practice.

It should be mentioned that THC, the psychoactive compound in marijuana, may increase psychosis for those at risk. CBD oil, on the other hand, only helps reduce psychosis and may even counteract psychosis brought on by marijuana use.

Improves Heart Health

Heart disease is a growing problem today. In fact, it's the leading cause of death in the U.S. A healthy diet and lifestyle are a tor priority for heart health, but CBD oil can also help. According to research cannabidiol reduces artery blockage, reduces stress induced cardiovascular response, and san reduce blood pressure. It may also reduce cholesterol.

As mentioned earlier, CBD oil is helpful in preventing oxidative stress and inflammation. Both of these are often precursors to heart disease.

Improves Skin Conditions

CBD oil can be used topically to treat skin conditions. Studies show CBD oil has a high potential for treating skin conditions like eczema by encouraging abnormal cell death. It can also help regulate the skin's oil production, reducing acne. CBD also contains many nutrients like vitamin E that help improve and protect the skin.

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For additional information, please review our certified lab analysis reports.

Exhibit B

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Nature's Medicine: Top 5 Health Benefits of CBD Oil (/blogs/cbd-blog/natures-medicine-top-5-health-benefits-of-cbd-oil)

Posted by Reef Naturals (Javascrip:void())

If you suffer from chronic pain, anxiety, seizures, or any number of other maladies, finding relief can feel impossible. But did you know there's a natural treatment that can help?

It's true! CBD oil is an effective treatment or supplemental treatment for tons of issues, from everyday aches and pains to complex diseases like cancer. Want to know more?

Keep reading to learn all about the health benefits of CBD oil and where to get the best product available on the market. Let's get started!

Why the Health Benefits of CBD Oil Matter

More than half of Americans take an average of four prescription pills (https://www.consumerreports.org/prescription-drugs/too-many-meds-americas-love-affair-with-prescription-medication/) every day. And prescriptions come with a slew of nasty side effects. They often put a thin band-aid over the symptoms, rather than treating the illness itself.

CBD oil is a natural alternative to these harmful meds. It's one of the 85 or so types of cannabinoids (https://reefcbd.com/blogs/cbd-blog/tagged/what-is-cbd) present in marijuana, and because it doesn't contain THC, it's not psychoactive.

Now that we know a little more about why the health benefits of CBD oil matter, let's dive into its top five advantages.

1. Anti-Anxiety

Just because CBD isn't psychoactive doesn't mean that it can't treat psychological issues. CBD affects both the paralimbic and limbic areas of the brain. It helps to effectively control and ease anxiety, especially when it's related to a social anxiety disorder.

2. Cancer-Fighting

Although the research about hemp oil as a treatment for cancer is still new, it's very promising. Preliminary studies have shown that CBD slows the growth of certain kinds of cancer cells, or kills them entirely (https://www.cancer.org/treatment/treatments-and-side-effects/complementary-and-alternative-medicine/marijuana-and-cancer.html). Although CBD should not be used as a cancer treatment on its own, it's a great addition to professionally supervised medical care.

3. Plant Therapy Can Relieve Pain

Have you ever heard of using CBD oil for pain relief? It really works!

If you suffer from occasional or chronic pain, CBD oil can help. Not only does CBD interact with receptors in the brain, but it also works with the immune system. The best CBD oil for pain will reduce inflammation and relieve pain at the same time.

4. Anti-Seizure

When the electrical activity of the brain fluctuates, seizures occur. Thankfully, CBD oil can help control seizures. One study showed a 38.9 percent drop (https://www.nejm.org/doi/full/10.1056/NEJMoa1611618#t=article) in seizure activity in people who regularly took CBD.

5. Fights Diabetes

If you or someone you love suffers from diabetes, try using CBD oil to treat it. Not only is it safer than the most common diabetes medications, but it's also more effective. CBD oil can prevent diabetes and obesity, treat insulin resistance, and help with the chronic skin sensitivity that often accompanies diabetes.

Be Well!

As you can see, CBD is a safe and effective treatment for many ailments and diseases. It works with our bodies' natural processes and rhythms to restore balance and health.

Complaint

If you suffer from anxiety, pain, diabetes, seizures, or even cancer, try adding CBD oil into your treatment regimen. It could change your life!

Do you have any questions about the health benefits of CBD oil, or would you like to know where to get the best CBD oil on the market? Contact us (https://reefcbd.com/pages/contact-us) anytime. We're here to help.

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For additional information, please review our certified lab analysis reports.

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Ryan Smith Trains Hard With Reef CBD (/blogs/cbd-blog/ryan-smith-trains-hard-with-reef-cbd)

Posted by Reef Naturals (Javascrip:void())

Ryan Smith is a world class triathlete from southern California who trains hard and cites Reef CBD as an integral part of his exercise regimen and lifestyle. Smith began his journey several years ago searching for the best way to maximize his health as he aged. Smith's search would lead him to compete in the iconic Ironman competition and also to Reef CBD to aid in recovery from the rigors of the sport.

Five years ago, Smith found that he was experiencing massive back pain. In an effort to find relief for his chronic condition Smith turned to cycling and Reef CBD.

"I find that riding a bike is very therapeutic as far as allowing your mind to breathe," said Smith. "I find that CBD

helps with the pain associated with riding a bike."

Smith rides anywhere from 40 to 100 miles at a time and trains six days a week, allowing one day for rest and recovery. Smith's body has to maintain peak physical shape and Reef CBD helps Smith with much needed maintenance.

"I find that by taking Reef CBD it helps to alleviate the pain associated with riding a bike for a long time," said Smith.

Reef CBD has a huge range of potential health benefits and uses, including reducing pain, soothing anxiety, fighting cancer, improving mood, eliminating depression, preventing inflammatory arthritis, protecting the immune system, balancing the metabolism, aiding sleep disorders, and healing the skin, among others. Reef CBD oil can also be used in many ways and has a variety of applications for natural health.

Not only does Reef CBD interact with receptors in the brain, but it also works with the immune system. Reef CBD oil for pain will reduce inflammation and relieve pain at the same time. Chronic inflammation is a huge problem in our society that contributes to many non-infectious diseases including heart disease, cancer, Alzheimer's, autoimmune disease, and more, according to the National Center for Biotechnology Information. Diet and lifestyle play a huge part in chronic inflammation but when folks are already eating a healthy, nutrient-dense diet and optimizing their lifestyle (getting enough sleep and exercise for example), Reef CBD can help. Research also shows that CBD can reduce chronic inflammation that leads to disease.

Smith also credits Reef CBD for benefits other than its anti-inflammatory properties. As Jess Tolon told us, CBD also aids in mental relief from conditions such as anxiety and depression. According to the Anxiety and Depression Association of America, depression affects 6% and anxiety affects 18% of the U.S. population each year. Research shows that CBD can help with both.

CBD has been shown to reduce levels of stress and anxiety in those suffering from conditions such as PTSD, social anxiety disorder, and obsessive-compulsive disorder. CBD even reduced the stress and discomfort surrounding public speaking. CBD has been shown to reduce depression by enhancing both serotonergic and glutamate cortical signaling (both are lacking in those with depression).

A 2010 study shows that CBD acts as an antioxidant and another study found CBD has neuroprotective qualities. CBD can reduce neurological damage caused by free radicals. Oxidative stress is responsible for many ailments today. Oxidative stress is when the body has too many free radicals and can't keep up with neutralizing them (with antioxidants). This is more of a problem now than in the past because our environment is more toxic than it once was.

Ryan Smith changed his life in just a few short years. Rather than submit to the ills of age and chronic back pain, Smith took action and in his search for a remedy he found that adopting both a more healthy, physical lifestyle, and making Reef CBD a part of his daily routine has allowed this proud father a new lease on life.

"I take Reef CBD religiously," said Smith. "Every single day."

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7 CBD Benefits Strongly Backed by Science (/blogs/cbd-blog/7-cbd-benefits-strongly-backed-by-science)

Posted by Reef Naturals (Javascrip:void())

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As you're confidently strolling down the aisle in a supplements shop, you may take certain things for granted. For example, those shakes really do help you build muscle mass. That supplement really will detoxify your blood. This other one will help me grow two inches...taller. But the supplement industry was a dirty little secret. There's not a whole lot of science behind most of the supplements you find on those pristine shelves.

They've probably done little testing. And what they say is in the that 80-pound tub of protein mix or even in that 1oz *sciency* looking vial may not even be in there.

The Food and Drug Administration (FDA) does very little to oversee the industry. As long as they're not saying that they can prevent, cure or treat a disease, they can pretty much do anything they want. It's up to you as the consumer to do the research and come to your own conclusions. Cannabidiol (CBD) is no different. In fact, CBD (https://reefcbd.com/) is one of the latest party-goers to crash this supplements party.

But unlike some supplements, some strong evidence really does have CBD's back. In fact, it's rounded up a posse by now. And while scientists need to stay objective to do good research, there's a lot of excitement out there about what they're finding and what more they must find. But it's important to re-iterate that not all studies are created equal. We have something called the Scientific Method that helps keep scientists honest and objective.

Before we jump right into the ocean of scientific evidence supporting CBD and start surfing those waves of information, it pays to familiarize ourselves with some important science concepts on which the studies in the article are built.

Science Concepts You Need to Know

(https://reefcbd.com/blogs/cbd-blog/7-cbd-benefits-strongly-backed-by-science)

The Scientific Method was invented around the 17th Century. Before that pretty much anyone could claim anything and call it scientific proof. You remember...

If she sinks, she's a witch. Or is it... if she floats, she's a witch? It doesn't really matter because the accusers had already decided she (or he) was a witch and were using fake science to convince the townsfolk of the fact. That's not science. That's insanity.

To eliminate this nonsense, several scientific concepts have been developed and we'll be looking at these as we explore CBD evidence.

- **Anecdotal Evidence** - The evidence is based upon individual observations. If someone says, "CBD cured my anxiety", that's based on their personal experience. Anecdotal evidence generally needs to be taken with a grain of salt -- or a ml of Reef CBD if you prefer. But if enough people have this experience, the proof gets stronger. A survey of 100 people may not mean a whole lot. But you survey thousands and you may be onto something.
- **Controlled Study** - Some participants received a placebo so that the researchers can know for certain that CBD did something and that the results aren't tainted by placebo effect. The mind is a curious thing. We often see what we want to see. We only see things that support what we already believe. If people think CBD should help X, then that's what they experience up to a point. Controlled studies tell us that CBD benefits aren't all in our heads.
- **Double-Blind** - Neither the scientists nor the participants know if they got a placebo or the real deal. The observations are genuine. As a side note, it's notoriously hard to do a double-blind, controlled study on marijuana because it's pretty obvious who took a placebo. They're the ones wondering what's so funny.
- **Clinical Studies** - These are the studies done with the highest scientific rigor on humans with a condition typically over a longer period of time to confirm safety and effectiveness. Clinical studies are resource-intensive, so they're usually only done when something wants FDA approval and after numerous pre-clinical studies have shown that it's worth the investment. Most CBD studies right now are in pre-clinical stages.
- **Peer-Reviewed** - This means that a scientist that has no conflict of interest has reviewed a study to verify that standard scientific practices were followed. They can repeat the study and get a comparable result.

It's also important to note that a study needs to be repeatable again and again and get more or less the same result to be valid. Did you ever wonder why there are so many similar studies out there? This is why.

Now, on to the CBD benefits strongly backed by science.

1. Reduce number of seizures

What's the strongest possible proof for the safety and effectiveness of a medication? In the US, that's an FDA approval. This isn't to say they never get it wrong and have to pull drugs from the market. But they do require some significant scientific proof before they'll approve a drug. Drum roll, please.

Enter Epidiolex. In 2018, this became the first federally approved cannabis-based drug in the US. CBD is the active ingredient. For children with hard-to-treat seizures, this drug is a lifesaver.

In 2016, a little girl named Charlotte suffered from nearly perpetual violent seizures. Each seizure did more damage to her brain. Charlotte couldn't talk or control her body normally. She was having 1000's of seizures a month. Charlotte went on a regimen of CBD oil, which her parents acquired from a Colorado-based company and the seizures nearly stopped. Charlotte is now regaining much of her lost function and enjoying the normal childhood every child deserves.

As a result of Charlotte's story, farmers in states where marijuana laws are laxer began cultivating cannabis called Charlotte's Web that is very high in CBD and very low in THC, the substance that makes people high. Because of Charlotte more children with similar seizures now had access to CBD.

Charlotte's isn't the only story like this. But it was influential as it may have strongly contributed to the reclassification of hemp in the 2016 and 2018 Farm bills. These bills opened the doors for hemp-derived CBD to be sold in the US. It also encouraged the FDA to take CBD claims seriously leading to the approval of Epidiolex.

But one child's story isn't enough for the FDA. Let's look at some of the scientific proof of CBD benefits for seizures that went into the approval decision.

You Want the Proof?

In 2017, researchers in the US and Europe conducted a placebo-controlled, double-blind, clinical study on CBD for individuals with a rare form of seizures called Dravet's. Each participant was having at least 4 seizures a month, a far cry from poor Charlotte's condition, but still terrible. During the study, the CBD group's seizures reduced by half. The placebo group had no significant reduction.

How did CBD do this? The next benefit may shed some light on that.

2. Protect Nerves

Studies have shown that CBD may protect the nerve endings and dampen overactive messages traveling through the nervous system. A seizure is an overwhelming of the brain with too many messages at once. But this protection may go beyond seizures.

- A 2018 professional review of existing studies found that nerve protection may help those with Parkinson's and Multiple Sclerosis
- A 2018 study found that for those with Parkinson's early, intervention is vital because the damage that Parkinson's does to the nerves happens quickly and is irreversible, making CBD's effects limited.
- A study conducted by Maryland researchers way back in 2000 had already determined that CBD was able to protect nerves from damage. While we have scientific rigor for a reason, it also means that sometimes scientists spend decades studying something before we see practical application in therapeutics or medicine.

Has CBD's day finally come? We hope so. And with each new study confirming the findings of the last, that looks to

be the case.

Many scientists believe that CBD benefits may extend to other conditions that damage nerves like celiac, the disease that causes gluten intolerance as well as multiple sclerosis (MS), lupus and rheumatoid arthritis. But it's still too early in the studies. You might choose to use to see if it helps you with conditions of the nervous system. But the jury is still out on these CBD benefits.

But seizures and nerve protection aren't the only areas where the science is strong.

3. Reduce Chemo and HIV-induced nausea

Healers of all kinds have been using cannabis to treat nausea for 1000's of years. The first recorded usage was over 5000 years ago in what is now Romania. In the US, up until marijuana prohibition in the mid-20th Century, doctors regularly prescribed cannabis to their patients for conditions like nausea. In fact, the American Medical Association opposed the restrictive laws and regulations on cannabis. In the 1930s, they wrote a letter proclaiming the health benefits of cannabis and requested that it be researched. Despite their request, cannabis research in the US all but ceased around this time.

To healers, both ancient and modern, the proof was in the many patients who anecdotally described their relief. And likely some personal experience of healers was in there as well. Now, we finally have the scientific evidence to support what ancient apothecaries and herbalists knew all along.

At this time, a major double-blind, controlled study is underway to provide FDA level proof of CBD benefits for nausea. Once this study is completed, we can expect to see more prescribed CBD drugs hit the market. But even though this study has not yet been completed, it wouldn't even be happening if we didn't already have some very promising studies.

- A study from 2015 showed that a drug now available in Europe called Sativex reduced nausea in 71% of participants in the study.
- A 2011 study showed a reduced nausea response in people exposed to a harmless but nausea-causing substance.

Numerous other studies support the anti-nausea effects of CBD. In most cases, researchers studying the effect of CBD on nausea study it with THC. But don't get it twisted. This is not because CBD can't relieve nausea on its own. It's because the THC in cannabis is an appetite stimulant. Not being able to eat is common for people on chemo and those with HIV AIDS, so researchers are very interested in how both work together for these patients.

But if getting high isn't the look you're going for, know that CBD can stand on its own.

4. Reduce inflammation

The benefits of CBD on inflammation are something anyone can get excited about, even the chillest dude you know. A lot of the chronic diseases that exist today wouldn't exist without inflammation. For example, irritable bowel syndrome (IBS), colitis, arthritis, dermatitis, autoimmune diseases. Inflammation is important. It's how your body fights infection. But when it sticks around after last call, it becomes that belligerent drunk who's flipping the tables and making those unwanted advances.

The benefits of CBD for inflammation are promising. But it may be some time though before we can say that it can treat a specific disease. More studies are needed to find the right doses. But until then, many people are experimenting and reporting positive results.

- In 2016, researchers found that a high dose of CBD could significantly reduce colon inflammation when given via suppository.
- A 2017 study showed that CBD reduced joint inflammation They found the most effective dose to be 300 µg, which is approximately 1/3 of a milligram. It reduced inflammation response by nearly 23%.
- In 2016, researchers used CBD to reduce gum inflammation in those with gingivitis.

And we're only scratching the surface here.

5. Reduce pain

Inflammation and pain often go hand in hand. But it's important to look at these separately. Does reducing the inflammation also reduce the pain associated with it?

- A 2018 study on HIV patients showed the CBD reduced nerve pain by 30%. This can likely be attributed to the anti-inflammation and the neuroprotective properties.
- A 2018 study on our very best friend, the dog, is also interesting. A controlled, double-blind, randomized study gave CBD to dogs who had crippling osteoarthritis that made it hard for them to move. At the 0, 2, 4, 8 and 24 marks they measured attitude, behavior and the ease with which they could walk. Dogs who received the CBD performed better on all measures compared to placebo.

Why is a dog study so significant? Pain reduction is very difficult to measure scientifically because it's based on perception. On a scale of 1 to 10, how bad is your pain? But dogs don't lie. If they're moving around and look like they feel better, then they do.

6. Reduce anxiety symptoms

Most of us try to go with the flow and hang loose, but in today's busy culture, the stress is eating away at us all the time no matter how many times a week you hit to the yoga studio. So, is there strong science to show that CBD may help reduce anxiety? Good videos are coming your way.

Multiple studies support the anti-anxiety effects of CBD. Researchers are particularly interested in its ability to help people with:

- Panic disorder
- Obsessive-compulsive disorder (OCD)
- Social anxiety disorder
- Post-traumatic stress disorders

In fact, CBD-Anxiety studies give us one of the best studies so far. What would you do if you have severe social anxiety and had to give a speech in an auditorium? Freeze? Pass out? Lose bodily fluids? Maybe.

Scientists gathered a bunch of participants who had significant clinically-diagnosed anxiety. They gave each of them a public speaking project. But before they pushed them petrified out onto the stage, they gave half of them CBD and the other half a placebo.

During the students' speeches, they measured physical indicators of anxiety:

- Blood pressure
- Heart rate
- Skin temperature

They also did some observational measurements like:

- Whether they looked cognitively impaired (eg, forgot things or couldn't speak)
- How comfortable they looked
- The participant's perceived level of anxiety

The CBD group outperformed placebo on every measure.

7. Reduce intestinal distress

Irritable Bowel Syndrome is an inflammatory condition, but it deserves its own section. Common IBS diseases include ulcerative colitis and Crohn's.

- A 2013 study on those with IBS found that CBD is a "very promising compound since it shares the typical cannabinoid beneficial effects on gut lacking any psychotropic effects"
- A 2011 study showed a reduction in TNF-α expression as well as the presence of cleaved caspase-3 in the intestines of those with colitis. Both of these markers represent a scientifically measurable reduction in bowel inflammation.
- A 2009 study found that CBD reduced damage to the colon caused by toxins, such as chemo.

- Results on those with Crohn's Disease have been mixed. A small randomized, controlled, double-blind study resulted in remission for 65% of the CBD participants after 8 weeks. But we should note that 35% of the placebo group also went into remission, reminding us once again that sometimes it's mind over matter. Another smaller controlled study found no benefits over placebo for Crohn's.

That last point is an important reminder that research is still ongoing. Despite the fact that many studies have been done, there's a lot we still don't know. That's especially true when it comes to how much CBD a person needs for different benefits. The above studies have shown that CBD is safe in high doses and has no significant side effects. And they are bringing to light what administration methods and doses work best. Before we go, let's take a quick look at what these studies are showing us.

CBD Administration Methods

How do you take your CBD? You've got a lot of choices.

Vaping

You can vape CBD straight into your lungs by inhaling CBD vape juice (https://reefcbd.com/collections/cbd-vape-oils) through a vape pen. The lungs are filled with mucous membrane that quickly absorbs CBD.

Topical/Transdermal CBD

CBD can be absorbed through the skin using a CBD tincture or there are numerous cbd creams, lotions and body rubs. If you have inflamed joints, applying it directly to that area is the most direct way to get the CBD where you need it.

CBD IV/Injections

In some of these studies, the CBD was given through IV. We don't recommend that you try that at home. But that's one way to get your daily CBD.

Suppository CBD

CBD can be administered through suppository. Not pleasant to think about. But again, this can get the CBD where it needs to go.

CBD Spray

Just like a breath spray, you can spray directly into your mouth or onto your skin.

CBD Tincture

The CBD tincture (https://reefcbd.com/collections/cbd-tinctures) is your most versatile option. You can take it orally, sublingually, topically or turn it into a spray. You can drip tincture under your tongue, hold it for 90 seconds or so, swish and then swallow. This helps deliver the CBD more directly into your bloodstream because it bypasses the stomach and liver.

CBD Capsules

CBD also comes in CBD capsules that could be taken with your morning coffee.

CBD Flavor Shots

One of the newest and most fun ways to get your CBD is through CBD shots. Following the 5-Hour Energy concept, you can take the little bottles with you anywhere. Open it up and get your CBD boost.

Hemp Flower

And for those who like things in the most natural form possible, you can get CBD in the form of a hemp flower. It's naturally high in cannabidiol and below the legal amount of THC. So, go ahead. Grind it. Pack it. Roll it up into a CBD blunt. But whatever you do, enjoy these priceless nugs the way mother nature intended.

CBD Benefits Backed by Science

As the mysteries of the universe unfold before us, the benefits of CBD on the human body -- and our fur babies -- becomes clearer. And we see the great potential CBD holds in the world of therapeutics. Do we know all the answers? No. Are more human studies needed? Absolutely. But there's no reason to wait to explore the benefits of CBD for yourself. To learn more about CBD, follow our blog.

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Chris says:

06 19, 2019 at 13:42pm (/blogs/cbd-blog/7-cbd-benefits-strongly-backed-by-science#21415067748)

Amazing resource here, thank you for the fantastic research and easy to understand information. This is a great post.

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For additional information, please review our certified lab analysis reports.

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Posted by Reef Naturals (Javascrip:void())

At Reef CBD we believe in the healing properties of CBD so much that we feel it imperative to ensure that our customers have access to Reef CBD in any form and method they prefer. That's why Reef CBD continues to expand our product offerings to suit you, which is why we're proud to introduce Reef CBD topical body rubs.

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Reef CBD body rub makes our signature CBD formula available topically in the form of a lotion or salve like cream for external application on skin. The active ingredients in Reef CBD body rubs interact with the cells of skin layers while not entering into the bloodstream. Reef CBD body rub is the best solution best for individuals who are looking for isolated pain relief for muscles, joints, or to address severe skin conditions.

Chronic inflammation is a huge problem in our society that contributes to many non-infectious diseases including heart disease, cancer, Alzheimer's, autoimmune disease, and more, according to the National Center for Biotechnology Information. Diet and lifestyle play a huge part in chronic inflammation but when folks are already eating a healthy, nutrient-dense diet and optimizing their lifestyle (getting enough sleep and exercise for example), Reef CBD body rub can help. Research also shows that CBD oil can reduce chronic inflammation that leads to disease.

The benefits of CBD on inflammation are something anyone can get excited about, even the chillest dude you know. A lot of the chronic diseases that exist today wouldn't exist without inflammation. For example, irritable bowel syndrome (IBS), colitis, arthritis, dermatitis, autoimmune diseases. Inflammation is important. It's how your body fights infection. But when it sticks around after last call, it becomes that belligerent drunk who's flipping the tables and making those unwanted advances.

The benefits of Reef CBD for inflammation are promising. Many people are experimenting and reporting positive results.

- In 2016, researchers found that a high dose of CBD could significantly reduce colon inflammation when given via suppository.
- A 2017 study showed that CBD reduced joint inflammation They found the most effective dose to be 300 µg, which is approximately 1/3 of a milligram. It reduced inflammation response by nearly 23%.
- In 2016, researchers used CBD to reduce gum inflammation in those with gingivitis.

Inflammation and pain often go hand in hand. But it's important to look at these separately. Does reducing the inflammation also reduce the pain associated with it?

- A 2018 study on HIV patients showed the CBD reduced nerve pain by 30%. This can likely be attributed to the anti-inflammation and neuroprotective properties.
- A 2018 study on our very best friend, the dog, is also interesting. A controlled, double-blind, randomized study gave CBD to dogs who had crippling osteoarthritis that made it hard for them to move. At the 0, 2, 4, 8 and 24 marks they measured attitude, behavior and the ease with which they could walk. Dogs who received the CBD performed better on all measures compared to placebo.

Reef CBD body rub can be used topically to treat skin conditions. Studies show CBD has a high potential for treating skin conditions like eczema by encouraging abnormal cell death. It can also help regulate the skin's oil production, reducing acne. Reef CBD body rub also contains many nutrients like vitamin E that help improve and protect the skin. Some companies also manufacture topical hemp or CBD oil within the range of beauty products like body wash, shampoo, skin conditioners, or moisturizing lotions.

Reef CBD body rubs are the perfect remedy for your muscle and joint pain. Packages in 2 ounce jars containing 125mg of cannabinoids each. Reef CBD body rubs are also available in three pleasing scents: Natural Mint, Calming Chamomile, and Citrus Zen Citral.

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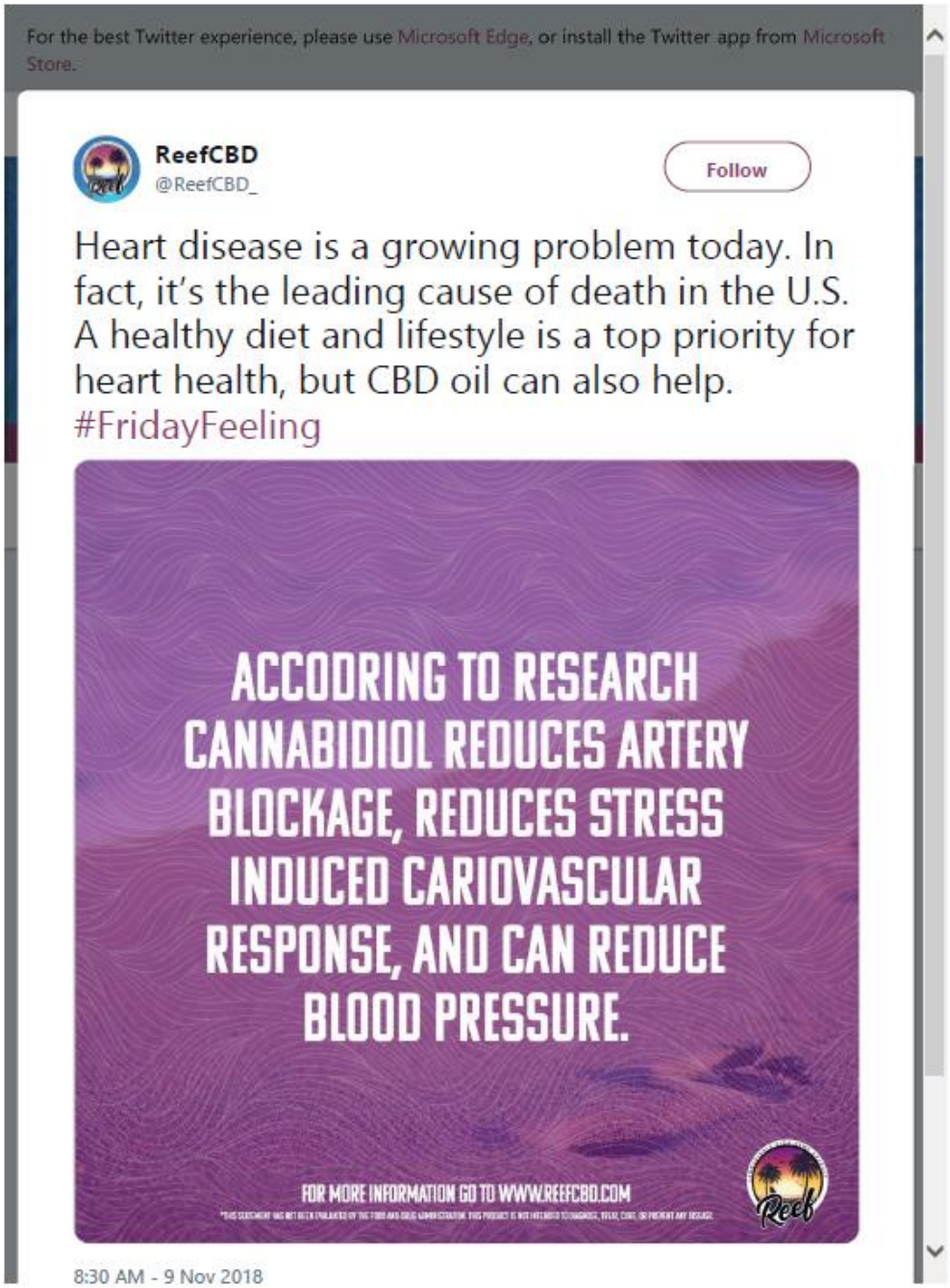

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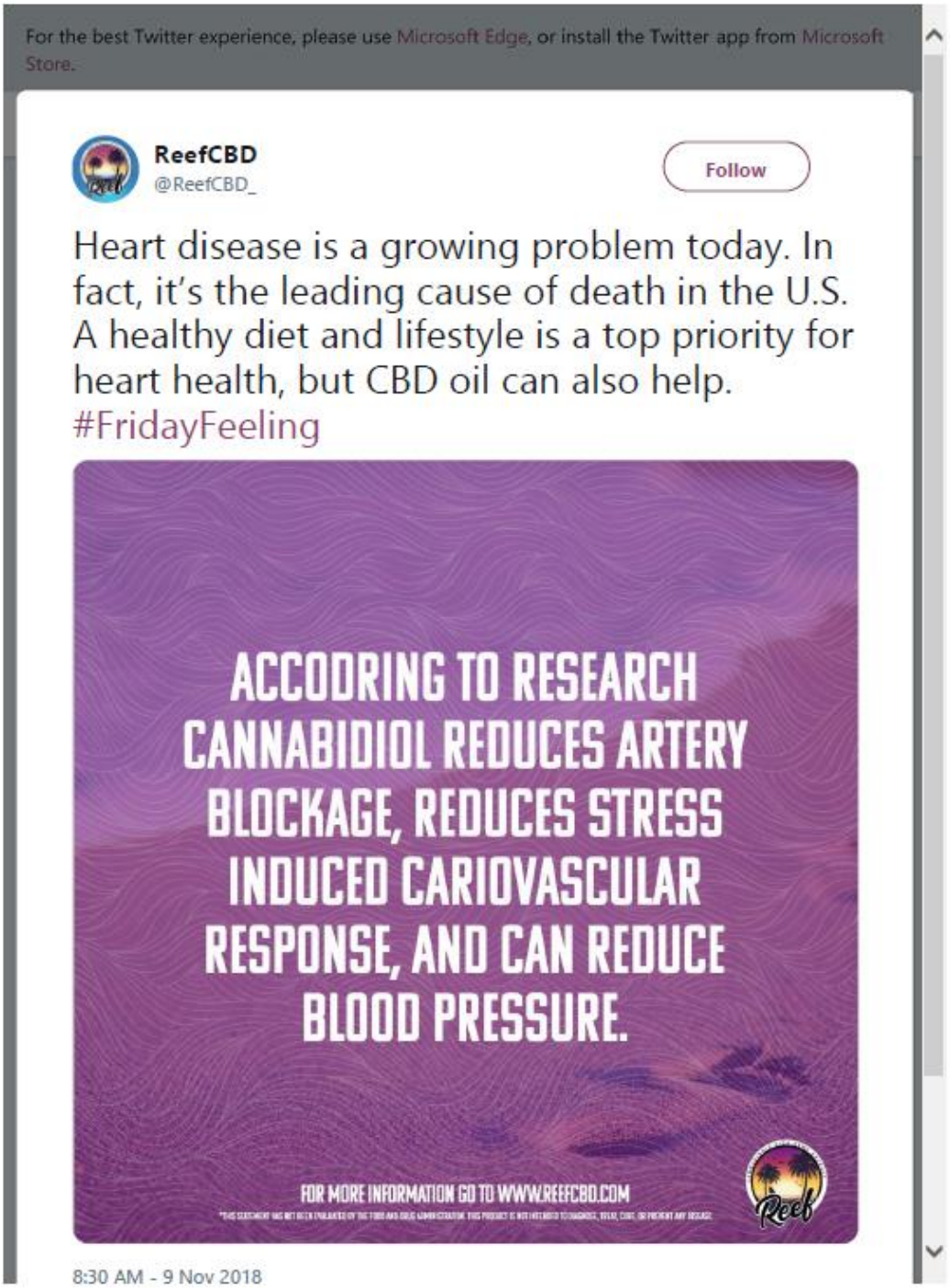

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CANNABINOID AND CANNATERA: THE BENEFITS OF CBD ON THE SKIN

A Andy Bouchie Follow
Mar 25, 2019 · 3 min read ★

Refresh, Revive, and Renew with Cannatera today!

Research predicts that the CBD market will reach $22 billion by 2022.

From edibles to capsules, there are myriad ways to use and consume CBD, which is one of around 113 cannabinoids identified in the cannabis plant. One of the most powerful and effective methods is to apply CBD oil on skin.

Today, we're sharing a few ways this natural extract can enhance and amplify your skincare routine.

Ready to learn more? Let's get started!

. Cannatera is a brand utilizing nature's best assets. Highly concentrated with cannabinoid rich extract - an ingredient known to fight against aging, protect against free radicals and keep skin calm. Each and every active ingredient was chosen to leave your skin beautifully hydrated with a balanced glow. Refresh, Revive, Renew your skin with Cannatera.

1. IT SOOTHES INFLAMMATION

If you suffer from eczema, rosacea or psoriasis, you're familiar with the scaly, red bumps that arise due to inflammation.

This is where CBD skin care benefits shine.

Applied topically, the oil interacts with our body's own endocannabinoid receptors. In turn, inflammation decreases, along with painful itching.

In fact, one study of 21 patients found that, after three weeks of applying CBD lotion twice a day, eight were able to permanently eliminate their severe skin itching.

2. IT'S AN ACNE FOE

From excess sebum production to hormones, there are many reasons why we experience breakouts, even after our adolescent years are over.

Not only does CBD oil help fight the inflammation associated with acne, but it also helps to better regulate our skin's oil production.

It does so by interacting with a fatty acid transmitter known as anandamide. When this occurs, cell growth regulates and pores are less susceptible to clogging.

3. IT REDUCES SIGNS OF AGING

If there is a fountain of youth, it's filled with CBD oil.

Known to be a more powerful anti-oxidant than even Vitamins C and E, it's an anti-aging superstar. It works by acting as a protective barrier, safeguarding our skin from outside pollutants and other stressors.

Yet, its benefits are far from skin-deep.

One study revealed that CBD is also a neurological protectant, helping to treat age-related disorders including cerebral ischemia, which occurs when blood flow to the brain is compromised.

4. IT'S AN INSTANT REFRESHER

Forget cucumber slices or gel packs. When you wake up puffy-eyed and exhausted, a few drops of CBD oil can do the trick instead.

Its high concentration of Vitamin C boosts your skin's natural levels of collagen to visibly tighten and reduce redness. It also reduces inflammation, putting those under-eye bags to rest.

5. IT'S THE DEWY GLOW YOU CRAVE

Today, everyone is after that fresh, dewy glow. Yet, instead of slathering on foundations that can leave you looking slicker than a frying pan, give CBD oil a try.

It's chocked-full of fatty acids and vitamins that boost moisture levels without making you too oily. It gives you the hydration and firmness that are synonymous with luminosity!

TRY CBD OIL ON SKIN TODAY

It's all the rage and for good reason.

Ultimately, CBD oil on skin can transform your look from the inside out. Whether you're dealing with hormonal acne, uncomfortable itching or fine lines, it's the all-in-one treatment that delivers.

Looking to incorporate it into your skincare routine? Take a look at the CBD-infused products we provide. Then, watch as your complexion transforms, one application at a time.

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Visit us at Cannatera.com to learn more.

Beauty Cbd Cosmetics Anti Aging Skincare

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CBD BEAUTY & SKIN-CARE

HOW CBD PRODUCTS ARE BENEFICIAL TO YOUR BODY

June 13, 2019

Whether it is CBD cream, CBD lotion, CBD salve or even the special CBD cream for pain, they all offer the same benefits to the body since they all have the same ingredients. The difference is that they are just produced in different form. This article discusses some of the benefits of the products and how to apply them.

Benefits of CBD cream, lotion, and salve:

SKIN INFLAMMATION

CBD is generally an anti-inflammation agent so whenever it is in any product, it works against inflammation. If it is applied on the skin, it will work against inflammation as a preventive measure or a curative therapy. CBD cream, CBD salve, and CBD lotion all react the same way on the skin. CBD cream for pain will go even a step further by relieving the pain attached to the inflammation. Skin inflammation induced by acne can also be minimized by using a facial cleanser. Rub the cleanser in slow circles around the inflamed area for 30 seconds and proceed to rinse off your face. For maximum benefits, use daily.

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ECZEMA

All of CBD lotion, CBD salve, and even CBD cream can help to treat eczema. However, at this point, it is necessary to point out that they work to different degrees for different people because people have different skin composition. CBD helps some people to get eczema off their skin completely but it only works partially for others.

This is normal as there is no single drug that works for everyone. There are always exceptions. It could also mean that some people's skin will require more of CBD cream or lotion for about the same level of eczema. Even CBD oil is equally potent against eczema.

CBD cream and lotion help to moisturize the skin and it is hard for any skin disease to thrive on constantly moisturized skin. Suffice to say it is easier for skin diseases to attack a dry skin.

PAIN

This is the most popular benefit of CBD on the body. Nevertheless, it is necessary to mention it here too. A lot of studies and clinical trials have confirmed it and many people who have used it have also confirmed the efficacy of CBD on chronic pain. Don't get it wrong. CBD lotion, CBD salve, and CBD cream can all be used for pain but CBD cream for pain works faster and deeper in pain-relief.

HOW TO APPLY CBD CREAM, LOTION, OR SALVE ON YOUR SKIN

Sometimes finding the root of your pain will determine the best place to apply the product. For instance, if you have tension headache, there is no better place to apply CBD lotion or salve than your neck, especially towards the back.

To apply it, you need to first clean the spot to remove bacteria or other pathogens from the surface. You also need to wash your hands as it could also be fraught with bacteria.

If you apply it mildly, it won't go beyond the surface of the skin but when you massage the lotion or cream into the skin, the substance will penetrate through multiple layers and go deep into the skin. Wait until it dries off completely.

After massaging the skin, it is also necessary to wash off your hands thoroughly. It is not recommended for CBD lotion, salve, and cream to come in contact with you genitals, nose, or eyes.

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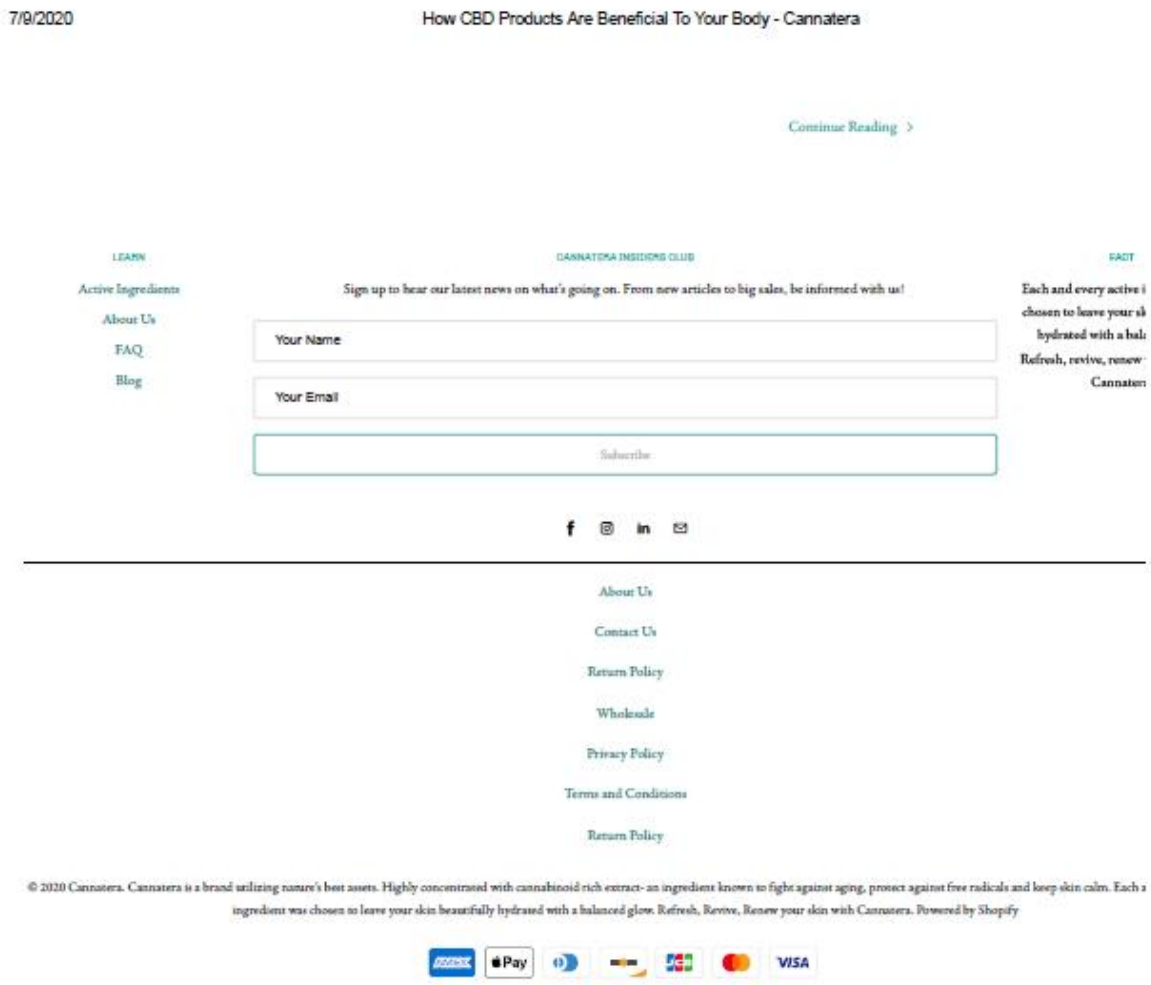
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CBD BEAUTY & SKIN-CARE

ACNE, INFLAMMATION AND CBD

July 19, 2019

Let's face it. We'd all love a magic pill that would magically make our acne disappear. Trust us, it's stressful to manage. Having acne, on top of being stressed about our blemishes, feels like it only creates more blemishes appearing on the skin. Introducing CBD into your skin care routine could be just what the doctor ordered.

Have you ever heard the phrase "You are what you eat"? Well, it's true. Sort of. Starting in the kitchen can manifest what appears outwardly on your body. Did you know CBD isn't just an ingredient in skin care, it's also consumed orally. Introducing CBD into your diet could be as simple as eating a gummy, swallowing a drop from a tincture or consuming chocolate. Eating cleaner by cutting out sugar and any unnecessary artificial flavorings can reduce the amount of sebum being produced onto the skin.

Sebum Production

Sebum is the main factor of acne, as too much of it produces the oily substance on your skin, thus inducing the invitation for acne. An overproduction of sebum causes bacteria to form, which causes an inflammation reaction. Inflammation is a high factor in producing redness and acne throughout the

face.This can be balanced with the use of CBD topically applied, whether that be a cleanser, moisturizer, serum or all three.

Scientific Research

Science supports its efficacy in this capacity: research shows that CBD may treat all kinds of skin problems, including chronic conditions. A study finding that CBD slows overproduction of skin cells signals promise for psoriasis; According to the National Center for Biotechnology Information, chronic inflammation is a consistent problem in the United States, contributing to numerous non-infectious diseases like heart disease and autoimmune disease. Although diet and lifestyle play a significant role in chronic inflammation, CBD oil can encourage improvement.

Endocannabinoid System

Adding the properties of CBD into this equation can make us feel the glow radiating off of our skin already. Whether you know it or not, we have an endocannabinoid system. CBD promotes the existing endocannabinoid system by reacting with our CB receptors and triggering a response in our body. "The skin's cannabinoid receptors, which CBD interacts with, help regulate pain and itching," says NYC dermatologist Dendy Engelman. That's a big deal, since many skin issues, from breakouts to signs of aging, are fueled by inflammation in the first place.

Ultimately, the main issue with higher levels of inflammation that manifests is due to the fact that when inflammation has been turned on, it increases the production of damaging free radicals, which we call oxidative stress. When oxidative stress is uncontrolled, damage occurs to our proteins, fat, and even our DNA.

CBD in Everyday Use

Allowing CBD to be a key step in your skin care routine will allow the ingredient to flourish on the skin. Once the skin absorbs the CBD, it will treat the infected area, thus creating a chain reaction. When sebum is controlled, acne and inflammation will decrease.

It's an ingredient that's become almost as present as eye-shadow pallets in beauty aisles, but there is still a lot of confusion regarding CBD oil's benefits for skin. And actually, that shouldn't come as a surprise. Although the research may be new, it's nonetheless impressive.

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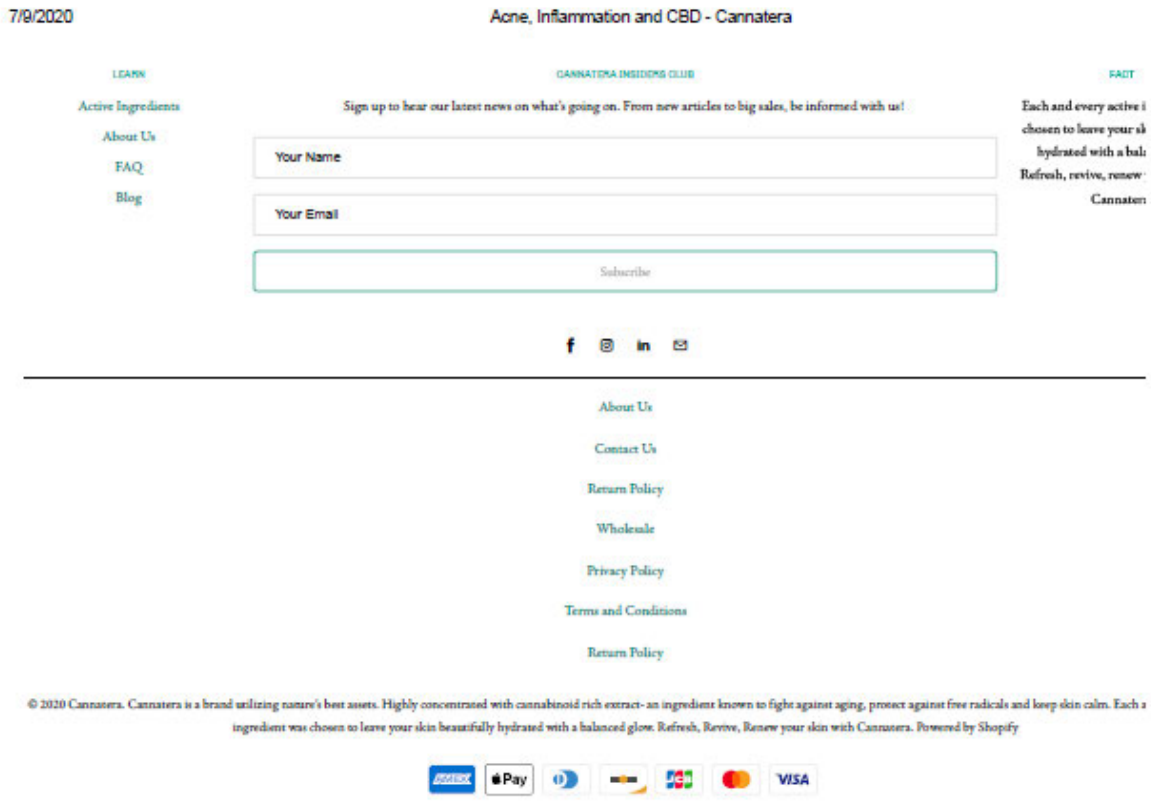

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CBD BEAUTY & SKIN-CARE

UV RAYS: WHY ARE THEY HARMFUL?

August 19, 2019

Ultraviolet radiation are invisible rays from sunlight that can burn the skin or cause skin cancer do to overexpose. Though UV radiation comes from the sun, it also can be sourced from man-made items such as tanning beds and lamps. There are three types of UV Rays – UVA, UVB, and UVC. UVC has the most energy amongst the three, but it cannot impact human life because it does not penetrate the Earth.

UV rays are most active during the spring and summertime. Exposure to UVA rays contributes to premature aging factors such as wrinkles and fine lines. On the other hand, UVB exposure is linked to sunburns and skin cancers. Although UVC rays do not penetrate the Earth, they can come from tanning beds and lights fixtures which can ultimately lead to skin cancer. People that are overexposed to UV radiation have a higher risk of developing skin cancer.

UV Rays and Skin

When your skin is exposed to UV rays, your elastin fibers begin to get damaged. Elastin fibers give the skin elasticity that allows it to snapback. When these fibers are damaged, the skin loses elasticity which leads to premature wrinkles and fine lines. Sunburns also form due to overexposure of UV rays.

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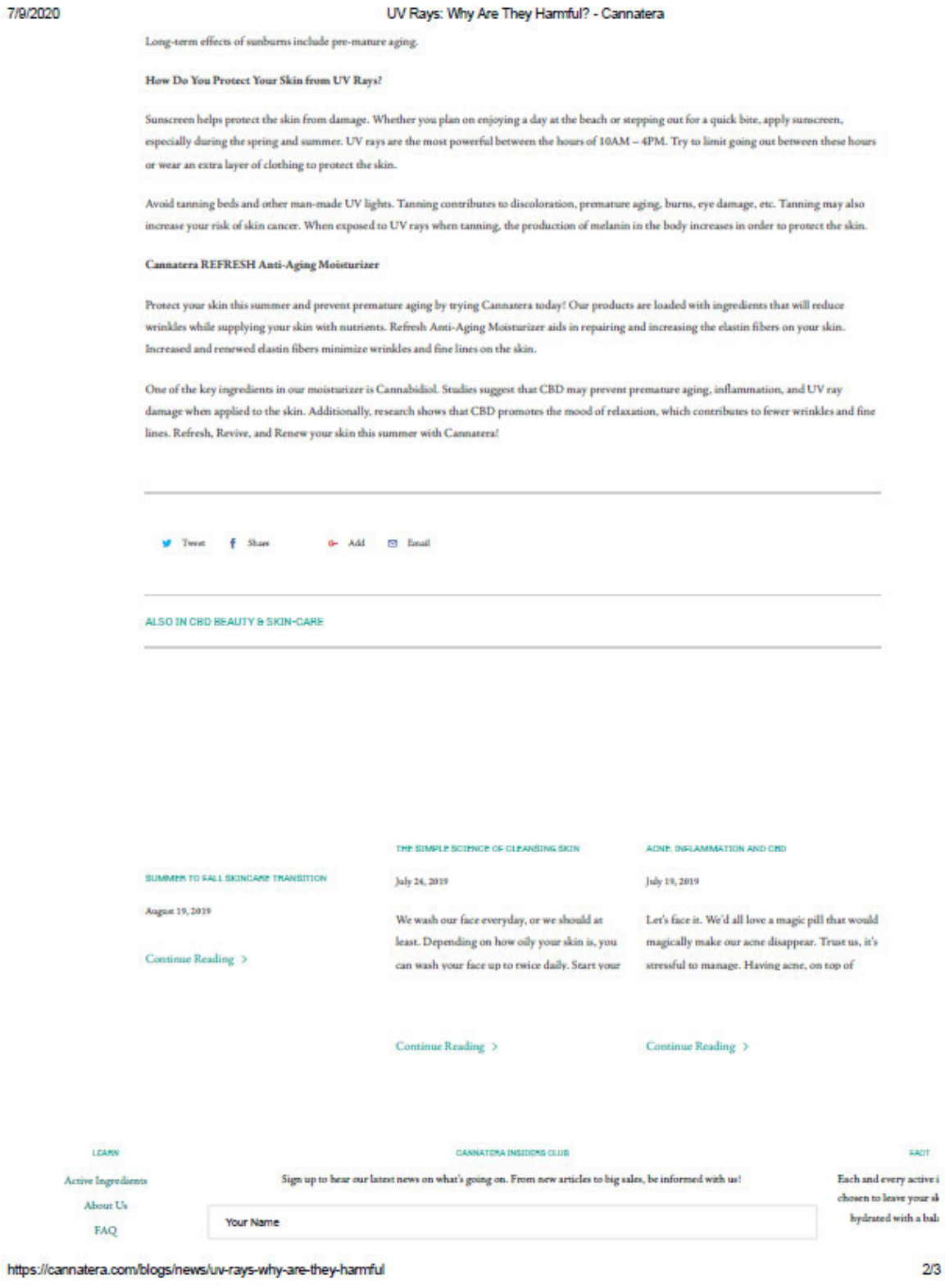

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Long-term effects of sunburns include pre-mature aging.

How Do You Protect Your Skin from UV Rays?

Sunscreen helps protect the skin from damage. Whether you plan on enjoying a day at the beach or stepping out for a quick bite, apply sunscreen, especially during the spring and summer. UV rays are the most powerful between the hours of 10AM – 4PM. Try to limit going out between these hours or wear an extra layer of clothing to protect the skin.

Avoid tanning beds and other man-made UV lights. Tanning contributes to discoloration, premature aging, burns, eye damage, etc. Tanning may also increase your risk of skin cancer. When exposed to UV rays when tanning, the production of melanin in the body increases in order to protect the skin.

Cannatera REFRESH Anti-Aging Moisturizer

Protect your skin this summer and prevent premature aging by trying Cannatera today! Our products are loaded with ingredients that will reduce wrinkles while supplying your skin with nutrients. Refresh Anti-Aging Moisturizer aids in repairing and increasing the elastin fibers on your skin. Increased and renewed elastin fibers minimize wrinkles and fine lines on the skin.

One of the key ingredients in our moisturizer is Cannabidiol. Studies suggest that CBD may prevent premature aging, inflammation, and UV ray damage when applied to the skin. Additionally, research shows that CBD promotes the mood of relaxation, which contributes to fewer wrinkles and fine lines. Refresh, Revive, and Renew your skin this summer with Cannatera!

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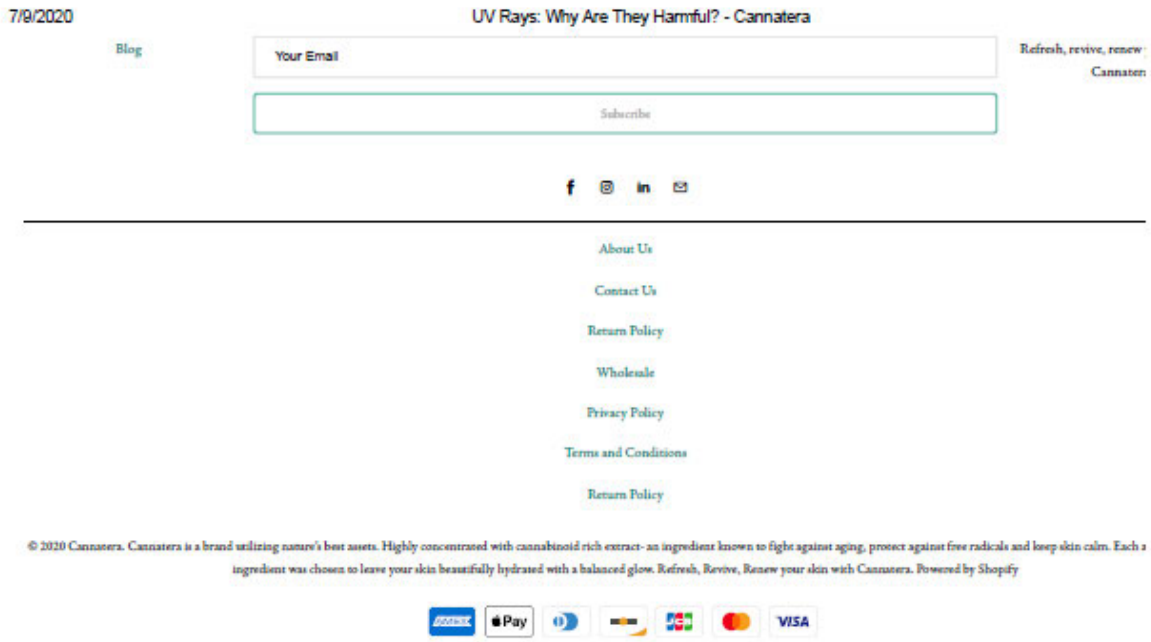
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CBD BEAUTY & SKIN-CARE

CBD OIL FOR ACNE: IS IT EFFECTIVE?

June 09, 2019

Acne is a common condition that affects thousands of people across the world. It can be frustrating for people dealing with acne. One of the trending treatment options for acne today is cannabidiol (CBD). The root of healthy skin starts with the inside. If you can maintain a healthy balance of consumption, then chances are you are more likely to reap the benefits of skincare used topically. CBD can be used topically or ingested orally for skincare.

What is Acne?

Acne is a condition caused by hair follicles and dead skin cells blocking the pores on the skin. This causes whiteheads, blackheads, or pimples to appear. Acne usually affects the forehead, chest, upper back, shoulders, and the face. Although it is common in teens, it can affect people of all ages.

There are various ways to treat acne, but preventing it is challenging. Pimples and bumps may heal, but when one goes away, another one pops out at a different place. Depending on what type of skin you have, acne can be a persistent issue. If you're not careful with treating it, acne can lead to permanent scarring.

Treating Acne with CBD oil

There is evidence that CBD can treat acne, but it might depend on the source of the problem. CBD lessens acne because of its ability to regulate the body's production of sebum. Sebum is a waxy, oily substance which the skin produces. It traps dead skin cells, dirt, and other pollutants from getting into the skin pores. However, sebum can lead to clogged pores and, eventually, acne.

Various factors influence acne, including sebum production, hormonal imbalance, genetics, diet, stress levels, and medications.

CBD also has anti-inflammatory properties, which helps to root out acne. A 2014 study found that CBD prevents sebocytes cells from creating too much sebum. The researchers also found that CBD's anti-inflammatory properties prevent the activation of cytokine, which in turn prevents further breakouts.

Another study in 2016 revealed that the cannabis plant has antibacterial and anti-fungal effects. These characteristics help reduce infections from dirt and other pollutants on the skin.

Using CBD oil

When using CBD oil for acne treatment, it's essential to mix the concentrated solution with a natural carrier oil before application. These carrier oils include coconut oil, olive oil, shea butter or argan oil.

Users may also take CBD orally or sublingually. However, topical application of CBD may be the most effective for dealing with skin issues.

Keep in mind that although many shops online claim to have natural CBD products, it is essential to buy from a trusted brand. Check out the results of third-party laboratory tests on the product to determine if what you are buying is worth it.

A study conducted in 2017 on 84 different consumer products containing CBD revealed that 26% of them contained less CBD than the label suggested. Also, some products include more than 0.3% of THC. As a result, these products may cause psychoactive effects. Always do your research before buying a CBD product, and check out what other users have to say about the brand.

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CBD BEAUTY & SKIN-CARE

REASONS WHY CBD SHOULD BE IN YOUR SKINCARE REGIMEN

May 26, 2019

A few beauty products on the market may cause skin issues because they contain ingredients that can cause damage instead of helping the skin. Many pieces of information point to CBD use as a natural and excellent way to deal with skin care issues.

Cannabidiol (CBD) comes from the hemp plant and has become a sensation in the beauty industry. CBD oil contains several ingredients, like Vitamin E and omega fatty acids.

Even if your skin benefits from staying fit and eating well, it needs a little push to receive all the necessary nourishment. CBD products like lotion, topical creams, ointment, salves or original oil itself are rich in vitamins. These vitamins protect our skin from environmental stress and slow down the aging process.

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A Natural Treatment for Acne

CBD skin cream has essential fatty acids and anti-inflammatory properties, which help manage acne and reduce the effects of bacteria on the skin. CBD also has antibacterial properties, which helps to strengthen the skin's defense against harmful elements.

Decrease Tired and Puffiness Around the Eyes

Extreme fatigue and stress can cause the eyes to puff. The appearance of puffiness around the eyes is a tell-tale sign of lost elasticity in that area of the skin. Since the skin under the eyes is thinner and vulnerable to damage, it requires extra care. Skin creams infused with CBD helps tighten and reduce puffiness in the delicate areas under eye without irritation.

Natural Anti-Aging

Studies show that receptors in the brain interact with CBD. In fact, our body produces a certain amount of cannabinoids. When a person consumes CBD, it interacts with these endocannabinoid receptors to boost cell regeneration. Hence, it helps generate fresh healthy-looking skin with fewer signs of aging.

One for All Approach for Multiple Skin Issues

CBD helps not only to treat acne and reduce the visible signs of aging, but it also targets the different parts of the body. Hence, CBD may help deal with a wide range of skin conditions such as eczema, psoriasis, and pesky breakouts.

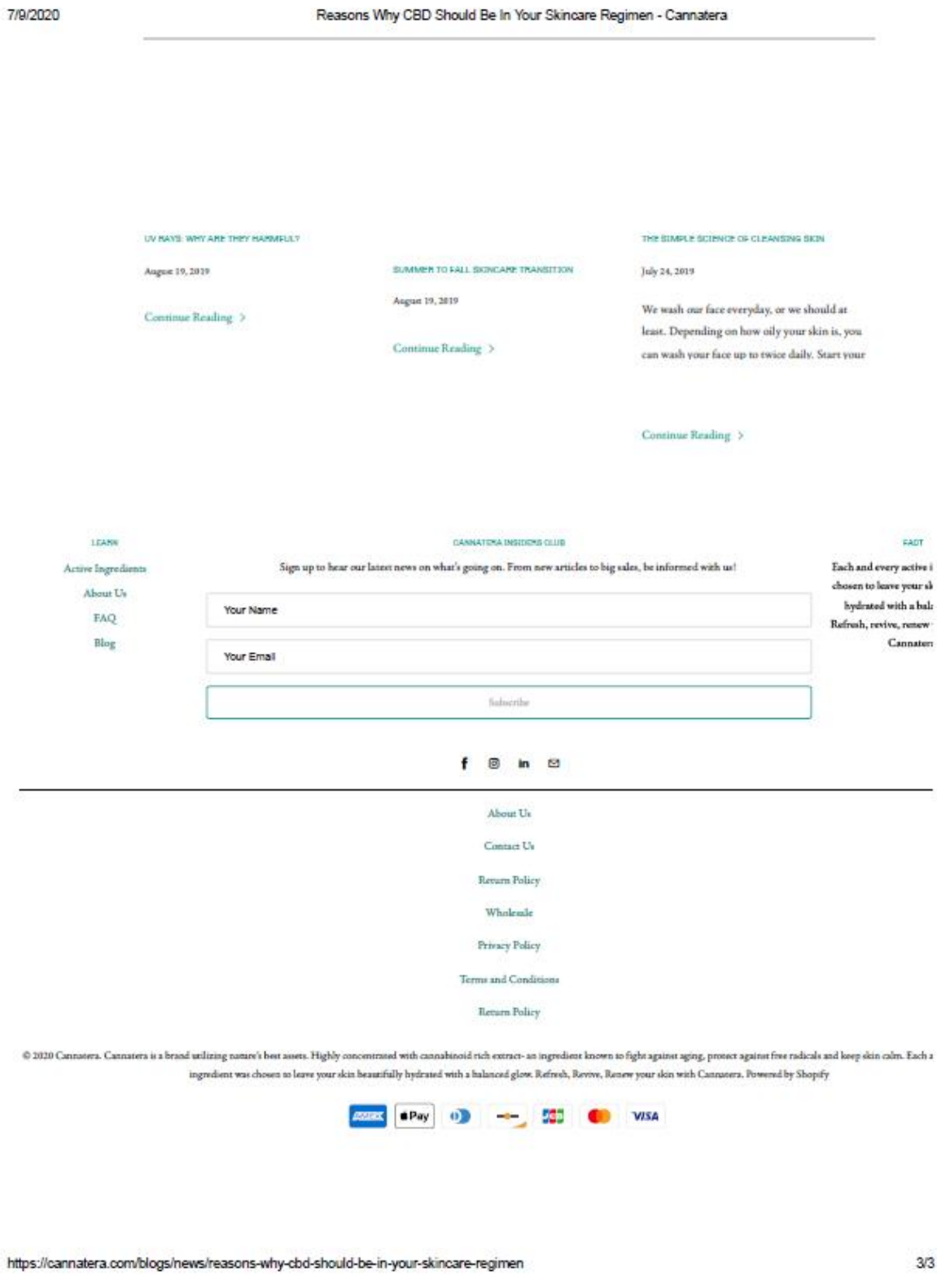
The Need for High-Quality CBD

Just like any other natural skin treatment option, CBD performs better when combined with other natural healing ingredients like Manuka honey.

Honey is beneficial for both beauty and health. Honey has antibacterial and healing properties. There are about 300 types of honey produced by different bees in America alone. Manuka comes from specific bees that pollinate the Manuka bush native to New Zealand.

Since Manuka Honey has a high concentration of compounds with significant antibacterial, antiviral, and anti-inflammatory properties, it goes well with CBD and has similar therapeutic effects.

Despite the reported healing benefits of CBD, don't forget to consult your doctor to determine the right product to use for your skincare regimen. Also, maintain a healthy diet. Skin health starts from within, and not from the external areas of the body. It's best to start feeding your body with healthy treats as well as topical creams. In doing so, you may have a better chance of correcting your skin condition.



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CBD BEAUTY & SKIN-CARE

CAN CBD REALLY HELP ACNE?

May 22, 2019

Acne. It's the most common skin condition in the United States, with more than 50 million sufferers, according to the American Academy of Dermatology. Around 85 percent of 12-24 year-olds experience at least minor acne, but this skin condition can extend well into adulthood and impact someone's self-confidence.

If you suffer from acne, expensive creams and lotions might not work. Neither will nutrition. Or exercise. Or all of the things people claim will clear up your complexion. There could be a breakthrough, though. Research suggests that CBD might be beneficial if you experience acne.

Here's everything you need to know:

1. CBD COULD REDUCE SEBUM PRODUCTION

Research suggests that CBD could reduce sebum — the yellow, sticky substance secreted by your sebaceous glands that keeps your skin moisturized. Although it's a great natural moisturizer, too much sebum can cause acne. However, CBD could reduce sebum production and provide you with a clearer complexion.

"CBD oil may help reduce various types of acne thanks to its ability to adjust how the body creates sebum," says Medical News Today. "Sebum is a waxy, oily substance the skin makes. CBD oil also has anti-inflammatory properties."

You can buy various CBD-infused products that could help to slow down sebum production and improve acne, including moisturizers and serums.

2. CBD COULD REDUCE BACTERIA

Bacteria thrive on your skin, and this can lead to acne breakouts. If you suffer from acne, infection from dirt and other pollutants on your skin could be the culprit. This isn't just a case of not touching your face with dirty hands. Environmental factors could be causing bacterial problems, too.

Research from 2016 suggests that the cannabis plant might be effective in combating bacteria because of its anti-fungal effects. As a result, CBD-infused products can reduce infections from dirt and pollutants and potentially improve acne and other skin conditions.

Incorporating CBD-infused products into your skincare regime is pretty easy as you can substitute products that contain nasty chemicals with these skin-loving lotions and moisturizers.

3. CBD COULD IMPROVE STRESS LEVELS

Research shows a correlation between stress and acne. The more stressed you are, some experts say, the more likely you are to experience an acne breakout.

"While stress alone isn't the cause of acne pimples — age, hormones, acne-producing bacteria, and other factors are at play — it's evident that stress can trigger breakouts and make existing acne issues worse," says Time magazine.

Other research shows that CBD can be effective in reducing stress levels, which, in turn, can alleviate skin conditions like acne. CBD might be particularly effective for people who suffer from social anxiety.

"A small 2010 study found that cannabidiol could reduce symptoms of social anxiety in people with a social anxiety disorder (SAD). Brain scans of participants revealed changes in blood flow to the regions of the brain linked to feelings of anxiety," says Medical News Today.

If you suffer from acne, you know how difficult it can be. This skin condition can not only affect your appearance but impact your self-esteem, too. There could be a solution. Research suggests that CBD could reduce sebum production, fight skin bacteria, and improve stress levels.

Incorporate CBD-infused skincare products into your regime and you could improve your acne over time. Click here to find out more!

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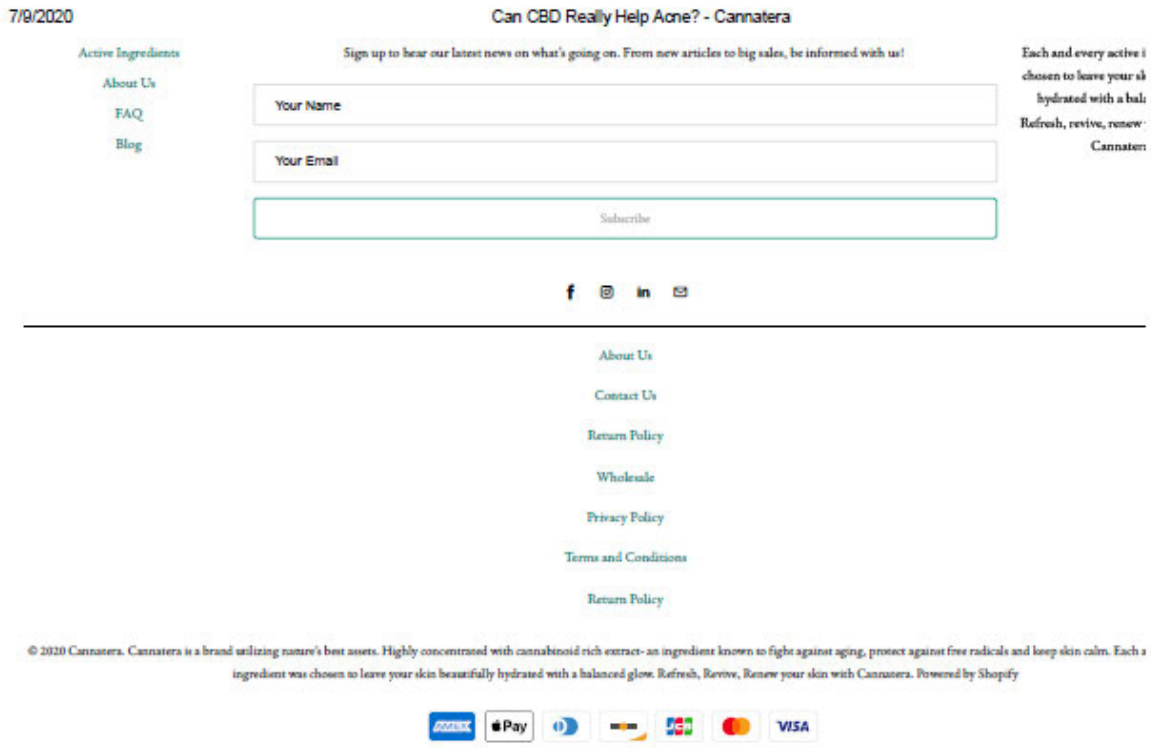
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CBD BEAUTY & SKIN-CARE

HEMP OIL SKIN CARE: HOW HEMP OIL BENEFITS YOUR SKIN

April 18, 2019

CBD has been gaining so much attention recently for all of its health benefits, as well as its sales.

With sales of CBD products projected to hit $22 billion by 2022, it's important to know why people are using it so much.

From helping diabetics, to preventing heart disease and anxiety, the benefits seem to be endless.

So what can hemp oil do for your beautiful skin? Let's talk about that.

HOW DOES HEMP OIL HELP WITH SKIN?

CBD is a cannabinoid found in the marijuana plant, but it does not get you high. Research is still being conducted for all of its health benefits, and the results are promising.

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While people use CBD in pills, sweeteners, candies, food, and a lot of other products, more people are using it in lotions and soaps. This only triggers curiosity for what hemp oil does to your skin, so let's start by saying: it does a lot.

MOISTURIZES

Hemp oil has one of the critical fatty acids in it, Omega-6, which is not naturally produced by the body. This is a natural oil that prevents inflammation and encourages skin regeneration.

Check out more about its anti-inflammatory benefits to learn more.

LOWERS BLOOD SUGAR

CBD is commonly used by diabetics for its regulating effects on blood sugar, but how does that affect your skin?

Hyperglycemia, high blood sugar, is believed to be a common cause of acne. CBD, even when absorbed through the skin, can help regulate that, lowering your risk of pesky pimples.

MODERATES OIL PRODUCTION

This is another great way that hemp oil fights acne. It can prevent dry skin without clogging pores, making it a perfect balance to prevent blackheads and whiteheads, keeping your skin looking young!

ANTI-AGING

Right when you thought CBD products couldn't get any better, hemp oil has anti-aging properties.

While moisturizing the skin is, itself, critical to preventing the aging effects on the skin, the linoleic and oleic acids found in hemp oil cannot be produced by the body. However, they can play a key role in anti-aging.

HEALTHY VITAMINS

Vitamin E is most commonly associated with skin health, and hemp seed oil is absolutely rich in it, as well as Vitamin A.

Not only that, but it also contains trace amounts of important minerals like potassium, magnesium, iron, zinc, calcium, and phosphorus.

These are great for improving blood flow to the skin, especially when taken as a dietary supplement. Find out more about what roles these vitamins and minerals play for skin health.

WHAT ELSE?

The benefits of hemp oil almost sound too good to be true. The antioxidant and anti-inflammatory benefits of its use are too great to pass up for proper skin care.

Using hemp oil for the skin is clearly beneficial, so do your research and try it for yourself!

Also, if you've ever wondered why some people look so young for their age, check out more skin care tips to find out and get started for yourself.

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CBD BEAUTY & SKIN-CARE

INFLAMMATORY CONDITIONS LEAD TO MANY SKIN PROBLEMS

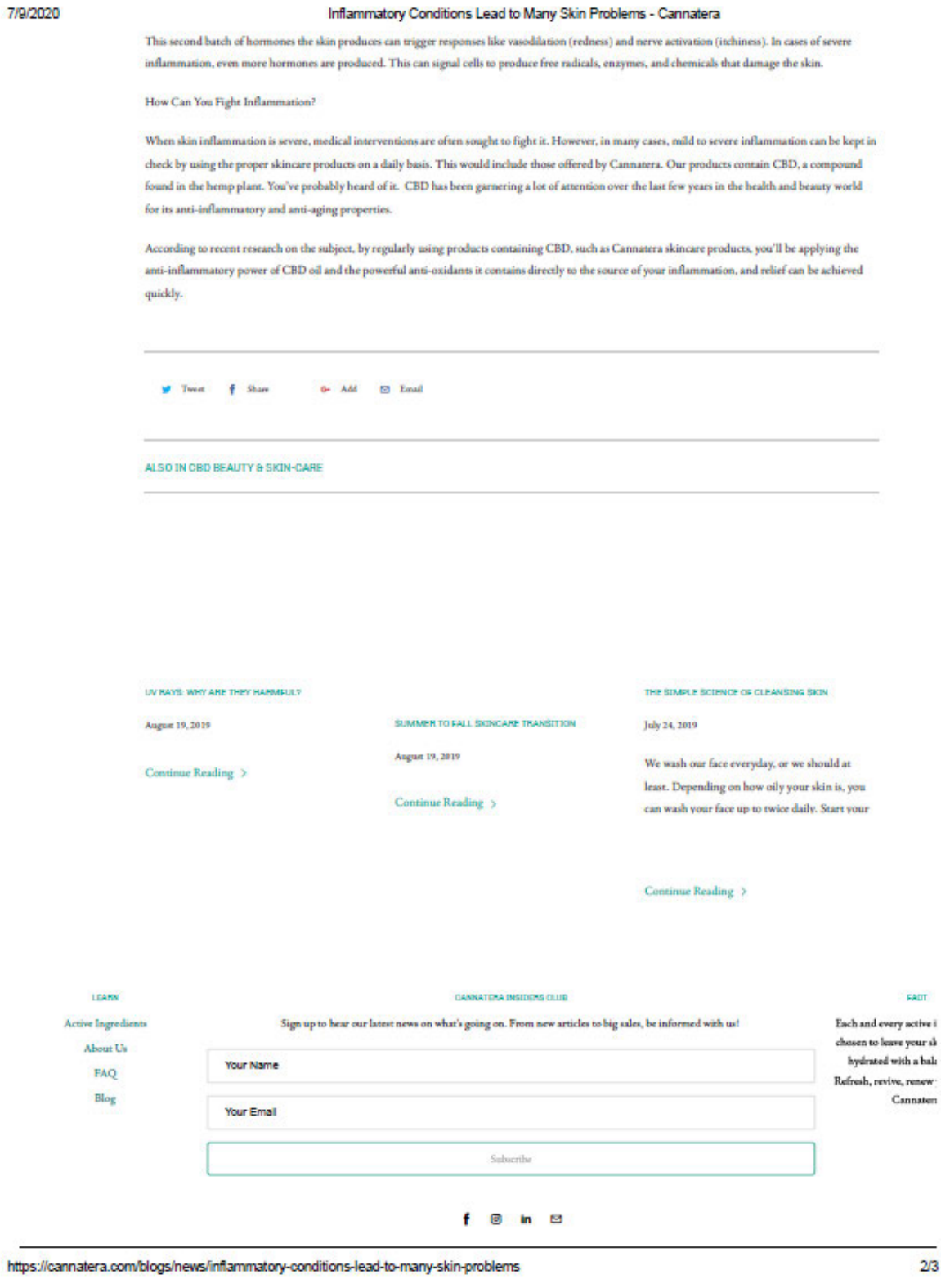
January 23, 2019

Inflammatory skin conditions are far and away the most common issues dermatologists see when their patients visit. In fact, some say they see these types of afflictions on a daily basis. What is inflammation and is it serious? The answer to this question is yes and no.

Inflammation causes an itchy rash that can often be treated and dealt with easily. Other times, inflammation leads to chronic conditions like eczema, psoriasis, rosacea, and seborrheic dermatitis that require ongoing treatment to keep under control.

What Causes Skin Inflammation?

The exact process of skin inflammation isn't completely understood. Generally, dermatologists believe that when the skin comes into contact with a certain irritant (which can be different for everyone) such as sunlight, dyes and fragrances, soaps, or allergens, inflammatory messenger hormones are produced in the skin. These hormones spread to other cells and trigger the production and release of additional hormones.



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This second batch of hormones the skin produces can trigger responses like vasodilation (redness) and nerve activation (itchiness). In cases of severe inflammation, even more hormones are produced. This can signal cells to produce free radicals, enzymes, and chemicals that damage the skin.

How Can You Fight Inflammation?

When skin inflammation is severe, medical interventions are often sought to fight it. However, in many cases, mild to severe inflammation can be kept in check by using the proper skincare products on a daily basis. This would include those offered by Cannatera. Our products contain CBD, a compound found in the hemp plant. You've probably heard of it. CBD has been garnering a lot of attention over the last few years in the health and beauty world for its anti-inflammatory and anti-aging properties.

According to recent research on the subject, by regularly using products containing CBD, such as Cannatera skincare products, you'll be applying the anti-inflammatory power of CBD oil and the powerful anti-oxidants it contains directly to the source of your inflammation, and relief can be achieved quickly.

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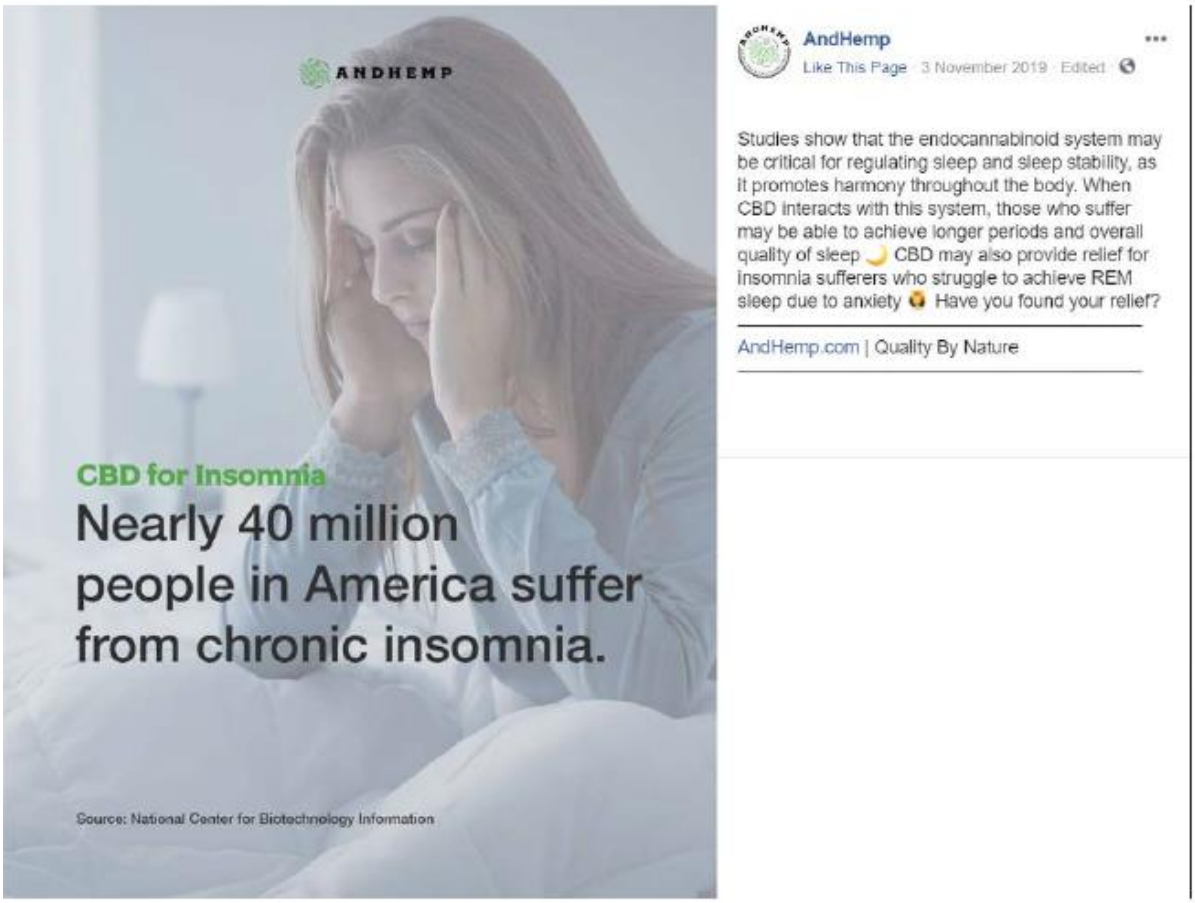

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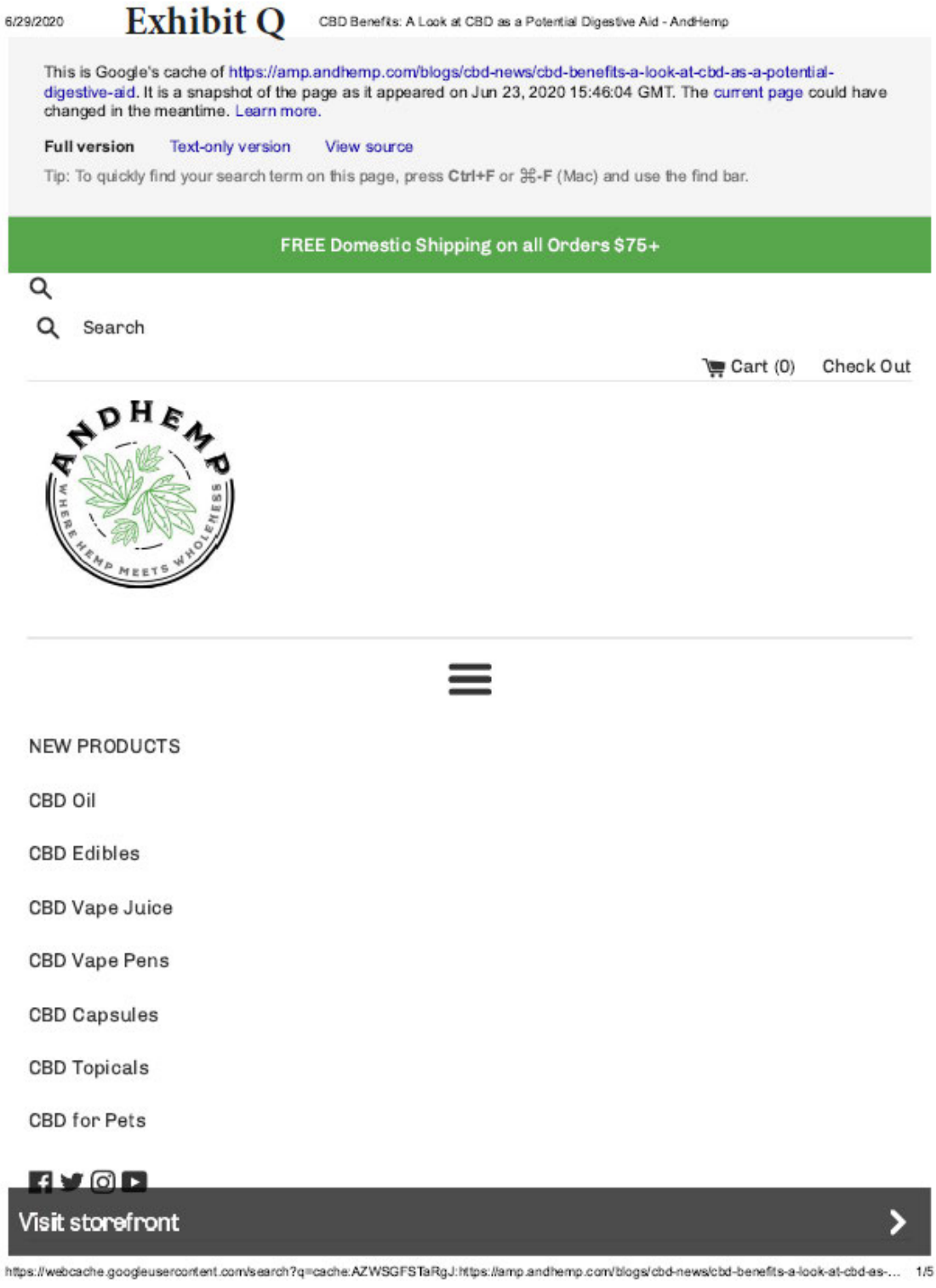

CBD Benefits: A Look at CBD as a Potential Digestive Aid

on July 08, 2019

Stomach aches, diarrhea, nausea—most of us have had problems with our digestive system at certain times, but for some people, problems with digestion can be so severe that they impede upon their lives in the most challenging ways. Digestive issues actually silently plague many people across the country, some of whom have been diagnosed with things like chronic inflammation of the bowels and digestive tract.

To date, the most effective methods of treatment for people with these debilitating conditions has been to offer some kind of medication to help combat symptoms. The cannabinoid cannabidiol (CBD), which is one of over a hundred cannabinoids found in the cannabis plant, could bring new levels of relief to people who have issues with things like irritable bowel syndrome or Chron's disease.

The Lowdown On Digestive Problems

A recent survey published by Fox News showed that as much as 74 percent of Americans have uncomfortable digestive symptoms to contend with, such as bloating and abdominal pain. These symptoms may seem like everyday occurrences that come along with eating, and a lot of people never really discuss anything with their doctor—as much as half of those surveyed, in fact.

Unfortunately, what seems like common discomfort relative to digestion can point to some pretty serious underlying health concerns. Celiac disease, exocrine pancreatic insufficiency (EPI), and Chron's disease are all good examples. Irritable bowel syndrome (IBS) is another chronic condition to blame, and this painful condition is estimated to affect as many as people 45 million people in the United States alone.

CBD for Digestion: What We Know About How CBD Works in the Digestive Tract

CBD, when introduced into the body, interacts with receptors that are part of the endocannabinoid system. This system plays a role in all kinds of bodily processes, including digestion. This system actually plays a role in things like immune regulation, your appetite, and how your body digests the food you take in. With CBD just taking center stage in recent years as a potentially very therapeutic agent, more studies have been carried out pertaining to CBD and digestion. There's actually evidence that supports the idea that there are a high number of cannabinoid receptors located in different [illegible]tive tract. Scientists have stated:

"Pharmacological modulation of the endogenous cannabinoid system could provide a new therapeutic target for the treatment of a number of gastrointestinal diseases..."

This is exciting news for people who deal with GI issues on a daily basis, especially when so many other prescription medication alternatives come along with side effects that can be just as troubling as the conditions alone.

There have been a few small formal studies to help solidify this abstract assumption that scientists have made about CBD . One small study of 46 people who had moderately severe Chron's disease showed that 65 percent of participants saw a full remission of their symptoms. There was a review published in 2008 by a neurologist that stated IBS could be a result of a clinical endocannabinoid deficiency. In 2011, one study found that CBD helped create a reduction in inflammation in the bowels caused by a pesky bacterium called bacterial lipopolysaccharides (LPS), which just happens to be a major thing in the bodies of people who have IBS.

Using CBD for Digestive Issues: How Does CBD Make You Feel?

One of the biggest reasons CBD is admired for its therapeutic effects is that it really does not have any psychoactive effects on the individual taking the supplement. CBD is now being produced from hemp, which naturally has extremely low amounts of THC (that little cannabinoid that causes the euphoric "high" feeling that cannabis is most known for). By law, CBD products legal for sale in all places must contain less than 0.03 percent THC.

What's all that mean? Basically, CBD isn't going to make you feel much of anything, except possibly better, of course. Side effects with CBD are rare, and when they are experienced, they are usually minimal. In a study published on PubMed, only one out of three people who used CBD to treat a medical condition had a non-serious side effect. The most common side effects reported have been:

- Dry mouth
- Hunger
- Fatigue

These common side effects are really nothing to complain about if you are dealing with something like chronic stomach pain or constant bathroom trips, and for many, the side effects are barely noticeable at all.

What CBD for Sale Is Best for Use as a Digestive Aid?

If you are looking to find CBD for sale that will be best to try to use to help with digestion, there are a few things to consider. You can purchase topical CBD , such as CBD cream for pain and CBD salve, but it is generally best to stick to CBD drops or some form of ingestable CBD product for digestion issues. Look for products that:

- Offer high potency levels of CBD for maximum effectiveness in the system
- Are easy to dose and control so you can adjust your dosage accordingly
- Are harvested from industrial-grade hemp so the contents are reliable
- Have been third-party tested for purity and ingredients

CBD as a digestive aid is something being heavily considered in scientific studies these days, and it is obvious why that is the case. Even though there is no definitive dosing guidelines or proof that CBD is a cure-all for digestive issues, it is an alternative treatment that could be worth a shot if you are suffering from GI issues. Check out the CBD oil for sale on AndHemp.

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SUBMIT

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DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

    a. Respondent Reef Industries, Inc., also doing business as Reefcbd.com and Reef Wellness, is a California corporation with its principal office or place of business at 3033 Bristol Street #G, Costa Mesa, California 92626.

    b. Respondent Cannatera, Inc., is a California corporation with its principal office or place of business at 1235 E. Francis Street Suite M, Ontario, California 9176.

    c. Respondent AndHemp, Ltd., is a United Kingdom limited company with its principal office or place of business at 1235 E. Francis Street, Ontario, California 91761.

    d. Respondent Andrew M. Bouchie is an officer, director, and principal shareholder of Reef Industries, Inc., officer of Cannatera, Inc., and President and co-owner of AndHemp, Ltd. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of

Reef, Industries, Inc., Cannatera, Inc., and AndHemp, Ltd. His principal office or place of business is the same as that of Reef Industries, Inc.

e. Respondent John R. Cavanaugh is an officer, director, and principal shareholder of Reef Industries, Inc. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of Reef Industries, Inc. His principal office or place of business is the same as that of Reef Industries, Inc.

f. Respondent Shaun Paquette is an officer and director of Reef Industries, Inc., officer of Cannatera, Inc., and co-owner of AndHemp, Ltd. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of Reef Industries, Inc., Cannatera, Inc., and AndHemp, Ltd. His principal office or place of business is the same as that of Reef Industries, Inc.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions apply:

A. "CBD Product" means any Dietary Supplement, Food, or Drug containing cannabidiol.

B. "CBG Product" means any Dietary Supplement, Food, or Drug containing cannabigerol.

C. "Covered Product" means any Dietary Supplement, Food, or Drug, including but not limited to CBD Products or CBG Products.

D. "Dietary Supplement" means: (1) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional Food or as a sole item of a meal or the diet.

E. "Drug" means: (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or

official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than Food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

F. "Essentially Equivalent Product" means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive binders, colors, fillers, excipients) in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

G. "Food" means: (1) any article used for food or drink for humans or other animals; (2) chewing gum; and (3) any article used for components of any such article.

H. "Respondents" means all of the Corporate Respondents and the Individual Respondents, individually, collectively, or in any combination.

1. "Corporate Respondents" means Reef Industries, Inc., a corporation, also doing business as Reefcbd.com and Reef Wellness, Cannatera, Inc., a corporation, AndHemp, Ltd., a limited company, and their successors and assigns.

2. "Individual Respondents" means Andrew M. Bouchie, John R. Cavanaugh, and Shaun Paquette.

PROVISIONS

I. PROHIBITED REPRESENTATIONS: REGARDING HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, or assist others in making, expressly or by implication, any representation that such product:

A. treats insulin resistance; or

B. cures, mitigates, or treats any disease, including but not limited to acne, Alzheimer's disease, arthritis, autoimmune diseases, cancer, celiac disease,

> childhood epilepsy, chronic inflammation, chronic insomnia, chronic pain (including chronic pain from fibromyalgia, multiple sclerosis, or cancer), colitis, Crohn's disease, damage to the colon due to chemotherapy, depression, diabetes, eczema, epilepsy, gingivitis, heart disease, irritable bowel syndrome (IBS), lupus, multiple sclerosis (MS), neurodegenerative disorders, neurological and age-related disorders (including cerebral ischemia), obsessive compulsive disorder (OCD), panic disorder, Parkinson's disease, post-traumatic stress disorder (PTSD), psoriasis, rosacea, seizures, seizure disorders, skin cancer, social anxiety disorder, or strokes,

unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Provision, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product must not make, or assist others in making, expressly or by implication, any representation, other than representations covered under the Provision of this Order entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, including that such product prevents Alzheimer's disease, autoimmune diseases, arthritis, cancer, diabetes, heart disease, seizures, skin cancer or other diseases, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity

affiliated with or acting on behalf of any Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Corporate Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

IV. PROHIBITED MISREPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not misrepresent, in any manner, expressly or by implication:

A. That any Covered Product is scientifically proven to treat acne, arthritis, autoimmune disease, cancer, childhood epilepsy, chronic inflammation, chronic insomnia, colitis, chronic pain (including chronic pain from fibromyalgia, multiple sclerosis, or cancer), Crohn's disease, damage to the colon due to chemotherapy, depression, epilepsy, gingivitis, heart disease, irritable bowel syndrome (IBS), multiple sclerosis (MS), neurological and age-related disorders (including cerebral ischemia), obsessive compulsive disorder (OCD), panic disorder, Parkinson's disease, post-traumatic stress disorder (PTSD), psoriasis, seizures, social anxiety disorder, or stroke;

B. That any Covered product is scientifically proven to prevent acne, heart disease, seizures, skin cancer, or skin infections;

C. That the performance or benefits of any product are scientifically or clinically proven or otherwise established; or

D. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V. FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them from:

A. For any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. For any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI. MONETARY RELIEF

IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $85,000.00, which Respondents stipulate their undersigned counsel holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

VII. ADDITIONAL MONETARY PROVISIONS

IT IS FURTHER ORDERED that:

A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondents have no right to challenge any activities pursuant to this Provision.

E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that payment is due, the entire amount will immediately become due and payable.

F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.

G. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers), which Respondents have previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

VIII. CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Respondents must directly or indirectly provide sufficient customer information, including sufficient identification of all resellers, to enable the Commission to efficiently administer consumer redress to all purchasers of Respondents' CBD Products. If a representative of the Commission requests in writing any information related to redress, Respondents must provide it, in the form prescribed by the Commission representative, within 14 days.

IX. NOTICES TO CUSTOMERS

IT IS FURTHER ORDERED that Respondents must notify customers as follows:

A. Respondents must identify all consumers who purchased CBD Products on or after January 1, 2019 ("eligible customers").

1. Such eligible customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody or control, including from third parties such as resellers;

2. Eligible customers include those identified at any time, including after Respondents' execution of the Agreement through the eligibility period, which runs for 1 year after the issuance date of the Order.

B. Respondents must notify all identified eligible customers by mailing each a notice:

1. The letter must be in the form shown in Attachment A.

2. The envelope containing the letter must be in the form shown in Attachment B.

3. The mailing of the notification letter must not include any other enclosures.

4. The mailing must be sent by first-class mail, postage prepaid, address correction service requested with forwarding and return postage guaranteed. For any mailings returned as undeliverable, Respondents must use standard address search methodologies such as re-checking Respondents' records and the Postal Service's National Change of Address database and re-mailing to the corrected address within 8 days.

C. Respondents must notify all eligible customers within 180 days after the issuance date of this Order and any eligible customers identified thereafter within 30 days of their identification.

D. Respondents must provide a notice on all of their social media accounts (including any Facebook, Twitter, Instagram, or YouTube accounts) and on the first page of their websites. Such notice must link to a copy of the Order, along with a toll-free telephone number and an email address for the redress administrator. The notice must be posted not later than 3 days after the effective date of the Order and for at least 1 year after the redress period ends.

E. Respondents must report on their notification program under penalty of perjury:

1. Respondents must submit a report annually and at the conclusion of the program summarizing its compliance to date, including the total number of eligible customers identified and notified.

2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Respondents must submit it within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

X. NOTICE TO AFFILIATES AND OTHER RESELLERS

IT IS FURTHER ORDERED that within 30 days of the effective date of this Order, Respondents must notify all affiliates and other resellers by sending each by first-class mail, postage paid and return receipt requested, or by courier service with signature proof of delivery, the notification letter attached as Attachment A. Respondents must include a copy of this Order, but no other document or enclosure.

XI. ACKNOWLEDGMENTS OF THE ORDER

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 20 years after the issuance date of this Order, each Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is the majority owner or controls directly or indirectly, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for labeling, manufacturing, advertising, marketing, promotion, distribution, offering for sale, or sale of CBD or CBG Products and all agents and representatives who participate in labeling, manufacturing, advertising, marketing, promotion, distribution, offering for sale, or sale of CBD or CBG Products; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

XII. COMPLIANCE REPORTS AND NOTICES

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. Sixty days after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with

Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondents must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, each Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. Each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, each Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Reef Industries, Inc., FTC File No. 202-3064.

XIII. RECORDKEEPING

IT IS FURTHER ORDERED that Respondents must create certain records for 20 years after the issuance date of the Order, and retain each such record for 5 years, unless otherwise specified below. Specifically, Corporate Respondents and each Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. Personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. Copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. A copy of each unique advertisement or other marketing material making a representation subject to this Order;

F. For 5 years from the date of the last dissemination of any representation covered by this Order:

1. All materials that were relied upon in making the representation; and

2. All tests, studies, analysis, other research, or other such evidence in Respondents' possession, custody, or control that contradicts, qualifies, or

otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

K. For 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communications relate to Respondents' compliance with this Order.

L. For 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents, that tend to show any lack of compliance by Respondents with this Order.

XIV. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Respondents, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XV. ORDER EFFECTIVE DATES

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the

Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ATTACHMENT A TO THE ORDER

CLAIMS ABOUT PRODUCTS CONTAINING CBD
In the Matter of Reef Industries, Inc., et al.

<Date>

Subject: [*Insert name of product customer will recognize*]

<Name of customer>
<mailing address of customer
including zip code>

Dear <Name of customer>:

Our records show that you bought [names of products] from [our company *or other name consumers will recognize – the retailer, perhaps*]. We are writing to tell you that the Federal Trade Commission (FTC), the nation's consumer protection agency, has charged us with deceptive or false advertising.

Specifically, the FTC sued [our company *or other name consumers will recognize – the retailer, perhaps*] for making misleading claims that our CBD products can effectively prevent, cure, treat, or ease serious diseases and health conditions, including the following:

> Acne; Alzheimer's disease; arthritis; autoimmune disease; cancer; celiac disease; childhood epilepsy; chronic inflammation; chronic insomnia; chronic pain (including chronic pain from fibromyalgia, multiple sclerosis, and cancer), colitis; Crohn's disease; damage to the colon due to chemotherapy; depression; diabetes; eczema; epilepsy; gingivitis; heart disease; insulin resistance; irritable bowel syndrome (IBS); lupus; multiple sclerosis; neurodegenerative disorders; neurological and age-related disorders (including cerebral ischemia); obsessive-compulsive disorder (OCD); panic disorder; Parkinson's disease; post-traumatic stress disorder (PTSD); psoriasis; rosacea; seizures; seizure disorders; skin cancer; skin infections; social anxiety disorder; and stroke.

To settle the FTC's lawsuit, we're contacting our customers to tell them that we don't have proof that our CBD products will effectively prevent, cure, treat, or improve the serious diseases and health conditions listed above.

As a part of this lawsuit, you may be entitled to a refund. Please visit [URL] for more information about refunds. If you have other questions about this lawsuit, visit [add URL].

CBD oil and other alternative treatments might be harmful to your medical care, and could interfere with your prescriptions. CBD products could also be dangerous if you take them with other medicines or at a high dose. Talk to your doctor before you take any treatments or stop any prescriptions. For more information about protecting yourself from bogus health product claims visit ftc.gov/health.

[signature]

[*identify Respondent/Defendant or other person responsible for signing the notification letter*]

ATTACHMENT B to the Order – Envelope Template:

The envelope for the notification letter must be in the following form, with the underlined text completed as directed:

[*Identify Respondent*
Street Address
City, State and Zip Code]

FORWARDING AND RETURN POSTAGE GUARANTEED ADDRESS CORRECTION SERVICE REQUESTED

[name and
mailing address of customer,
including zip code]

ABOUT YOUR PURCHASE OF [NAME PRODUCT]

STATEMENT OF COMMISSIONER ROHIT CHOPRA

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish – and unlawful – claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine "a competitor's ability to compete" on honest attributes.[1]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID-19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to

1 *In re Pfizer, Inc.*, 81 F.T.C. 23, 62 (1972).

greater dependence on opioids.[2] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer Americans into high-cost, subpar treatment centers, and some even hire intermediaries – so-called "body brokers" – who collect kickbacks from this harmful practice.[3]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[4] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[5]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[6] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

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2 *See, e.g.*, Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL STREET J. (Sept. 8, 2020), https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; *Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic*, AMERICAN MEDICAL ASSOCIATION (last updated on Oct. 31, 2020), https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.

3 For example, recent reporting describes the "Florida Shuffle," where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America*, VOX (Mar. 2, 2020), https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-brijayne. *See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), https://www ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid (calling on the FTC to do more to tackle this problem).

4 Pub. L. No. 115-271 §§ 8021-8023 (codified in 15 U.S.C. § 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

5 Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.

6 Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[7] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[8] Under the Penalty Offense Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[9] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[10] and apprising firms of these findings – along with a warning that noncompliance can result in penalties – makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a "high level of voluntary compliance achieved quickly and at a low cost."[11] Going forward, we should pursue this strategy.[12]

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7 In one of these matters, the respondents are paying nothing.

8 15 U.S.C. § 45(m)(1)(b).

9 *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256. Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

10 This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc.*, *supra* note 2 (finding that "[f]airness to the consumer, as well as fairness to competitors" compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.*, 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that "a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act." *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.*, 155 F.T.C. 1, 6 (2013).

11 Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an "extremely effective and efficient way to enforce the law." Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.

12 My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.

CONCURRING STATEMENT OF COMMISSIONER CHRISTINE S. WILSON

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication.

The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters[1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

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1 Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions*, Oct. 22, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims; Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis*, Sept. 10, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused; Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases*, Apr. 2, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.

2 Press Release, *FTC Order Stops the Marketer of "Thrive" Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID-19*, July 10, 2020, available at https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.

Concurring Statement

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo- controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions – specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that "[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes."[6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

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3 *See, e.g.*, Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

4 *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.

5 *See, e.g.*, Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC v. Avrom Boris Lasarow, et al.* (Feb. 2015), https://www ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health; Statement of Commissioner Joshua D. Wright, *FTC v. Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin; Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), https://www ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru; Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part; Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC v. Springtech 77376, et al.* (July 2013), https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; *see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12-49 (May 2012), available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.

6 *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order with Reef Industries, Inc., a corporation, Cannatera, Inc., a corporation, AndHemp, Ltd., a limited company, and Andrew M. Bouchie, John R. Cavanaugh, and Shaun Paquette, individually and as officers and/or owners of Reef Industries, Inc., Cannatera, Inc., and/or AndHemp, Ltd. (collectively, "Respondents").

The proposed consent order ("Order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Order and the comments received, and will decide whether it should withdraw the Order or make it final.

This matter involves the respondent's advertising of cannabidiol (CBD), a cannabinoid compound found in hemp and cannabis. The complaint alleges that respondent violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) CBD products can effectively prevent, cure, treat, or mitigate multiple diseases and other health conditions; and (2) studies or scientific research prove that CBD products effectively prevent, cure, treat, or mitigate multiple diseases and other health conditions.

The Order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food the respondent sells, markets, promotes, or advertises.

Provision I requires randomized, double-blind, placebo-controlled clinical testing for the challenged claims or any disease treatment, mitigation, or cure claim for a Covered Product. The Order defines "Covered Product" as any dietary supplement, food, or drug including but not limited to CBD products or cannabigerol (CBG) products.

Provision II prohibits other misleading or unsubstantiated representations about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or essentially equivalent product. It also covers prevention claims not specifically included in Provision I.

Provision III requires the preservation of certain records for any testing Respondents rely upon as competent and reliable scientific evidence.

Provision IV addresses Respondents' false establishment claims and generally prohibits misrepresentations regarding the scientifically or clinically proven benefits of any product.

Provision V provides a safe harbor for FDA-approved claims.

Provisions VI and VII contain monetary payment provisions.

Provisions VIII, IX, and X requires the Respondents to provide customer information to the Commission and to provide notice of the order to customers, affiliates and other resellers.

Provision XI requires an acknowledgement of receipt of the order. It also requires the individual Respondents to deliver a copy of the order to certain individuals in any business for which they are the majority owner or which they control directly or indirectly.

Provisions XII, XIII, and XIV provide the required reporting, recordkeeping, and compliance monitoring programs that must be put in place.

Provision XV explains when the Order is final and effective.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

Complaint

IN THE MATTER OF

CHEMENCE, INC.,
AND
JAMES COOKE

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4738; File No. X160032
Complaint, February 9, 2021 – Decision, February 9, 2021

This consent order addresses Chemence, Inc.'s advertising, labeling, sale, and distribution of cyanoacrylate "superglue" products as made in the United States. The complaint alleges that Respondents engaged in deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act by representing that the cyanoacrylate "superglue" products they manufactured and supplied to trade customers were all or virtually all made in the United States and violated a 2016 federal court order in the process. The consent order prohibits Respondents from making any country-of-origin claim about a product or service unless the claim is true, not misleading, and Respondents have a reasonable basis substantiating the representation.

Participants

For the *Commission*: *Julia Solomon Ensor* and *Adrienne J. Lighten.*

For the *Respondents*: *Robert Wilson, Wilson & Wilson Co., L.P.A.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Chemence, Inc., a corporation, and James Cooke, individually and as an officer of Chemence, Inc., (collectively, "Respondents") have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Chemence, Inc. ("Chemence") is an Ohio corporation with its principal office or principal place of business at 185 Bluegrass Valley Parkway, Alpharetta, GA 30005.

2. Chemence advertises, labels, offers for sale, and distributes products to consumers, including, but not limited to, cyanoacrylate glue products ("cyanoacrylates"). Cyanoacrylates are strong, fast-acting adhesives, also known as "power glues" or "superglues," with industrial, medical, and household uses. Chemence advertises these products in stores and on its website, www.chemence-us.com, and offers for sale, sells, and distributes them directly to the public throughout the United States.

3. Chemence provides third parties with marketing materials so third parties can market and sell products under its own brand names.

4. Chemence also manufactures private-labeled products sold under retailer brand names, and provides those retailers with labeling and promotional materials for use in the marketing and sale of private-labeled products.

5. Respondent James Cooke ("Cooke") is the president of Chemence. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices of Chemence, including the acts and practices alleged in this complaint. Since at least 2014, he has communicated with the Federal Trade Commission on Chemence's behalf regarding the acts and practices alleged in this complaint. In 2017, he personally signed the Report described *infra* ¶¶13-17, in which he designated himself the Federal Trade Commission's primary point of contact regarding the acts and practices alleged in this complaint, and expressly assumed liability for Chemence's compliance with the 2016 Order described *infra* ¶ 8. His principal office or place of business is the same as that of Chemence.

6. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

2016 Action and Order

7. On February 1, 2016, the Federal Trade Commission ("FTC") filed the complaint in the Northern District of Ohio attached as **Exhibit A** alleging that Chemence violated Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a), by deceptively representing that its cyanoacrylates, including the materials used to make such products, were all or virtually all made in the United States. In fact, the complaint alleged, a significant proportion (approximately 55%) of the cost of the chemical inputs to Chemence's cyanoacrylates is attributable to imported chemicals, and these imported chemicals are essential to the function of Chemence's glue products. The complaint further alleged that Chemence provided the means and instrumentalities to third-party retailers to commit deceptive acts and practices by providing such retailers with deceptive marketing materials for use in the marketing and sale of private-labeled products.

8. On October 13, 2016, the Northern District of Ohio entered the Stipulated Order for Permanent Injunction and Monetary Judgment attached as **Exhibit B** (the "2016 Order"), resolving all matters then in dispute between Chemence and the FTC.

9. In addition to monetary relief and compliance-monitoring provisions, the 2016 Order contained two injunctive relief provisions.

10. Part I of the 2016 Order permanently enjoins Chemence from representing, expressly or by implication, that a product or service is of U.S. origin unless: (1) the final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States; or (2) a clear and conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients, and/or processing.

11. Part II of the 2016 Order permanently enjoins Chemence from providing others with the "means and instrumentalities" to make any representation prohibited by Part I. The 2016 Order defines "means and instrumentalities" as any information, including but not limited to, any advertising, labeling, promotional, sales training, or purported substantiation materials, for use by trade customers in the marketing of any product or service.

12. Part V.A. of the 2016 Order requires Chemence to submit a compliance report one year after entry of the Order.

2017 Compliance Report

13. On October 17, 2017, Chemence submitted the required one-year compliance report, attached as **Exhibit C** (the "2017 Report").

14. The 2017 Report describes Chemence's efforts to comply with each provision of the 2016 Order. In addition to these efforts, the 2017 Report states, "To assure future compliance with the Order, Chemence has instructed members of its respective staffs having responsibility for the requirements of the Order and of their responsibility to ensure compliance with the Order . . . Chemence is confident that those instructions are sufficient to ensure compliance with the Order." *See* Exhibit C, p.2.

15. The 2017 Report further includes a declaration under penalty of perjury that, as of October 13, 2017, "Chemence has changed the labeling on all of Chemence's cyanoacrylate glue/superglue adhesive products sold, distributed or offered for sale or distribution, by or on behalf of Chemence to consumers to read 'Made in USA with US and globally sourced materials.'" *Id. at* 3-4.

16. As Chemence's President, Cooke personally signed the 2017 Report, declaring it true and correct under penalty of perjury. *Id.* at 6.

17. The 2017 Report also includes Cooke's executed Acknowledgement by Declaration of Receipt of the 2016 Order. *Id.* at 31.

Private-Labeled Products

18. Since entry of the 2016 Order, Respondents continued to manufacture private-labeled products sold under retailer brand names, and provide those trade customers with labeling and promotional materials for use in the marketing and sale of private-labeled products.

19. In numerous instances since entry of the 2016 Order and through at least March 2020, despite the statement described in Paragraph 15, Respondents supplied such trade customers with pre-labeled and pre-packaged cyanoacrylates containing unqualified "Made in USA" claims on promotional materials or labels. Examples include, but are not limited to, the promotional materials and labels depicted in attached **Exhibit D**.

20. In numerous instances, including, but not limited to, the promotional materials and labels shown in **Exhibit D**, Respondents represented the private-labeled cyanoacrylates it supplied to trade customers were all or virtually all made in the United States.

21. In fact, significant proportions of the chemical inputs, and overall costs, to manufacture Respondents' cyanoacrylates are attributable to foreign materials. In numerous instances, foreign materials accounted for more than 80% of materials costs and more than 50% of overall manufacturing costs for these products.

22. Therefore, Respondents' claims that their private-labeled cyanoacrylates are all or virtually all made in the United States deceive consumers.

23. Respondents' claims also violate Part I of the 2016 Order because Respondents represented their cyanoacrylates were of U.S.-origin, with no qualification, despite the fact that they contain significant ingredients sourced outside the United States.

24. Respondents further violated Part II of the 2016 Order because they provided labeling and promotional materials containing representations prohibited by Part I to third-party trade customers for use in the marketing of private-labeled cyanoacrylates.

25. Despite knowing or consciously avoiding knowing that Chemence's private-labeled cyanoacrylates are labeled "Made in USA" without qualification, in the 2017 Compliance Report, Cooke nonetheless declared under penalty of perjury that Chemence had "changed the labeling on all of Chemence's cyanoacrylate glue/superglue adhesive products sold, distributed or offered for sale or distribution by or on behalf of Chemence customers to read 'Made in USA with US and globally sourced materials.'"

26. Entry of an administrative order against Respondents will make civil penalties for future violations available to the Commission pursuant to Section 5(*l*) of the FTC Act, 15 U.S.C. § 45(*l*), as modified by Section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, and Section 1.98(c) of the FTC's Rules of Practice, 16 C.F.R. § 1.98(c), which directs that a Respondent who violates an order of the Commission after it has become final, and while such order is in effect, "shall forfeit and pay to the United States a civil penalty of not more than [$43,280] for each violation."

27. Therefore, an administrative action is in the public interest.

COUNT I
False or Misleading Representation

28. In connection with the advertising, promotion, offering for sale, or sale of cyanoacrylates, Respondents have represented, directly or indirectly, expressly or by implication, that such cyanoacrylates, including the raw materials used to make such products, are all or virtually all made in the United States.

29. In fact, a significant proportion of the costs of the materials used and a significant proportion of the overall costs to make Respondents' cyanoacrylates are attributable to imported materials. Therefore, the representation set forth in Paragraph 28 is false or misleading.

COUNT II
Means and Instrumentalities

30. Respondents have distributed the promotional materials described in Paragraphs 19 and 20 to trade customers for use in the marketing and sale of Respondents' products, including private-labeled products. In so doing, Respondents have provided the means and instrumentalities to these third-party retailers for the commission of deceptive acts or practices.

VIOLATION OF SECTION 5

31. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this ninth day of February, 2021, has issued this Complaint against Respondents.

By the Commission.

Complaint

Exhibit A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

FEDERAL TRADE COMMISSION, Plaintiff, v. CHEMENCE, INC., an Ohio corporation, Defendant.	**Case No. 1:16-cv-228** **COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF**

Plaintiff, the Federal Trade Commission ("FTC"), for its Complaint alleges:

1. The FTC brings this action under Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), to obtain temporary, preliminary, and permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendant's acts or practices in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a), 53(b), and other applicable provisions.

3. Venue is proper in this district under 28 U.S.C. § 1391(b)(1), (b)(2), (c)(2), and (d), and 15 U.S.C. § 53(b).

PLAINTIFF

4. The FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce.

5. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. § 53(b).

DEFENDANT

6. Defendant Chemence, Inc. ("Chemence") is an Ohio corporation with its principal place of business at 185 Bluegrass Valley Parkway, Alpharetta, GA 30005. Chemence transacts or has transacted business in this district and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Chemence has advertised, marketed, distributed, or sold cyanoacrylate glues to consumers throughout the United States.

COMMERCE

7. At all times material to this Complaint, Defendant has maintained a substantial course of trade in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANT'S BUSINESS ACTIVITIES

8. Defendant advertises, labels, offers for sale, and distributes products to consumers, including, but not limited to, cyanoacrylate glues. Cyanoacrylates are strong, fast-acting adhesives, also known as "power glues" or "superglues," with industrial, medical, and household uses. Defendant advertises these products in stores and on its website, www.chemence-us.com, and offers for sale, sells, and distributes them directly to the public throughout the United States.

9. Defendant provides third parties with marketing materials so third parties can market and sell Defendant's own products.

10. Defendant manufactures rebranded, private-labeled products sold under retailer brand names, and provides those retailers with marketing materials for use in the marketing and sale of rebranded, private-labeled products.

11. To induce consumers to purchase cyanoacrylate glues, Defendant has disseminated, or has caused to be disseminated, advertisements, packaging, and promotional materials for its products. These materials contain the following statements, among others:

A. "Proudly Made in the USA";

(Kwik-Frame Product Packaging; Chemence Product Packaging)

B. "Made in the USA."

(Chemence Product Packaging)

12. In numerous instances, including, but not limited to, the promotional materials referenced in Paragraph 11, Defendant has represented that its cyanoacrylate glue products, including raw materials, are all or virtually all made in the USA.

13. In fact, a significant proportion (approximately 55%) of the cost of the chemical inputs to Defendant's cyanoacrylate glue products is attributable to imported chemicals, and these imported chemicals are essential to the function of Defendant's glue products.

14. Therefore, Defendant's claims that its cyanoacrylate glues are made in the USA deceive consumers because Defendant's products are actually made in the USA with domestic and imported materials.

VIOLATIONS OF THE FTC ACT

15. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits "unfair or deceptive acts or practices in or affecting commerce."

16. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

Count I (False or Misleading Representation)

17. Through the means described in Paragraphs 11 and 12, Defendant has represented, directly or indirectly, expressly or by implication, that its cyanoacrylate glue products, including the materials used to make such products, are all or virtually all made in the United States.

18. In truth and in fact, Defendant's cyanoacrylate glue products, including the materials used to make such products, are not all or virtually all made in the United States.

19. Therefore, the making of the representation as set forth in Paragraph 17 of this Complaint constitutes a deceptive act or practice, in or affecting commerce in violation of Section 5(a) of the FTC Act.

Count II (Means and Instrumentalities)

20. As described in Paragraph 10, Defendant has distributed the promotional materials described in Paragraphs 11 and 12 to third-party retailers for use in the marketing and sale of Defendant's products, including rebranded products.

21. In so doing, Defendant has provided the means and instrumentalities to these third-party retailers for the commission of deceptive acts or practices.

22. Therefore, Defendant's practices, as described in Paragraphs 20 and 21, constitute deceptive acts or practices in violation of Section 5 of the FTC Act.

CONSUMER INJURY

23. Consumers have suffered and will continue to suffer substantial injury as a result of Defendant's violations of the FTC Act. In addition, Defendant has been unjustly enriched as a result of its unlawful acts or practices. Absent injunctive relief by this Court, Defendant is likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

24. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

PRAYER FOR RELIEF

Wherefore, Plaintiff FTC, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and the Court's own equitable powers, requests that the Court:

A. Award Plaintiff such preliminary injunctive and ancillary relief as may be necessary to avert the likelihood of consumer injury during the pendency of this action and to preserve the possibility of effective final relief, including but not limited to, temporary and preliminary injunctions;

B. Enter a permanent injunction to prevent future violations of the FTC Act by Defendant;

C. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendant's violations of the FTC Act, including but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies; and

D. Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Respectfully submitted,

JONATHAN E. NUECHTERLEIN
General Counsel

Dated: 02/01/2016

JULIA SOLOMON ENSOR
COLIN D. A. MACDONALD
Federal Trade Commission
600 Pennsylvania Ave. NW
Mail Stop CC-9528
Washington, D.C. 20580
(202) 326-2377 (Ensor)
(202) 326-3192 (MacDonald)
(202) 326-3197 (Fax)
jensor@ftc.gov
cmacdonald@ftc.gov

Attorneys for Plaintiff
FEDERAL TRADE COMMISSION

Complaint

Exhibit B

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

FEDERAL TRADE COMMISSION Plaintiff, v. CHEMENCE, INC., an Ohio corporation, Defendant.	Case No. 1:16-cv-228-PAG **STIPULATED ORDER FOR PERMANENT INJUNCTION AND MONETARY JUDGMENT**

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint for Permanent Injunction and Other Equitable Relief ("Complaint"), for a permanent injunction and other equitable relief in this matter, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendant stipulate to the entry of this Stipulated Order for Permanent Injunction and Monetary Judgment ("Order") to resolve all matters in dispute in this action between them.

THEREFORE, IT IS ORDERED as follows:

FINDINGS

1. This Court has jurisdiction over this matter.

2. The Complaint charges that Defendant participated in deceptive acts or practices in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, in the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of cyanoacrylate glue as "Made in the USA" or "Proudly Made in the USA."

3. Defendant neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Order. Only for purposes of this action, Defendant admits the facts necessary to establish jurisdiction.

4. Defendant waives any claim that it may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agrees to bear its own costs and attorney fees.

5. Defendant waives all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

For the purpose of this Order, the following definitions apply:

A. "**Clear(ly) and conspicuous(ly)**" means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a

television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means.

2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

4. On a product label, the disclosure must be presented on the same display panel as the claim being qualified.

5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.

6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.

7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.

8. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

B. "**Made in the United States**" shall mean any representation, express or implied, that a Product or Service, or a specified component thereof, is of U.S.-origin, including, but not limited to, a representation that such Product or Service is "made," "manufactured," "built," or "produced" in the United States, or any other U.S.-origin claim.

C. "**Product or Service**" means any good or service offered by Defendant.

ORDER

I. PROHIBITION AGAINST MISREPRESENTATIONS

IT IS FURTHER ORDERED that Defendant, and Defendant's officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of cyanoacrylate glue or any other Product or Service are permanently restrained and enjoined from misrepresenting, expressly or by implication, that a Product or Service is Made in the United States, unless:

1. The final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States; or
2. A clear and conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients, and/or processing.

II. MEANS AND INSTRUMENTALITIES

IT IS FURTHER ORDERED that Defendant, and Defendant's officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of cyanoacrylate glue or any other Product or Service must not provide to others the means and instrumentalities with which to make any representation prohibited by Part I above. For the purposes of this Part, "means and instrumentalities" means any information, including, but not necessarily limited to, any advertising, labeling, promotional, sales training, or purported substantiation materials, for use by trade customers in its marketing of any Product or Service.

III. MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

A. Judgment in the amount of Two Hundred Twenty Thousand ($220,000) is entered in favor of the Commission against Defendant as equitable monetary relief.

B. Defendant is ordered to pay to the Commission Two Hundred Twenty Thousand ($220,000), which, as Defendant stipulates, its undersigned counsel holds in escrow for no purpose other than payment to the Commission. Such payment must be made within 7 days of entry of this Order by electronic fund transfer in accordance with instructions previously provided by a representative of the Commission.

C. Defendant relinquishes dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

D. The facts alleged in the Complaint will be taken as true, without further proof, in any

subsequent civil litigation by or on behalf of the Commission, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

E. The facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

F. Defendant acknowledges that its Taxpayer Identification Numbers (Employer Identification Numbers), which Defendant must submit to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. §7701.

G. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendant's practices alleged in the Complaint. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Defendant has no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

IV. ORDER ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendant obtain acknowledgments of receipt of this Order:

A. Defendant, within 7 days of entry of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 5 years after entry of this Order, Defendant must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Defendant delivered a copy of this Order, Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

V. COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendant make timely submissions to the Commission:

A. One year after entry of this Order, Defendant must submit a compliance report, sworn under penalty of perjury. Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant; (b) identify all of Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses;

(c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales; (d) describe in detail whether and how Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

B. For 20 years after entry of this Order, Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following: (a) any designated point of contact; or (b) the structure of Defendant any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

C. Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Defendant within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington,

DC 20580. The subject line must begin: FTC v. Chemence, Inc.

VI. RECORDKEEPING

IT IS FURTHER ORDERED that Defendant must create certain records for 20 years after entry of the Order, and retain each such record for 5 years. Specifically, Defendant must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold;

B. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

D. A copy of each unique advertisement or other marketing material;

E. All materials that were relied upon in disseminating the representation; and

F. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VII. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendant's compliance with this Order, including any failure to transfer any assets as required by this Order:

A. Within 14 days of receipt of a written request from a representative of the Commission, Defendant must: submit additional compliance reports or other requested information, which

must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, the Commission is authorized to communicate directly with Defendant. Defendant must permit representatives of the Commission to interview any employee or other person affiliated with Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission may use all other lawful means, including posing, through its representatives as consumers, suppliers, or other individuals or entities, to Defendant or any individual or entity affiliated with Defendant, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

VIII. RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO ORDERED this 13th **day of** October **, 2016.**

/s/ Patricia A. Gaughan
PATRICIA A. GAUGHAN
UNITED STATES DISTRICT JUDGE

SO STIPULATED AND AGREED:

FOR PLAINTIFF:

Date: 10/6/2016

Julia Solomon Ensor
Colin D. A. MacDonald
Federal Trade Commission
600 Pennsylvania Ave. NW
Mail-Stop CC-9528
Washington, DC 20580
202-326-2377 (Ensor)
202-326-3192 (MacDonald)
202-326-3197 (Fax)
jensor@ftc.gov
cmacdonald@ftc.gov

Attorneys for Plaintiff
FEDERAL TRADE COMMISSION

FOR DEFENDANT:

Lisa A Messner Date: 8/21/16

Helen Mac Murray – Reg. # 0038782
Lisa A. Messner – Reg. # 0074034
Erika Frank – Reg. # 0095179
Mac Murray, Petersen & Shuster LLP
6530 West Campus Oval, Suite 210
New Albany, Ohio 43054
Telephone: 614-939-9955
Facsimile: 614-939-9954
E-mail: hmacmurray@mpslawyers.com
E-mail: lmessner@mpslayers.com
E-mail: efrank@mpslawyers.com

Attorneys for Defendant
CHEMENCE, INC.

DEFENDANT: Chemence, Inc.

Date: August 2, 2016

Hugh Cooke
President, Chemence, Inc.

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

FEDERAL TRADE COMMISSION Plaintiff, v. CHEMENCE, INC., an Ohio corporation, Defendant.	Case No. 1:16-cv-228-PAG **ACKNOWLEDGMENT BY AFFIDAVIT OF RECEIPT OF ORDER BY DEFENDANT CHEMENCE, INC.**

1. My name is _____, my job title is _____, and I am authorized to accept service of process on Chemence, Inc.. I am a U.S. citizen over the age of eighteen, and I have personal knowledge of the facts set forth in this Acknowledgment.

2. Chemence, Inc. was a Defendant in *FTC v. Chemence, Inc.*, which is the court case listed near the top of this page.

3. On [_____ ___, 201_], Chemence, Inc. received a copy of the Stipulated Order for Permanent Injunction and Monetary Judgment, which was signed by the Honorable Patricia A. Gaughan and entered by the Court on [_____ ___, 201_]. The copy of the Order attached to this Acknowledgment is a true and correct copy of the Order it received.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on [_____ __, 201_].

[NAME]
[*Officer*] of Chemence, Inc.

State of _____, City of _____

Subscribed and sworn to before me
this _____ day of _____, 201__.

_____
Notary Public

My commission expires:

_____

Case: 1:16-cv-00228-PAG Doc #: 53 Filed: 10/13/16 14 of 14. PageID #: 584

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

FEDERAL TRADE COMMISSION Plaintiff, v. CHEMENCE, INC., an Ohio corporation, Defendant.	Case No. 1:16-cv-228-PAG **ACKNOWLEDGMENT BY DECLARATION OF RECEIPT OF ORDER BY NON PARTY**

I, _____, received a copy of the Stipulated Order for Permanent Injunction and Monetary Judgment, in *FTC v. Chemence, Inc.*, on _____ ___, 20___.

I was not a Defendant in that court case. My title or relationship with Defendant Chemence, Inc. is _____.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on _____ __, 20__.

Signed:

Exhibit C

WILSON & WILSON CO., L.P.A.
16716 Chillicothe Road, Suite 100
Chagrin Falls, Ohio 44023

Telephone
(440) 708-0445
Robert D. Wilson*+
E-mail: rdwilson@wwcolpa.com
Licensed: *Ohio; +Georgia

Fax
(440) 708-0511
Michael J. Wilson*
mjwilson@wwcolpa.com

October 17, 2017

SENT VIA EMAIL ONLY TO DEbrief@ftc.gov

Re: FTC v. Chemence, Inc.
Case No.: 1:16-cv-228
U.S. District Court, Northern District of Ohio

To whom it may concern:

Enclosed please find the attached compliance report from Chemence, Inc. pursuant to the Stipulated Order for the above mentioned case. Also attached are Acknowledgements and a Product Labeling Schedule as part of such compliance report.

Should you have any questions, comments or need further information, please feel free to contact me.

Sincerely,

Robert D. Wilson

Enclosures

Complaint

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

FEDERAL TRADE COMMISSION,	)	
	)	
Plaintiff,	)	
	)	Case No.: 1:16-cv-228
v.	)	
	)	
CHEMENCE, INC.	)	
	)	
Defendant.	)	

CHEMENCE, INC.'S ONE YEAR COMPLIANCE REPORT PURSUANT TO STIPULATED ORDER FOR PERMANENT INJUNCTION AND MONETARY JUDGMENT

Defendant Chemence, Inc. ("Chemence") hereby submits the following compliance report pursuant to the Stipulated Order for Permanent Injunction and Monetary Judgment (the "Order") on or about one year after entry of the Order, which was entered in this case on October 13, 2016. As required by Section V. COMPLIANCE REPORTING A.(d) of the Order, this report describes in detail whether and how Chemence is in compliance with each Section of this Order.

DETAILED DESCRIPTION OF CHEMENCE'S COMPLIANCE EFFORTS

As required by the Order, this section describes in detail "whether and how Defendant is in compliance with each Section of this Order." Specifically, the actions Chemence has taken and is taking to comply with each Section of the Order are described below. To assure future compliance with the Order, Chemence has instructed members of its respective staffs having responsibility for the requirements of the Order and of their responsibility to ensure compliance with the Order. The specific contents of those instructions reflect confidential legal advice and are protected from disclosure pursuant to the attorney-client privilege and the work product doctrine. Because the Order principally restricts deceptive acts or practices in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, in the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of cyanoacrylate glue as "Made in the USA," which is already subject to the supervision and control of its respective key personnel in the ordinary course of Chemence's business, Chemence is confident that those instructions are sufficient to ensure compliance with the Order. Nonetheless, where Chemence believes that additional measures are prudent to further compliance with specific provisions of the Order, they are further described below.

I. PROHIBITION AGAINST MISREPRESENTATIONS

Section I prohibits Chemence and its officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of cyanoacrylate glue or any other Product or Service from misrepresenting, expressly or by implication, that a Product or Service is Made in the United States, unless:

1. The final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States; or
2. A clear and conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients, and/or processing.

Chemence has informed current employees and will inform new employees responsible for manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of cyanoacrylate glue or any other Product or Service regarding the requirements of this Order. In compliance with the Order, Chemence has changed the labeling on all of Chemence's cyanoacrylate glue/superglue adhesive products sold, distributed, or offered for sale or distribution, by or on behalf of Chemence to consumers to read "Made in USA with US and globally sourced materials." The labels on Chemence's products for industrial and non-consumer use do not reference any country of origin so that no change in labeling was required in connection with the Order. See the attached Products Schedule for revised product labeling. In addition, Chemence has informed affected business customers of the Order and its requirements and that Chemence has changed the labeling on all of Chemence's cyanoacrylate glue/superglue adhesive products sold, distributed or offered for sale or distribution, by or on behalf of Chemence to consumers to read "Made in USA with US and globally sourced materials." These actions are in fulfillment of the implementation plan previously submitted by Chemence to the FTC to comply with the Order.

II. MEANS AND INSTRUMENTALITIES

Section II prohibits Chemence and its officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of cyanoacrylate glue or any other Product or Service from providing to others the means and instrumentalities with which to make any representation prohibited by Part I above.

Chemence has informed current employees and will inform new employees responsible for manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of cyanoacrylate glue or any other Product or Service regarding the requirements of this Order regarding use by trade customers in their marketing of any Product or Service. Chemence has informed its affected business customers of the Order and its requirements and that Chemence has changed the labeling on all of Chemence's cyanoacrylate glue/superglue adhesive products

sold, distributed or offered for sale or distribution, by or on behalf of Chemence to consumers to read "Made in USA with US and globally sourced materials." In addition, customers are not permitted to unilaterally change any advertising, labeling, promotional, sales training, or substantiation materials provided to them by Chemence. Furthermore, any advertising, labeling, promotional, sales training, or substantiation materials desired to be used by customers, which was not provided to them by Chemence, must be approved by Chemence in advance of use. Since the date of the Order, Chemence has not approved any customer initiated material changes for use and is in compliance with this Section.

III. MONETARY JUDGMENT

Section III required Chemence to pay the FTC Two Hundred Twenty Thousand Dollars ($220,000) as equitable monetary relief. Chemence complied with this requirement by timely paying the FTC Hundred Twenty Thousand Dollars ($220,000) on or about October 20, 2016. The rest of Section III does not impose any other relevant compliance obligations on Chemence.

IV. ORDER ACKNOWLEDGMENTS

Section IV imposes certain obligations on Chemence to obtain acknowledgments of receipt of the Order and deliver a copy to all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities. From each individual or entity to which Chemence delivered a copy of this Order, Chemence must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order. Chemence has complied with this Section by delivering the Order to and receiving Acknowledgements from the following individuals:

Hugh V. Cooke – Chief Executive Officer and Director;
James Cooke – President and Director;
Michael Pomykala - Global Marketing Director; and
Jason Schmidt – Controller.

V. COMPLIANCE REPORTING

Section V imposes certain obligations on Chemence to make timely submissions to the Commission one year after entry of the Order by submitting this Compliance Report. Chemence must do the following:

A. (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant;

James Cooke – President
185 Bluegrass Valley Parkway, Alpharetta, GA 30005

jcooke@chemence.com
Phone no. 404-434-8327

(b) identify all of Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses;

Chemence, Inc.
770-664-6624
185 Bluegrass Valley Parkway, Alpharetta, GA 30005
http://www.chemence.com/

(c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales;

Chemence is considered a single business. Chemence is a specialty performance chemical manufacturer that sells formulated resins. Product lines include adhesives for industrial, medical and consumer applications, photopolymers for flexographic printing and hand stamps, and vacuum impregnation sealants to seal porous metal castings. Chemence products are sold and marketed in business-to-business and business-to-consumer segments. The consumer product line is sold directly to major retailers and private labeled goods. The industrial product lines (including adhesives, photopolymers and impregnation sealants) are sold to industrial customers either directly or through distribution channels. Advertising for all product lines include a high mix of tradeshows, print ads, social media channels, digital ads and direct selling.

(d) describe in detail whether and how Defendant is in compliance with each Section of this Order;

As described in this Compliance Report.

(e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

Attached hereto.

B. For 20 years after entry of this Order, Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following: (a) any designated point of contact; or (b) the structure of Defendant any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

There have been no such changes since the date of the Order.

C. Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Defendant within 14 days of its filing.

There have been no such proceedings since the date of the Order.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746.

Such oath has been stated hereinafter.

E. All submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov with the subject line beginning: FTC v. Chemence, Inc.

This Compliance Report was emailed to DEbrief@ftc.gov with such subject line.

VI. RECORDKEEPING

Section VI. imposes obligations on Chemence to create certain records for 20 years after entry of the Order, and retain each such record for 5 years. Chemence must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold;

These accounting records have been and will be created and retained for the specified periods.

B. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

These personnel records have been and will be created and retained for the specified periods.

C. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

These compliance records have been and will be created and retained for the specified periods.

D. A copy of each unique advertisement or other marketing material;

Unique advertisement and marketing materials have been and will be retained for the specified periods.

E. All materials that were relied upon in disseminating the representation;

All materials that were relied upon in disseminating the representation have been and will be retained for the specified periods.

F. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon

for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

All tests, reports, studies, surveys, demonstrations, or other evidence in Chemence's possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations have been and will be retained for the specified periods.

VII. COMPLIANCE MONITORING

Section VII imposes certain obligations on Chemence to timely respond to requests of the Commission. Also, the Commission is authorized to communicate directly with Chemence and Chemence must permit representatives of the Commission to interview any employee or other person affiliated with Chemence who has agreed to such an interview. Further, the Commission may use all other lawful means, including posing, through its representatives as consumers, suppliers, or other individuals or entities, to Chemence or any individual or entity affiliated with Chemence, without the necessity of identification or prior notice.

This Section does not impose any current compliance obligation on Chemence, since to the best of Chemence's information, knowledge and belief there have been no such requests, communication initiatives or posing by the Commission after the date of the Order. However, should Chemence receive any requests, communication initiatives or posing by the Commission, Chemence will comply with the requirements of Section VII. of the Order.

VIII. RETENTION OF JURISDICTION

Section VIII orders that the trial Court retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

Section VIII of the Order does not impose any relevant compliance obligations on Chemence.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: October 13, 2017

Chemence, Inc:

By: James Cooke
Its: President

Complaint

Chemence, Inc. Product Labeling Schedule	
Line Item No.	**Labeling: Revised = "Made In USA with US and globally sourced materials" or "blank" for no country of origin marking**
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000000FN300	
000000MSA	
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034-WC1	
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035563/8928340	
035578/ 8930453	
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041-WC1	
042-WC1	
060-WC1	
080-WC1	
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Complaint

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503 5000S	REVISED
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509 534 AC70	
509 541 SIGEL	
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511 590 FM0003	
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534 BOG304
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534 DGBGL04
534 DGBL04
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534 KBGL05C
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539 173 6643
539 173 6650
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539 595 6673
539 595 6687
539 600 DD6585
539 600 DD6612

Complaint

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576 186 SI1500
576 186 SI5
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585 554 SI1500
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Complaint

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Complaint

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647 071 TL62

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661 015 SI300		
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661 731 AC45		
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665 030-WC1		
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690 995 0012CLP	REVISED
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694 02421	REVISED
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694 725 002995	REVISED
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Complaint

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JS60100CFX		
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JS9LB3XPX		
JSBLK1GALBT		
JSCGPS6JEHW		
JSCL350		
JSDAYTSVC		
JSDIEMSVC		
JSDRVX364		
JSESCLN1LT		
JSFEEDCTRL		
JSJC1GAL		
JSJC55GAL		
JSM1000CLNM01K		
JSM1000CLNM02C		
JSM1000CLNM03M		
JSM1000CLNM04Y		
JSM1000KAPI01K		
JSM1000KAPI02C		
JSM1000KAPI03M		
JSM1000KAPI03R		
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JSM1000SPI04-Y		
JSPM24100		
JSPROX344		
JSPROX364		

JSRIPDRV	
JST69CLNSOL	
JSTECTRV	
JSV24200	
JSV44200	
JSV60200	
JSX364CR24	
SB311M	
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VB50801252	
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ZRM105	
ZRM94	

Complaint

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

FEDERAL TRADE COMMISSION Plaintiff, v. CHEMENCE, INC., an Ohio corporation, Defendant.	Case No. 1:16-cv-228-PAG **ACKNOWLEDGMENT BY DECLARATION OF RECEIPT OF ORDER BY NON PARTY**

I, Hugh Cooke, received a copy of the Stipulated Order for Permanent Injunction and Monetary Judgment, in *FTC v. Chemence, Inc.*, on October 13, 2016.

I was not a Defendant in that court case. My title or relationship with Defendant Chemence, Inc. is Chief Executive Officer and Director.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on Oct. 17, 2016.

Signed: X

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

FEDERAL TRADE COMMISSION Plaintiff, v. CHEMENCE, INC., an Ohio corporation, Defendant.	Case No. 1:16-cv-228-PAG **ACKNOWLEDGMENT BY DECLARATION OF RECEIPT OF ORDER BY NON PARTY**

I, James Cooke, received a copy of the Stipulated Order for Permanent Injunction and Monetary Judgment, in *FTC v. Chemence, Inc.*, on October 13, 2016.

I was not a Defendant in that court case. My title or relationship with Defendant Chemence, Inc. is President and Director.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on Oct. 17, 2016.

Signed: X

Complaint

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

FEDERAL TRADE COMMISSION Plaintiff, v. CHEMENCE, INC., an Ohio corporation, Defendant.	Case No. 1:16-cv-228-PAG **ACKNOWLEDGMENT BY DECLARATION OF RECEIPT OF ORDER BY NON PARTY**

I, Michael Pomykala, received a copy of the Stipulated Order for Permanent Injunction and Monetary Judgment, in *FTC v. Chemence, Inc.*, on October 13, 2016.

I was not a Defendant in that court case. My title or relationship with Defendant Chemence, Inc. is Global Marketing Director.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on Oct. 17, 2016

Signed: X

Exhibit C
p. 32 of 33

Case: 1:16-cv-00228-PAG Doc #: 53 Filed: 10/13/16 14 of 14. PageID #: 584

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

FEDERAL TRADE COMMISSION Plaintiff, v. CHEMENCE, INC., an Ohio corporation, Defendant.	Case No. 1:16-cv-228-PAG **ACKNOWLEDGMENT BY DECLARATION OF RECEIPT OF ORDER BY NON PARTY**

I, Jason Schmidt, received a copy of the Stipulated Order for Permanent Injunction and Monetary Judgment, in *FTC v. Chemence, Inc.*, on October 13, 2016.

I was not a Defendant in that court case. My title or relationship with Defendant Chemence, Inc. is Controller.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on Oct 17, 2016

Signed: x J. P Schmidt

Exhibit C
p. 33 of 33

Complaint

Exhibit D

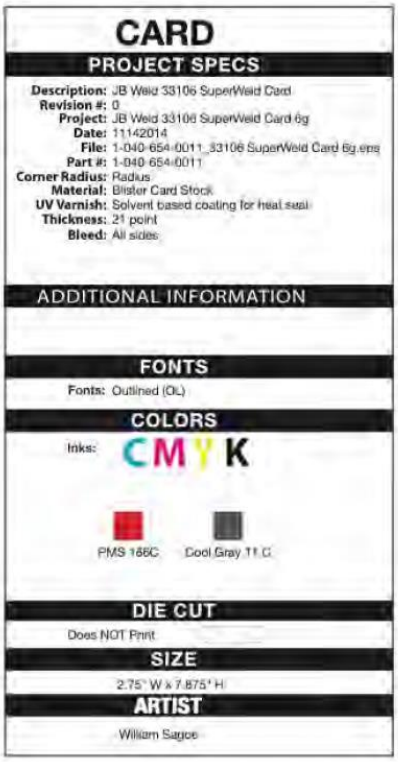

Exhibit D
p. 2 of 6

Complaint

Exhibit D
p. 3 of 6

Complaint

Exhibit D
p. 4 of 6

SAATI
201 Fairview St. Extension
Fountain Inn, SC 29644
Tel: 800-431-2200
Fax: 864-862-0089
Hours: Monday - Friday 8:30am - 5:00pm EST
www.saati.com
Email: info.us@saati.com

24-hour Emergency Telephone (Infotrac in US): 1-800-535-5053
International: +1-352-323-3500

Trademark of The SAATI Group

FOR INDUSTRIAL USE ONLY

FIRST AID
EYES: Flush with water, seek medical attention.
SKIN: Soak in warm soapy water.
INGESTION: Ingestion not likely due to polymerization.
INHALATION: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

SPILL RESPONSE
Ventilate area of spill. Flood area with water to polymerize. Absorb with sand / earth and dispose in accordance with local, state, and federal regulations.

STORAGE AND HANDLING
Material should be stored at or below 22C. Avoid skin contact and inhalation of vapor.

SAATI

ULTRAFIX CA - MV

1 Part Cyanoacrylate Spray- Activated Frame Adhesive

DIRECTIONS FOR USE: To obtain optimal adhesion, degrease the frame. Stretch the fabric over the frame providing good contact between the two. Squeeze a thin bead of adhesive onto fabric around the frame perimeter and spread evenly. Lightly spray the applied adhesive with Ultrafix CA Activator A (aerosol) or Ultrafix CA Activator P (pump style), which sets in less than 30 seconds. Release tension and remove the screen from the stretching system.

FIRE RESPONSE
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Wear self contained breathing apparatus for fire fighting if necessary.

WARNING

SCAS03300LOZ16

7XXXXXXXXXX

16 OZ

GHS CLASSIFICATIONS
Skin Irritation, Category 3 Eye Irritation, Category 2A Flammable Liquids, Category 4

HAZARD STATEMENTS
H227 : Combustible liquid. **H316** : Causes mild skin irritation. **H319** : Causes serious eye irritation.

PRECAUTIONARY STATEMENTS
P210 : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. **P280** : Wear protective gloves/protective clothing/eye protection/face protection. P264: Wash skin thoroughly after handling. P370+P378: In case of fire: Use water spray, alcohol resistant foam, dry chemical or carbon dioxide to extinguish. **P332+P313** : If skin irritation occurs: Get medical advice/attention. **P305+P351+P338** : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P337+P313** : If eye irritation persists: Get medical advice/attention. **P403** : Store in a well-ventilated place. P501: Dispose of contents/container in accordance to federal/state/local regulations.

MADE IN THE USA 02/26/2020

Exhibit D
p. 5 of 6

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

    a. Respondent Chemence, Inc., an Ohio corporation with its principal office or principal place of business at 185 Bluegrass Valley Parkway, Alpharetta, GA 30005.

    b. Respondent James Cooke, an officer of the Corporate Respondent, Chemence, Inc. Individually or in concert with others, he controlled or had the authority to control, or participated in the acts and practices of Chemence, Inc. His principal office or place of business is the same as that of Chemence, Inc.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "**Clear(ly) and conspicuous(ly)**" means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

    1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure ("triggering representation") is made through only one means.

    2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

    3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

    4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.

5. On a product label, the disclosure must be presented on the principal display panel.

6. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the triggering representation appears.

7. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.

8. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.

9. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

B. "**Made in the United States**" means any representation, express or implied, that a product or service, or a specified component thereof, is of U.S.-origin, including, but not limited to, a representation that such product or service is "made," "manufactured," "built," "produced," or "crafted" in the United States or in America, or any other U.S.-origin claim.

C. "**Respondents**" means the Corporate Respondent and the Individual Respondent, individually, collectively, or in any combination.

1. "Corporate Respondent" means Chemence, Inc., and its successors and assigns.

2. "Individual Respondent" means James Cooke.

Provisions

I.
Prohibited Misrepresentations Regarding U.S.-Origin Claims

IT IS ORDERED that Respondents, and Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any cyanoacrylate glue product, or any other product or service, must not make any representation, expressly or by implication, that a product is Made in the United States unless:

A. The final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and

all or virtually all ingredients or components of the product are made and sourced in the United States; or

B. A Clear and Conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients or components, and/or processing; or

C. For a claim that a product is assembled in the United States, the product is last substantially transformed in the United States, the product's principal assembly takes place in the United States, and United States assembly operations are substantial.

II.
Prohibited Misleading and Unsubstantiated Country-of-Origin Representations

IT IS FURTHER ORDERED that Respondents, and Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any cyanoacrylate glue product, or any other product or service, must not make any representation, expressly or by implication, regarding the country of origin of any product or service unless the representation is non-misleading, including that, at the time such representation is made, Respondents possess and rely upon a reasonable basis for the representation.

III.
Means and Instrumentalities

IT IS FURTHER ORDERED that Respondents, and Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any cyanoacrylate glue product, or any other product or service, must not provide to others the means and instrumentalities with which to make any representation prohibited by Provision I or II above. For the purposes of this Provision, "means and instrumentalities" means any information, including, but not necessarily limited to, any advertising, labeling, promotional, sales training, or purported substantiation materials, for use by trade customers in the marketing of any product or service.

IV.
Monetary Relief

IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $1,200,000, which Respondents stipulate their undersigned counsel holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

V.
Additional Monetary Provisions

IT IS FURTHER ORDERED that:

A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondents have no right to challenge any activities pursuant to this Provision.

E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10

days beyond the date that payment is due, the entire amount will immediately become due and payable.

F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.

G. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers) may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

VI.
Customer Information

IT IS FURTHER ORDERED that Respondents must directly or indirectly provide sufficient customer information, including sufficient identification of all resellers, to enable the Commission to efficiently administer consumer redress. If a representative of the Commission requests in writing any information related to redress, Respondents must provide it, in the form prescribed by the Commission representative, within 14 days.

VII.
Notice to Customers

IT IS FURTHER ORDERED that Respondents must notify customers as follows:

A. Respondents must identify all third-party trade customers who purchased pre-labeled or pre-packaged cyanoacrylate glue products from Corporate Respondent with unqualified representations that the products were Made in the United States on or after October 13, 2016 ("Eligible Customers").

1. Such Eligible Customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody, or control;

2. Eligible Customers include those identified at any time, including after Respondents' execution of the Agreement through the eligibility period, which runs for 1 year after the issuance date of the Order.

B. Respondents must notify all identified Eligible Customers by mailing or emailing each a notice in the form shown in Attachment A. The communication containing the notification letter may contain a copy of this Order, but no other document or enclosure.

C. Respondents must notify all Eligible Customers within 30 days after the issuance date of this Order and any Eligible Customers identified thereafter within 30 days of their identification.

D. Respondents must report on their notification program under penalty of perjury:

1. Respondents must submit a report within 60 days of entry of this Order and at the conclusion of the program summarizing its compliance to date.

2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Respondents must submit it within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

VIII.
Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. Individual Respondent, for any business that such Respondent, individually or collectively with Corporate Respondent, is the majority owner or controls directly or indirectly, and Corporate Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

IX.
Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondent must describe if he knows or should know due to his own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services, whether as an employee or otherwise, and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. Each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services, whether as an employee or otherwise, and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Chemence, Inc., X160032.

X.
Recordkeeping

IT IS FURTHER ORDERED that Respondents must create certain records and retain each such record for 5 years. Specifically, Corporate Respondent and Individual Respondent, for any business that such Respondent, individually or collectively with Corporate Respondent, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. Personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. Records of all customer complaints and refund requests concerning the subject matter of this Order, whether received directly or indirectly, such as through a third party, and any response;

D. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. A copy of each unique advertisement, label, or other marketing material making a representation subject to this Order; and

F. For 5 years from the date of the last dissemination of any representation covered by this Order, all materials that were relied upon in making the representation.

XI.
Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Respondent, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XII.
Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court

alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ATTACHMENT A: NOTICE TO CUSTOMERS

The notification email or letter must be in the following form, from an authorized Chemence, Inc. address or email address, appearing on Chemence, Inc.'s letterhead if in letter form, and containing a Chemence, Inc. signature line with the sender's full contact information:

Subject: Settlement of FTC deceptive advertising case

Dear <Name of customer>:

Our records show that you bought cyanoacrylate glue products from Chemence, Inc. that we provided to you in packages or with labels making "Made in USA" claims. We're writing to tell you that the Federal Trade Commission, the nation's consumer protection agency, has sued us for deceptive or false advertising. According to the FTC, we made misleading claims that our glues were all or virtually all made in the United States.

To settle the FTC's lawsuit, we're contacting our customers to tell them that our cyanoacrylate glue products contain significant imported ingredients and therefore should have been labeled with qualified claims – for example, "Made in USA with Globally Sourced Materials."

If you have questions about this lawsuit, visit [get short URL]. For more information about "Made in USA" advertising, visit [get short URL].

Sincerely,

[signature]
[Chemence, Inc. signature block]

STATEMENT OF COMMISSIONER ROHIT CHOPRA

Summary

- Made in USA fraud harms both consumers and honest competitors. Yet for decades, FTC Commissioners pursued a no-money, no-fault settlement strategy to tackle this problem, ignoring Congressional authority to penalize bad actors.

- Over the last two years, the Commission has begun to turn the page on its checkered record, obtaining significant judgments for Made in USA fraud and initiating a rulemaking to trigger damages and penalties.

- Today's action against Chemence and a top executive is another step forward in protecting the Made in USA brand and restoring the Commission's law enforcement credibility.

For markets to function fairly, the Federal Trade Commission must be a credible watchdog, ensuring that companies have an incentive to follow the law and adhere to the agency's rules and orders. Corporate defendants that blatantly lie about their products have been able to convince Commissioners that their conduct caused no harm, allowing them to extract settlements with virtually no consequences whatsoever. Robert Pitofsky, who served as a Commissioner and later as the agency's Chairman, described these no-money, no-fault orders as "scandalously weak."[1]

Longstanding FTC policies recognize that blatant deception harms consumers and diverts sales from honest competitors.[2] But, over the years, Commissioners quietly adopted a permissive

1 *See* Irving Scher et al., *Part II – FTC Improvement Act*, 45 ANTITRUST L.J. 96, 117 (1976).

2 For example, the Commission's Policy Statement on Deception notes that "[t]he prohibitions of Section 5 are intended to prevent injury to competitors as well as to consumers." FTC Policy Statement on Deception, 103 F.T.C. 174, 175 (1984) (appended to Cliffdale Assocs., Inc., 103 F.T.C. 110 (1984)), https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception.

approach toward corporate fraud, while bringing down the hammer on small, fly-by-night operations. Going hard on small businesses can give the appearance of active enforcement, even as more established companies face few consequences for their wrongdoing.

However, there are promising signs that this is changing. One of the best examples of our moving away from lax enforcement is our Made in USA fraud program. Today, the Commission is announcing another action against an established corporate actor, showing we are turning the page on our permissive policy of the past.

FTC's Flawed Made in USA Enforcement Strategy

Consumers prefer goods that are produced domestically, and they are even willing to pay more for them.[3] This gives bad actors an incentive to unlawfully parade their products with the "Made in USA" brand. Government enforcement can ensure that this strategy does not pay off.

However, for decades, there was bipartisan consensus at the Federal Trade Commission that Made in USA fraud should not be penalized. Even in egregious cases, most matters were resolved with no-money, no-fault settlements, and many violators received nothing more than closing letters. In 1994, Congress authorized the Commission to do more – granting the agency new authority to trigger penalties and damages for Made in USA fraud – but past Commissioners declined to even propose implementing this new authority, allowing it to languish for a quarter century.[4]

This lack of deterrence contributed to brazen Made in USA fraud, as seen in some of the Commission's recent cases. In 2018, for example, the FTC sued Patriot Puck, which branded its product as "The Only American Made Hockey Puck." In fact, according to the Commission's lawsuit, these pucks were made in China.[5] That same year, the FTC sued a seller of military bags

3 *See, e.g.*, Kong, Xinyao and Rao, Anita (June 8, 2020). "Do Made in USA Claims Matter?," University of Chicago, Becker Friedman Institute for Economics Working Paper No. 2019-138, Available at SSRN: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3468543.

4 *See generally* Statement of Commissioner Rohit Chopra Regarding Activating Civil Penalties for Made in USA Fraud (Apr. 17, 2019), https://www ftc.gov/public-statements/2019/04/statement-commissioner-rohit-chopra-regarding-activating-civil-penalties. In fact, under pressure from interest groups in the 1990s, Commissioners tried to weaken the Made in USA standard in light of globalized supply chains. Request for Public Comment on Proposed Guides for the use of U.S. Origin Claims, 62 Fed. Reg. 25020 (May 7, 1997), https://www.govinfo.gov/content/pkg/FR-1997-05-07/pdf/97-11814.pdf. *See also* Bruce Ingersoll, *FTC May Ease Its Guidelines For the 'Made in USA' Label*, WALL STREET J. (May 6, 1997), https://www.wsj.com/articles/SB862863598530948000. This effort was widely opposed, and it failed. *See* Matthew Bales, Jr., *Implications and Effects of the FTC's Decision to Retain the "All or Virtually All" Standard*, 30 U. MIAMI INTER-AM. L. REV. 727 (1999).

5 Press Release, Fed. Trade Comm'n, FTC Approves Final Consents Settling Charges that Hockey Puck Seller, Companies Selling Recreational and Outdoor Equipment Made False 'Made in USA' Claims (Apr. 17, 2020), https://www.ftc.gov/news-events/press-releases/2019/04/ftc-approves-final-consents-settling-charges-hockey-puck-seller; Statement of Commissioner Rohit Chopra In the Matter of Nectar Sleep, Sandpiper/PiperGear USA, and Patriot Puck (Sep. 12, 2018), https://www ftc.gov/public-statements/2018/09/statement-commissioner-chopra (hereinafter Dissenting Statement on No-Consequences Made in USA Settlements).

and other gear, charging the firm with inserting fraudulent Made in USA labels into imported products, and marketing these products on military bases.[6] These practices harmed both consumers and honest competitors.[7]

Even firms that the FTC warned were seemingly undeterred. In 2017, the FTC required iSpring Water Systems to stop mislabeling its products. Last year, iSpring violated this order.[8] In 2018, the FTC warned Williams-Sonoma to stop falsely marketing products as Made in USA;[9] earlier this year, they were charged with doing it anyway.[10] The fact that these repeat offenders were caught is a testament to our staff's vigilance, but offenders' willingness to break the law twice demonstrates the flaws of the strategy pursued by past Commissions.

Recently, we have seen how that strategy is changing. iSpring was ordered to pay a civil penalty, and the company admitted that it broke the law. Williams-Sonoma was required to pay $1 million to resolve the Commission's allegations – a small sum, perhaps, for Williams-Sonoma, but a record for the FTC's Made in USA enforcement program. And in July, the Commission *finally* proposed codifying the Made in USA standard into a rule.[11] This rule would help to end the agency's reliance on no-money settlements, allowing the Commission to seek civil penalties, damages, and other sanctions for Made in USA violations.[12]

Turning the Page

Today's action against Chemence and its top executive marks another turning point for the FTC's enforcement strategy. Chemence is an established player in the adhesives and sealants

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6 *Id.*

7 In fact, one competitor formally complained to the FTC that it lost out on a valuable Army and Air Force exchange listing based on Sandpiper's deception. *See* Advantus, Corp. (Comment #5) at 3–4, https://www.ftc.gov/system/files/documents/public_comments/2018/10/00005-155955.pdf.

8 Press Release, Fed. Trade Comm'n, Marketer of Water Filtration Systems to Pay $110,000 Civil Penalty for Deceptive Made-in-USA Advertisements in Violation of 2017 Order (Apr. 12, 2019), https://www ftc.gov/news-events/press-releases/2019/04/marketer-water-filtration-systems-pay-110000-civil-penalty.

9 Closing letter to Danielle M. Hohos, Esq., Deputy General Counsel for Williams-Sonoma, Inc. (June 13, 2018), https://www.ftc.gov/system/files/documents/closing_letters/nid/musa_williams-sonoma_closing_letter.pdf.

10 Press Release, Fed. Trade Comm'n, Williams-Sonoma, Inc. Settles with FTC, Agrees to Stop Making Overly Broad and Misleading 'Made in USA' Claims about Houseware and Furniture Products (Mar. 30, 2020), https://www.ftc.gov/news-events/press-releases/2020/03/williams-sonoma-inc-settles-ftc-agrees-stop-making-overly-broad.

11 Press Release, Fed. Trade Comm'n, FTC Issues Staff Report on Made in USA Workshop, Seeks Comment on Related Proposed Rulemaking for Labeling Rule (June 22, 2020), https://www ftc.gov/news-events/press-releases/2020/06/ftc-issues-staff-report-on-made-in-usa-workshop.

12 Of course, not every Made in USA violation requires a lawsuit, or justifies a large judgment. But seeking and accepting no money and no meaningful consequences undermines our credibility.

business. The order announced today imposes real consequences – a major difference from the Commission's past Made in USA settlements.

First, the proposed order requires Chemence to forfeit $1.2 million in revenue stemming from the company's failures. This is another record judgment for the FTC's Made in USA enforcement program, and it represents a sea change from the era of no-money settlements. It is encouraging to see the FTC reducing its reliance on no-money orders, both here and in other program areas.

Second, this order reminds businesses that FTC orders are not suggestions.[13] The FTC's complaint highlights false compliance reports filed by Chemence, and charges the company's president personally for his involvement in the alleged violations.[14] This stands in stark contrast to other actions against repeat offenders, where the FTC granted broad releases to executives who oversaw egregious violations. The approach in this matter is far more effective.[15]

Third, the proposed order requires Chemence to notify consumers of this action. Notice confers benefits in cases like this. It helps to erase any competitive advantage a firm realized through deception, and it accords consumers the dignity of knowing what happened. I have long argued we should seek notice in Made in USA and other matters,[16] and I am pleased to see this provision incorporated into this enforcement action.

Our new approach is a critical step forward for protecting the Made in USA brand, and it is a model for other FTC enforcement areas. There is more work to do, including finalizing a Made in USA fraud rule, but we are clearly moving in the right direction.

While it is tempting for any government agency to think that the status quo is working well, we do our best work when we engage in self-critical analysis and strive for continuous improvement. I congratulate all of the agency's staff who fought for this outcome, as well as the many stakeholders who have worked with us to turn the page on the policy inherited from our predecessor Commissioners.[17] These efforts to reboot the Made in USA enforcement program represent real progress.

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13 Memorandum from Commissioner Chopra to FTC Staff Regarding Repeat Offenders (May 14, 2018), https://www.ftc.gov/public-statements/2018/05/commissioners-memorandum-2018-01-repeat-offenders.

14 Compl. ¶¶ 13-16, *In the Matter of Chemence, Inc. et al.*, Docket No. X160032.

15 In addition, by filing this case administratively, the Commission has triggered civil penalties for future violations, even if in the absence of a final Made in USA fraud rule.

16 Dissenting Statement on No-Consequences Made in USA Settlements, *supra* note 4, https://www.ftc.gov/system/files/documents/public_statements/1407380/rchopra_musa_statement-sept_12.pdf.

17 *See, e.g.*, Press Release, Truth in Advertising, Inc. (TINA.org), Ad Watchdog TINA.org Petitions FTC for Made in USA Rule (Aug. 22, 2019), https://www.truthinadvertising.org/made-in-usa-press-release/; Consumer Reports (Comment #6), https://www ftc.gov/policy/public-comments/2018/10/12/comment-00006-0; Alliance for American Manufacturing (Comment #5), https://www ftc.gov/policy/public-comments/2018/10/12/comment-00005-0.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Chemence, Inc. and James Cooke ("Respondents").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves Respondents' advertising, labeling, sale, and distribution of cyanoacrylate "superglue" products as made in the United States. According to the FTC's complaint, Respondents represented that the cyanoacrylate "superglue" products they manufactured and supplied to trade customers were all or virtually all made in the United States. In fact, significant proportions of the chemical inputs, and overall costs, to manufacture Respondents' cyanoacrylate "superglues" are attributable to foreign materials. In numerous instances, foreign materials accounted for more than 80% of materials costs and more than 50% of overall manufacturing costs for these products. The complaint also alleges that, by distributing promotional materials containing misrepresentations regarding the U.S. origin of their products, Respondents provided trade customers the means and instrumentalities to commit deceptive acts or practices. Based on the foregoing, the complaint alleges that Respondents engaged in deceptive acts or practices in violation of Section 5(a) of the FTC Act, and violated a 2016 federal court order in the process.

The proposed consent order contains provisions designed to prevent Respondents from engaging in similar acts and practices in the future. Consistent with the FTC's Enforcement Policy Statement on U.S. Origin Claims, Part I prohibits Respondents from making U.S.-origin claims for their products unless either: (1) the final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States; (2) a clear and conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients or components, and/or processing; or (3) for a claim that a product is assembled in the United States, the product is last substantially transformed in the United States, the product's principal assembly takes place in the United States, and United States assembly operations are substantial.

Part II prohibits Respondents from making any country-of-origin claim about a product or service unless the claim is true, not misleading, and Respondents have a reasonable basis substantiating the representation.

Part III prohibits Respondents from providing third parties with the means and instrumentalities to make the claims prohibited in Parts I or II.

Parts IV through VI are monetary provisions. Part IV imposes a judgment of $1,200,000. Part V includes additional monetary provisions relating to collections. Part VI requires Respondents to provide sufficient customer information to enable the Commission to administer consumer redress, if appropriate.

Part VII is a notice provision requiring Respondents to identify and notify certain third-party trade customers of the FTC's action within 30 days after the issuance of the order, or within 30 days of the customer's identification, if identified later. Respondents are also required to submit reports regarding their notification program.

Parts VIII through XI are reporting and compliance provisions. Part VIII requires Respondents to acknowledge receipt of the order, to provide a copy of the order to certain current and future principals, officers, directors, and employees, and to obtain an acknowledgement from each such person that they have received a copy of the order. Part IX requires Respondents to file a compliance report within one year after the order becomes final and to notify the Commission within 14 days of certain changes that would affect compliance with the order. Part X requires Respondents to maintain certain records, including records necessary to demonstrate compliance with the order. Part XI requires Respondents to submit additional compliance reports when requested by the Commission and to permit the Commission or its representatives to interview Respondents' personnel.

Finally, Part XII is a "sunset" provision terminating the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

Complaint

IN THE MATTER OF

STEVES DISTRIBUTING, LLC
D/B/A
STEVE'S GOODS,
AND
STEVEN TAYLOR SCHULTHEIS

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4739; File No. 202 3065
Complaint, March 2, 2021 – Decision, March 2, 2021

This consent order addresses Steves Distributing, LLC's advertising of cannabidiol ("CBD") and cannabigerol ("CBG"), cannabinoid compounds found in hemp and cannabis. The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) CBD and CBG products can effectively prevent, treat, or mitigate multiple diseases and other health conditions; and (2) studies or scientific research prove that CBD and CBG products effectively prevent, treat, or mitigate multiple diseases and other health conditions. The consent order requires randomized, double-blind, placebo-controlled clinical testing for the challenged claims or any disease treatment, mitigation, or cure claim for any dietary supplement, food, or drug including but not limited to CBD products or CBG products. The consent order also prohibits other misleading or unsubstantiated representations about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or essentially equivalent product.

Participants

For the *Commission*: *Laura Fremont* and *Ronnie Solomon.*

For the *Respondents*: *David Bush, Donni Emmie,* and *Larry Mishkin, Hoban Law Group.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Steves Distributing, LLC, a limited liability company, and Steven Taylor Schultheis, individually and as an officer and owner of Steves Distributing, LLC (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Steves Distributing, LLC ("Steves"), also doing business as "Steve's Goods," is a limited liability company registered in Colorado, with its principal office or place of business at 1500 Kansas Avenue, Suite 2C, Longmont, Colorado 80501.

2. Respondent Steven Taylor Schultheis ("Schultheis") is the Chief Executive Officer, President, and principal shareholder of Steves. Schultheis currently holds a 95% equity interest in the Company. As founder and CEO, Schultheis has control over the operations and decisions of the Company. Individually or in concert with others, he controlled or had the

authority to control, or participated in the acts and practices of Steves, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Steves.

3. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Respondents' Marketing of CBD and CBG Products

4. Cannabidiol ("CBD") and cannabigerol ("CBG") are non-psychoactive cannabinoids, naturally occurring in, and that can be extracted from, the hemp plant, *cannabis sativa*. CBG is a minor cannabinoid and precursor molecule of CBD and THC. Respondents have manufactured, labeled, advertised, promoted, offered for sale, sold, and distributed products containing CBD ("CBD Products") and products containing CBG ("CBG Products") that are intended for human use. These CBD Products and CBG Products are "food" and/or "drugs," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

5. Steves sells a variety of CBD Products and CBG Products, including but not limited to tinctures, gummies, capsules, topical balms, suppositories, and coffee. Consumers can purchase Steves' CBD Products and CBG Products from Respondents by ordering them through Respondents' website at stevesgoods.com, by telephone, or at a brick and mortar retail store located at 1264 S. Hover Street, Longmont, Colorado 80501.

6. According to the product labels and Steves' website, dosages vary. For example, Steves' website advertises edible CBD gummies containing 10 mg of CBD. One dosage could range from 10 mg to 50 mg, depending on a variety of factors, including the user's weight.

7. Respondents promoted CBD Products and CBG Products through a variety of means, including through their website, stevesgoods.com, and through social media platforms such as Twitter.

8. Schultheis has been directly involved in the promotion and advertising of the Company's CBD and CBG Products. Schultheis appears in the Company's promotional and social media content relating to CBD and/or CBG, and is frequently quoted in press articles about the Company and the CBD and/or CBG industries.

Claims about CBD Products

9. Respondents have disseminated or have caused to be disseminated advertisements for CBD Products, including but not necessarily limited to the attached Exhibits A through F. These advertisements have or had the following statements:

a. Steve's Goods (@stevesgoods)

Endocannabinoid System

The human endocannabinoid system (ECS) is a network of receptors spread through-out our entire body that control some of our most vital life functions, including our immune system, memory, appetite, sleep pattern, mood, and pain sensation.

***Disorders CBD assists with*:**

CTE
Alzheimer's
Glioblastoma
Parkinson's
Amyotrophic Lateral Sclerosis (ALS)
PTSD
Asthma
Hypertension
Crohn's Disease
Irritable Bowel Syndrome
Testicular Cancer
Prostate Cancer
Osteoporosis
Migraines
Multiple Sclerosis
Fibromyalgia
Depression
Epilepsy
Breast Cancer
Diabetes
. . .
Rheumatoid Arthritis

. . .

CBD (Hemp Extract) – Key benefits

Anti-bacterial
Inhibits cancer cell growth
Neuro-protective
Promotes bone growth
Reduces seizures and convulsions
Reduces blood sugar levels
. . .
Reduces risk of artery blockage

. . .
Slows bacterial growth
. . .
Treats psoriasis
Vasorelaxant

[Exhibit A, @stevesgoods, *Twitter*, posted on Aug. 16, 2018, retrieved on July 7, 2020.]

b. Steve's Goods (@stevesgoods)

CBD

Reduces blood sugar levels
Helps control seizures
Reduces risk of nerve damage
Decreases pressure in blood vessels
#StevesGoodies
. . .

[Exhibit B, @stevesgoods, *Twitter*, posted Apr. 17, 2018, retrieved on July 7, 2020.]

c. Steve's Goods (@stevesgoods)

The Endocannabinoid System is where our cannabinoid receptors reside in our body! Project CBD provides a great introductory insight into what the Endocannabinoid System is with references to support their findings.

. . .
Endocannabinoid System

DISORDERS CBD ASSISTS WITH:

PTSD
Alzheimers [sic]
Glioblastoma
Parkinson's
Amyotrophic Lateral Sclerosis (ALS)
Asthma
Hypertension
Crohn's Disease
Irritable Bowel Syndrome
Testicular Cancer
Prostate Cancer
Osteoporosis

Migraines
Multiple Sclerosis
Fibromyalgia
Depression
Epilepsy
Breast Cancer
Diabetes
Rheumatoid Arthritis
. . .

#StevesGoodies
StevesGoods.com

[Exhibit C, @stevesgoods, *Twitter*, posted Aug. 23, 2018, retrieved on July 7, 2020.]

d. **Why CBD Edibles Are A Hot Commodity in 2019 │ Steve's Goods**

. . .

Explaining Commonly Misunderstood Facts About CBD Products and Edibles

. . .

Essentially, store-bought CBD has roughly similar effects to most over-the-counter medications with a far more holistic approach to personal care. Plus, this hemp-derived cannabinoid is available in many different forms including CBD oil, wax, dietary supplement, in addition to edibles.

As such, the familiarity combined with finding the method for delivering effective CBD a [sic] the form that most users are comfortable with makes it easy for everyone to try as an alternative to prescription medications.

[Exhibit D, https://stevesgoods.com/why-cbd-edibles-are-a-hot-commodity, retrieved on Feb. 6, 2020.]

e. **CBD Edibles vs CBD Suppositories: Exploring CBD From Both Ends**

. . .

Plumbing the Depths of CBD Suppository Benefits

. . .

CBD suppositories have been purported to be invaluable for sufferers of digestive-related maladies including Crohn's disease, anal fissures,

irritable bowel syndrome and recurring hemorrhoids due to their specific application to the regions of the body most affected by those ailments.

. . .

CBD is ideal for users with digestive, nausea, or dietary issues

. . .

In addition, suppository CBD is ideal for users with digestive issues, nausea, or dietary issues including diabetes.

[Exhibit E, https://stevesgoods.com/cbd-edibles-vs-cbd-suppositories, retrieved on Feb. 6, 2020.]

f. CBD HEMP OIL TINCTURES

. . .

CBD Oil by Steve's Goods

. . .

As far as benefits, studies have shown that CBD may be useful in helping with pain, inflammation, anxiety, cancer, neuro-disorders, and other health issues all with few if any side effects. It's an exciting time in cannabinoid research.

. . .

CBD Oil Dosage for Anti-Inflammation

When you suffer from day-to-day inflammation, you know it can sneak up on you. . . . If you have inflammation on a regular basis, you may want to supplement with CBD daily.

. . .

There is nothing sweeter than relief from pain, chronic or acute.

. . .

If you have pain on a regular basis, you may want to supplement with CBD daily.

[Exhibit F, https://stevesgoods.com/cbd-oil/, retrieved on Aug. 5, 2020.]

Claims about CBG Products

10. Respondents have disseminated or have caused to be disseminated advertisements for CBG Products, including but not necessarily limited to the attached Exhibits G through I. These advertisements contain the following statements:

a. What is CBG, How Does it Work, & What Are the Potential Benefits?

. . .

Benefits of CBG Oil

. . .

It's been found in research [hyperlink], by the US National Institute [sic] of Health, to inhibit the growth of colon cancer, and has positive effects on glaucoma and irritable bowel syndrome known as IBS.

. . .

[Exhibit G, https://stevesgoods.com/blog/what-is-cbg-oil/, retrieved on Feb. 6, 2020.]

b. Stevesgoods.com:

Studies on CBG have revealed a wide range of possible benefits:

Stimulates bone formation and healing
Slows tumor growth
Antifungal and antibacterial treatment
Relieves pain
Reduces Inflammation
Overactive bladder treatment
Psoriasis and skin treatment
Glaucoma treatment
Depression and anxiety treatment
Neuroprotective effects

[Exhibit H, excerpt from live chat on stevesgoods.com recorded on Jan. 21, 2020.]

c. **The ABCs of CBG - Steves Goods**

. . .

How is cannabigerol used?

. . .

> Various scientific studies have revealed use cases for ailments ranging from ocular diseases to inflammatory bowel conditions. Other studies have shown CBG to carry antibacterial and anti-inflammatory effects on the body.
>
> [Exhibit I, https://stevesgoods.com/abcs-of-cbg/, retrieved on Feb. 6, 2020.]

Count I
False or Unsubstantiated Efficacy Claims Regarding CBD Products

11. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBD Products, Respondents have represented, directly or indirectly, expressly or by implication, that CBD Products:

a. have antibacterial properties;

b. prevent or reduce the risk of artery blockage, heart attacks, heart disease, and stroke;

c. reduce blood sugar levels;

d. promote bone growth;

e. prevent or reduce the risk of nerve damage;

f. prevent or reduce the risk of seizures and convulsions;

g. effectively treat or mitigate Alzheimer's disease, amyotrophic lateral sclerosis, anal fissures, asthma, cancer, chronic inflammation, chronic pain, chronic traumatic encephalopathy, Crohn's disease, depression, diabetes, epilepsy, fibromyalgia, glioblastoma, hemorrhoids, hypertension, irritable bowel syndrome ("IBS"), migraines, multiple sclerosis, neurological disorders, osteoporosis, Parkinson's disease, post-traumatic stress disorder ("PTSD"), psoriasis, rheumatoid arthritis, and seizures; and

h. treat or mitigate diseases and health conditions as effectively as most over-the-counter medications and are effective alternatives to prescription medications.

12. The representations set forth in Paragraph 11 are false or misleading, or were not substantiated at the time the representations were made.

Count II
False or Unsubstantiated Efficacy Claims Regarding CBG Products

13. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBG Products, Respondents have represented, directly or indirectly, expressly or by implication, that CBG Products:

a. have antibacterial properties;

b. stimulate bone formation and healing;

c. have neuroprotective effects; and

d. effectively treat or mitigate cancer, depression, glaucoma, inflammatory bowel conditions, IBS, ocular diseases, overactive bladder, and psoriasis.

14. The representations set forth in Paragraph 13 are false or misleading, or were not substantiated at the time the representations were made.

Count III
False Establishment Claims Regarding CBD Products

15. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBD Products, Respondents have represented, directly or indirectly, expressly or by implication, that studies or scientific research prove that CBD Products effectively treat or mitigate anxiety, cancer, inflammation, neurological disorders, and pain.

16. In fact, studies or scientific research do not prove that CBD Products effectively treat or mitigate anxiety, cancer, inflammation, neurological disorders, and pain. Therefore, the representations set forth in Paragraph 15 are false or misleading.

Count IV
False Establishment Claims Regarding CBG Products

17. In connection with the advertising, promotion, offering for sale, sale, or distribution of CBG Products, Respondents have represented, directly or indirectly, expressly or by implication, that studies or scientific research prove that CBG Products:

a. have antibacterial properties;

b. stimulate bone formation and healing;

c. have neuroprotective effects; and

d. effectively treat or mitigate anxiety, cancer, depression, glaucoma, inflammation, inflammatory bowel conditions, IBS, ocular diseases, overactive bladder, pain, and psoriasis.

18. In fact, studies or scientific research do not prove that CBG Products:

a. have antibacterial properties;

b. stimulate bone formation and healing;

c. have neuroprotective effects; and

d. effectively treat or mitigate anxiety, cancer, depression, glaucoma, inflammation, inflammatory bowel conditions, IBS, ocular diseases, overactive bladder, pain, and psoriasis.

Therefore, the representations set forth in Paragraph 17 are false or misleading.

Violations of Sections 5 and 12

19. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this second day of March, 2021, has issued this Complaint against Respondents.

By the Commission.

Complaint

Exhibit A

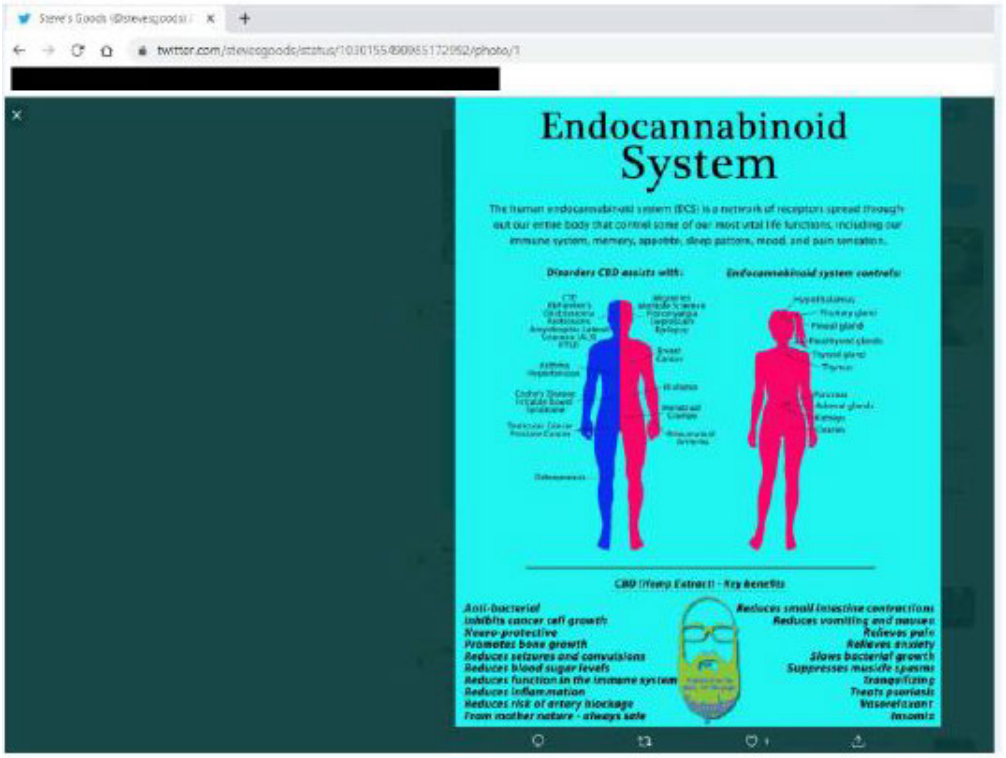
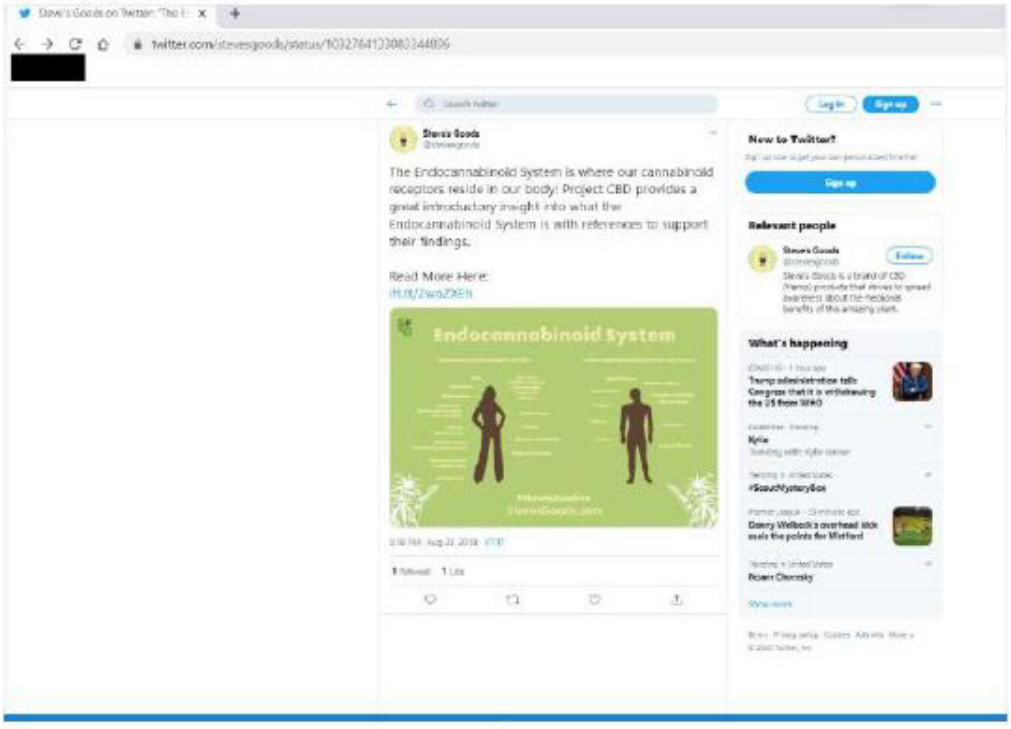


Exhibit B

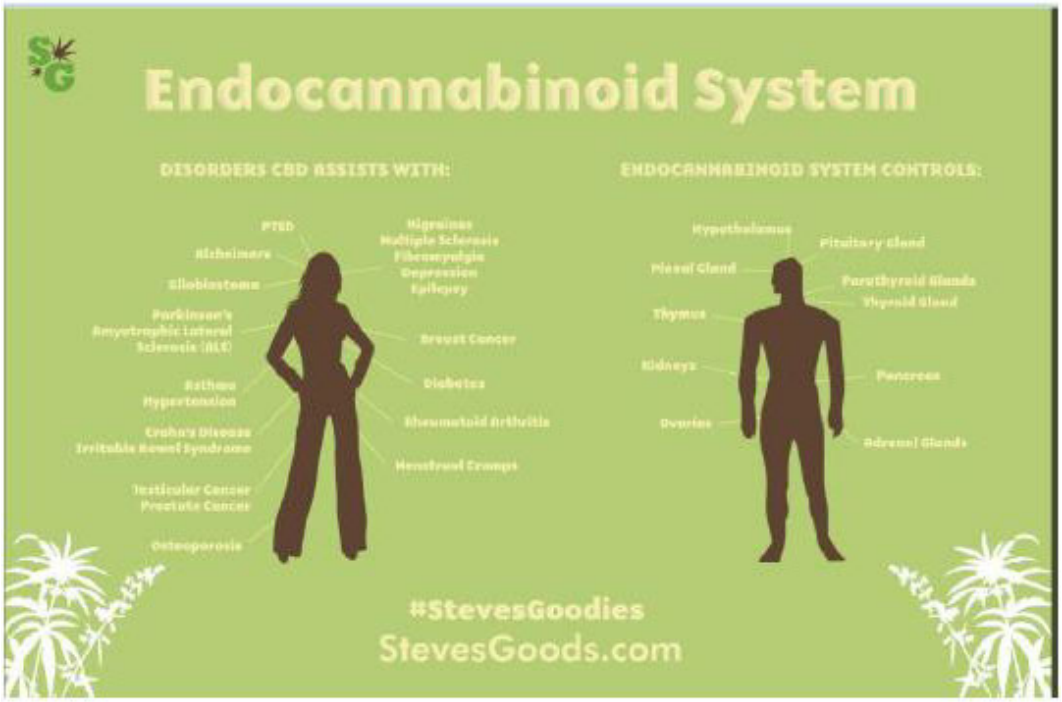

CBD
Reduces blood sugar levels
Helps control seizures
Reduces risk of nerve damage
Decreases pressure in blood vessels
#StevesGoodies

Complaint

Exhibit C



(Blow up of graphic in Tweet, which expands when clicked)



Complaint

Exhibit D

Why CBD Edibles Are A Hot Commodity in 2019 | Steve's Goods

Eli Mann

Get the Supplements Without the Stigma: Why CBD Edibles are Having A Moment

As scientific developments discover new ways to help people live fuller, happier lives, **CBD edibles** have become a popular item found in pockets, purses, and bags all over the world. Offering an unexplored wealth of benefits that may help society address everything from pain relief to anxiety without a doctor's prescription. 2019 seems to be a milestone year in popularity for people taking CBD edibles and supplements for a broad range of purposes – *without the stigma of smoking cannabis.*

One of the most popular methods for ingesting the daily supplements required for the desired results is by taking CBD edibles. However, with all the purported claims regarding how full spectrum CBD products may improve your quality of life, it was important to discover why exactly 2019 seemed to be a renaissance for the popularity of edible CBD. Initially, the boost in visibility came from the quantifiable conclusion of government studies proving that CBD could be used to treat chronic seizures caused by a range of genetic conditions.

Tracing the Popularity of CBD Edibles Through Policy Change

After years of openly advocating the use of hemp-derived supplements, activists were presented with a measure of legitimacy following governmental approval of CBD based product Epidiolex. Though the FDA only approved a single laboratory engineered, synthetic CBD medication, the measurable results of the studies were proof that quality CBD products could possibly be used as a supplement to address other chronic health issues.

Since CBD has no psychotropic effects, it is more easily attainable and sold everywhere from the local health food store to Amazon, an online retailer famously restrictive for the products they allow to be sold through their website. In fact, because it can not be used as a recreational drug and has a low probability for abuse, the DEA reclassified a range of hemp-derived CBD products from Schedule I to Schedule V, **clearly separating it from the rest of the cannabis family.**

With trusted backing from the medical, scientific and governmental communities, people from every corner of society were empowered to sample potable products like CBD gummies, CBD Capsules, and full spectrum CBD coffee. These tasty edibles with CBD incorporated in their creation have been celebrated for their use against chronic pain and social anxiety. Essentially, anyone can have direct access to effective, potent supplements that may help them achieve a level of comfort and normalcy they hadn't imagined possible from over-the-counter medications previously.

Why Users Are Choosing Edible CBD Over Other Methods

Since every form has its compromises, it's crucial to explore edible CBD products specifically to fully understand their recent rise in popularity. In the last ten years, vaping cannabis has enjoyed a renaissance, with a massive number of devices and pre-filled wax cartridges becoming more readily available with the sweeping legalization of medical and recreational marijuana becoming more prevalent. However, it helps to understand that the majority of CBD consumables have minuscule amounts, if any THC, and produce no mind-altering effects.

It is this knowledge that allowed CBD to become a universally accepted way to redefine its context as something completely separate from recreational cannabis. Vaping CBD is a prevalent way to administer it, due largely to the active absorption rate and how quickly it is taken into the bloodstream before being broken down. With that in mind, the intensity of CBD dosage using edibles is milder than inhalation, but still potent enough to deliver an effective amount. **This is especially true when sourcing CBD products purchased from trusted retailers** that provide honest and transparent methods of production and potency.

Although the traditionally tainted context of products with CBD are breaking down leading to wider usage and greater benefit, there is still the desire amongst many users for discretion. As such, items such as edible CBD gummies and lollipops are making it easier than ever to administer the dosages for everyone's needs without shouting it from the rooftops. They travel well, don't require any equipment, and can be taken in any social setting – which makes taking CBD edibles in public even more commonplace than popping a multivitamin.

Explaining Commonly Misunderstood Facts About CBD Products and Edibles

The knowledge that edibles with CBD won't produce any undesired effects or impairments created a growing confidence in this popular hemp-based supplement to not only offer users relief, but allows them to retain normal motor skills, cognitive abilities and self-control as well. Essentially, store-bought CBD has roughly similar effects to most over-the-counter medications with a far more holistic approach to personal care. Plus, this hemp-derived cannabinoid is available in many different forms including CBD oil, wax, dietary supplement, in addition to edibles.

As such, the familiarity combined with finding the method for delivering effective CBD a the form that most users are comfortable with makes it easy for everyone to try as an alternative to prescription medications. Edibles with CBD are among the easiest for new users to accept as a supplemental regimen, due to their incorporation within some of the best tasting snack foods and their pre-measured doses. While it can be confusing to deduce how to most effectively implement precise amounts of forms such as oil and CBD concentrates, edibles are typically pre-formed and made to exact measurements by volume to ensure users get the exact amount labeled on the package every time.

Are CBD Edibles A Passing Fad? Consistency Is the Key to Results

Over the last decade, fad diets, exercise regimens, and other health crazes have become common fixtures in our daily lives. In fact, considering the naturally occurring terpenes in CBD, it helps to interpret how they can complement the natural compounds and attributes of foods we eat every day. Creating a healthy meal plan can require discipline and dedication to fully experience the rewards of feeling healthier in addition to paying for expensive meal prep. Adding CBD edibles products to your daily routine can be unbelievably easy to adhere to and readily accessible to everyone – without prior knowledge or experience to try out.

This is truly valuable when you explore the benefits of CBD gummies for anxiety and the way in which they put users at ease or allow them to interact more freely can help them live fuller more robust social lives. Beyond the most common benefits of taking CBD as an edible, the unstudied riches yet to be uncovered for making full use of the human body's endocannabinoid system may be delivering unexpected enrichment that will be revealed by future scientific discoveries.

Since the approval of a CBD-based treatment by the FDA and the reclassification of hemp-derived products, there has never been a more advantageous moment in time to get the relief you need to live a healthy, normal life. Experience CBD for all its benefits in the present and find out why CBD edibles may be the best tool to start living your best life today.

Exhibit E

CBD Edibles vs CBD Suppositories: Exploring CBD From Both Ends

Eli Mann

Exploring CBD From Both Ends: Comparing CBD Edibles and CBD Suppositories

It's widely accepted that people can get their regular doses of CBD by eating delicious snacks packed with its beneficial properties. Comparing **CBD edibles vs CBD suppositories**, few users know there are other ways to get their daily supplement of cannabinol without swallowing pills, gummies or oils. This primer may help to provide users with the information they need to see the potential from either side of the discussion.

Although CBD edibles have become a convenient and popular way to experience the benefits of therapeutic cannabinoids, the increasing availability of other application methods including directly applying it inside of the body is becoming more prevalent. To fully understand what sets them apart, it's important to break down how they function and what specific uses each serves to choose the most effective method for every user. We look into the comparison of CBD edibles and CBD suppositories to learn more about the benefits offered by each.

Looking Inside for Relief: How CBD Suppositories Differ From CBD Edibles

It's clear that taking CBD gummies orally can provide full body effects and relief to a wide range of areas in the human body, but what if users want to target specific locations within the human body? There aren't products developed yet that can target specific bodily systems or purposes, but suppositories with CBD for pain seem to most commonly localize their effects to the pelvic region. To explain, this is mostly due to how the cannabinoid is absorbed directly into receptive capillaries inside of body cavities as well as how it can radiate spectrally from the point of introduction as opposed to the full-body effect created by CBD edibles.

Essentially, the conduits which the CBD travels through are concentrated to the vaginal or rectal cavity, the digestive system, spinal cord and other systems in the surrounding areas. While users may still experience similar relief to eating edibles, it is unlikely the intensity of its allocation will manifest itself as similarly than comparing smoking cannabis vs taking CBD. Understand, each administration method carries its own properties and introducing a CBD infused suppository carries specific benefits to the region in which the initial full intensity is introduced.

Generally, the effects of CBD edibles seem to create an all-over sense of euphoria that isn't singularly concentrated in a single area of the body. This has to do with the need for digestion of compounds taken

EXHIBIT E Page 1 of 3

orally. Even CBD oils, which is a simple form to process CBD, but still requires processing in the gut to break down, and allocate to the bloodstream before being circulated throughout the body. Reflexively, CBD suppositories for hemorrhoids, menstrual pain or lower back pain and other ailments closely affecting that region of the body are applied directly to a point of dispersal where it can be directly absorbed and allocated.

Plumbing the Depths of CBD Suppository Benefits

There has been a great deal of publicized theory relating the relationship of the hip region to the storing of emotional pain, but what if that baggage could be unloaded through physical action or therapeutic application of certain cannabinoids? Even without scientific study, it at least helps to understand the tangible uses for CBD as it relates to physical pain and relief created using the interactivity and connections of the human body.

CBD can be applied to desensitize pain receptors; research has shown that it helps to decrease active nerve pain by plugging into the CB1 endocannabinoid receptors. In addition, methods which introduce cannabinoids directly into the bloodstream which aren't broken down or diffused by digestion and processing have a more focused intensity. In other words, the CBD suppository retains more of its original intensity and has more intrinsic value regardless of dosage compared to edible CBD of the same amount. Where a user may not experience the effects of CBD edibles quickly, suppositories can become active and valuable almost immediately, not unlike tinctures but without the detrimental addition of alcohol which many CBD tinctures contain due to the distillation process.

One of the most popular uses for CBD suppositories relates to menstrual health and the typical symptoms associated with the onset of a period. Essentially, administering CBD directly to the region most affected by menstrual cramps can help to alleviate the inflammation and intensity. Likewise, CBD suppositories have been purported to be invaluable for sufferers of digestive-related maladies including Crohn's disease, anal fissures, irritable bowel syndrome and recurring hemorrhoids due to their specific application to the regions of the body most affected by those ailments.

An Unobstructed View of CBD Suppositories vs CBD Edibles

Suppositories have helped users experience incredible results by directing the flow of cannabinoids to their pelvic region, while edible CBD methods provide them with cumulative relief in a full-body effect that disseminates the intensity where it is needed. That said, there are other peripheral effects produced by using CBD suppositories vs CBD edibles because the rectal cavity is so close to the spinal column and may have positive effects on sexual arousal and stimulation as well. In addition, suppository CBD is ideal for users with digestive issues, nausea, or dietary issues including diabetes.

Administering CBD this way allows users to control their diet with the knowledge that they are still getting an effective dosage of cannabinoids. Plus, it is possibly the most discreet way of taking CBD without anyone knowing that continues to take effect long after it is initially used. In all, there are endless benefits to taking CBD suppositories for intensity localized to the pelvic region. Bear in mind, the drawbacks are relatively intense, the most obvious being the invasive nature of inserting a foreign object into your body cavity. Another is the inconvenience of finding a private place to insert them, though any restroom will do.

Reflexively, you can ingest edibles anywhere that allows food or drink (and if you're sneaky, places that don't). As soon as you feel the intensity of the previous CBD waning, you can simply take another. With suppositories, users have to hunt down a quiet place to insert them. For some users, this is a reasonable compromise to assuage their symptoms, but for others uncomfortable with the application, it can be a dealbreaker.

Getting Out What You Put In With CBD Edibles and Suppositories

With all aspects of choosing the best way to get effective doses of CBD, there are always compromises to compare to the benefits and the division of edible CBD goods from their suppository counterparts are no exception. However, discovering the right method for every user simply requires personal research, experience, and an open mind to internalize which is best for everyone. The full benefits resulting from each change with every user, but the fringe benefits of less inflammation and more comfort throughout your daily life are aspects everyone can appreciate.

The greatest divergence is with the reach and dissemination of active cannabinoids, where suppositories are predominantly localized to a central area of the body in their intensity, the act of digesting edibles with CBD seems to spread their active impact through the human body. We as yet do not entirely understand the full functionality of the endocannabinoid system and its receptors. Understanding how concentrations on specific regions of the body may retain the greatest benefits of CBD suppositories and edibles will require personalized research and study. As such, many of us will stick with edibles and enjoy the expected benefits and convenience they offer ahead of further scientific exploration into the bowels of therapeutic applications of cannabinoids.

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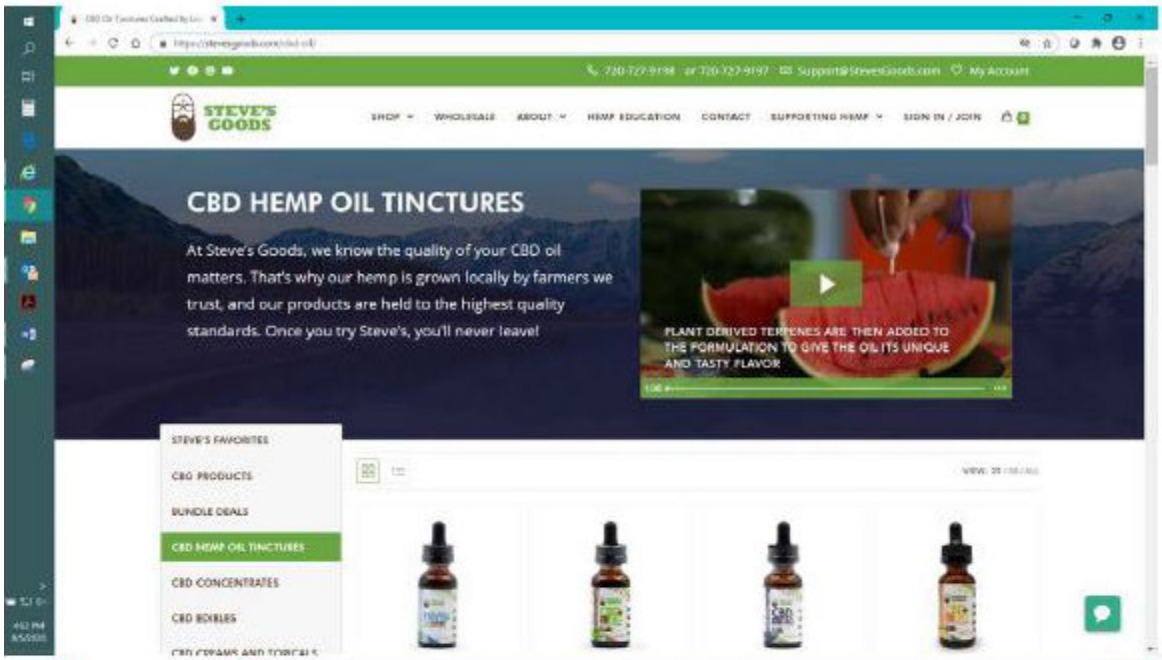

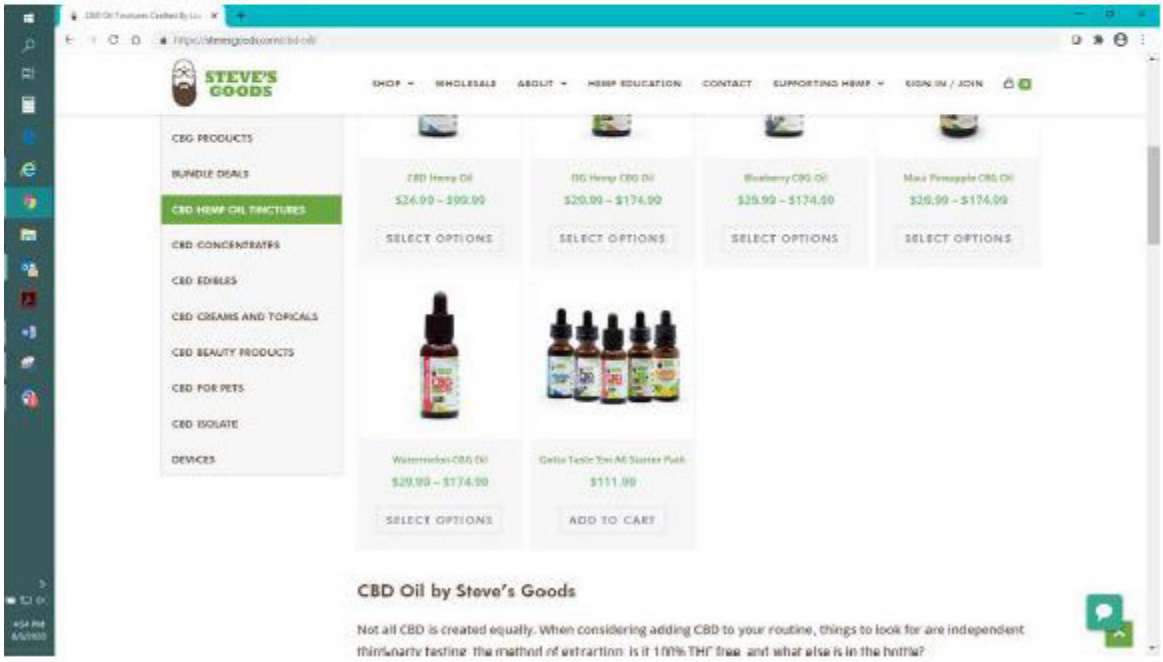

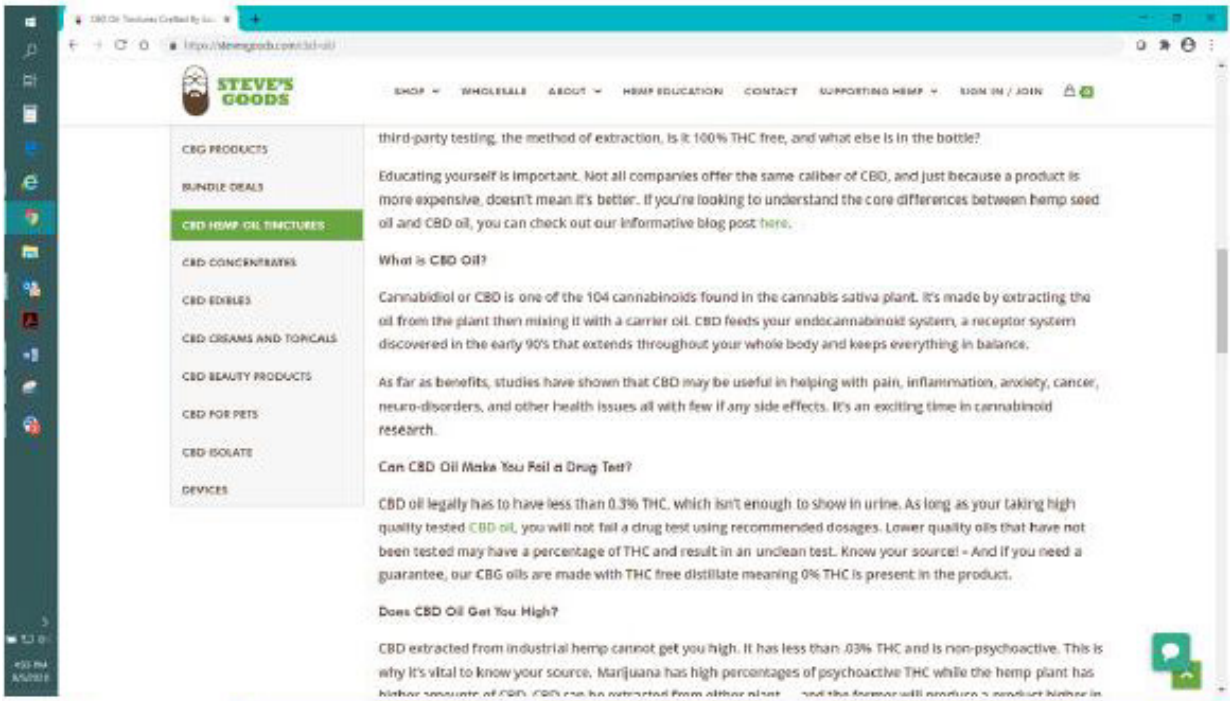
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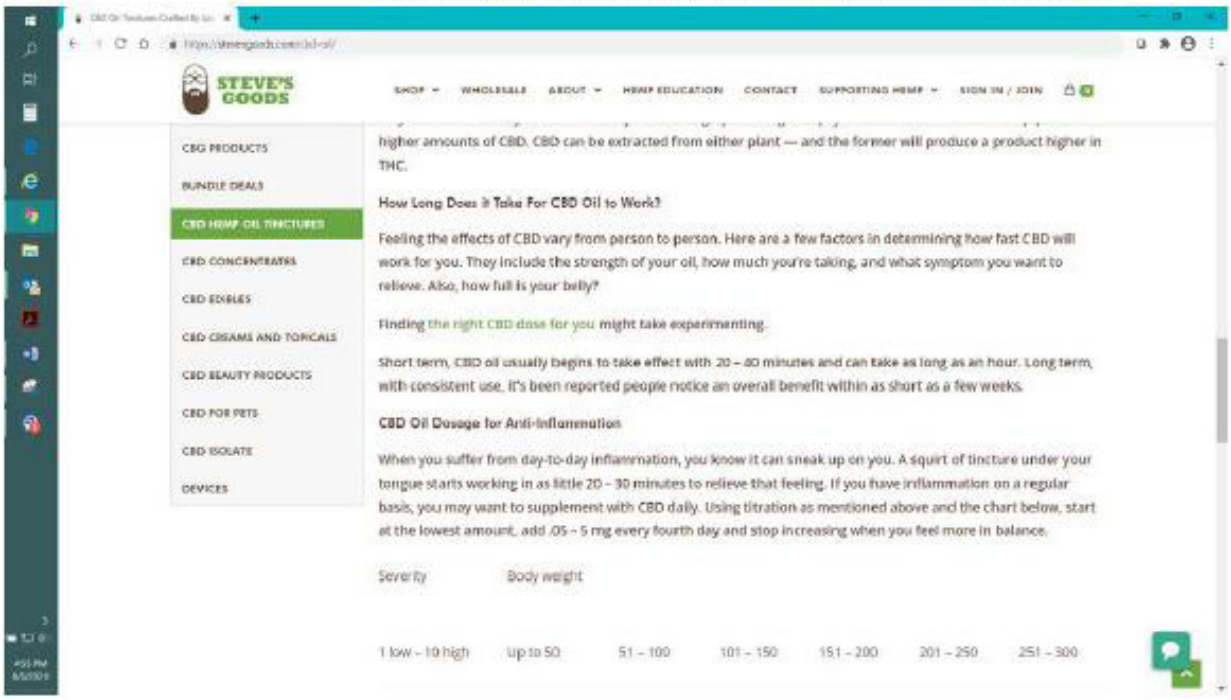
CBD FOR PETS
CBD ISOLATE
DEVICES
third-party testing, the method of extraction, is it 100% THC free, and what else is in the bottle?
Educating yourself is important. Not all companies offer the same caliber of CBD, and just because a product is more expensive, doesn't mean it's better. If you're looking to understand the core differences between hemp seed oil and CBD oil, you can check out our informative blog post here.
What is CBD Oil?
Cannabidiol or CBD is one of the 104 cannabinoids found in the cannabis sativa plant. It's made by extracting the oil from the plant then mixing it with a carrier oil. CBD feeds your endocannabinoid system, a receptor system discovered in the early 90's that extends throughout your whole body and keeps everything in balance.
As far as benefits, studies have shown that CBD may be useful in helping with pain, inflammation, anxiety, cancer, neuro-disorders, and other health issues all with few if any side effects. It's an exciting time in cannabinoid research.
Can CBD Oil Make You Fail a Drug Test?
CBD oil legally has to have less than 0.3% THC, which isn't enough to show in urine. As long as your taking high quality tested CBD oil, you will not fail a drug test using recommended dosages. Lower quality oils that have not been tested may have a percentage of THC and result in an unclean test. Know your source! - And if you need a guarantee, our CBG oils are made with THC free distillate meaning 0% THC is present in the product.
Does CBD Oil Get You High?
CBD extracted from industrial hemp cannot get you high. It has less than .03% THC and is non-psychoactive. This is why it's vital to know your source. Marijuana has high percentages of psychoactive THC while the hemp plant has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CBD FOR PETS
CBD ISOLATE
DEVICES
higher amounts of CBD. CBD can be extracted from either plant — and the former will produce a product higher in THC.
How Long Does it Take For CBD Oil to Work?
Feeling the effects of CBD vary from person to person. Here are a few factors in determining how fast CBD will work for you. They include the strength of your oil, how much you're taking, and what symptom you want to relieve. Also, how full is your belly?
Finding the right CBD dose for you might take experimenting.
Short term, CBD oil usually begins to take effect with 20 – 40 minutes and can take as long as an hour. Long term, with consistent use, it's been reported people notice an overall benefit within as short as a few weeks.
CBD Oil Dosage for Anti-Inflammation
When you suffer from day-to-day inflammation, you know it can sneak up on you. A squirt of tincture under your tongue starts working in as little 20 – 30 minutes to relieve that feeling. If you have inflammation on a regular basis, you may want to supplement with CBD daily. Using titration as mentioned above and the chart below, start at the lowest amount, add .05 – 5 mg every fourth day and stop increasing when you feel more in balance.
Severity
Body weight
1 low – 10 high
Up to 50
51 – 100
101 – 150
151 – 200
201 – 250
251 – 300

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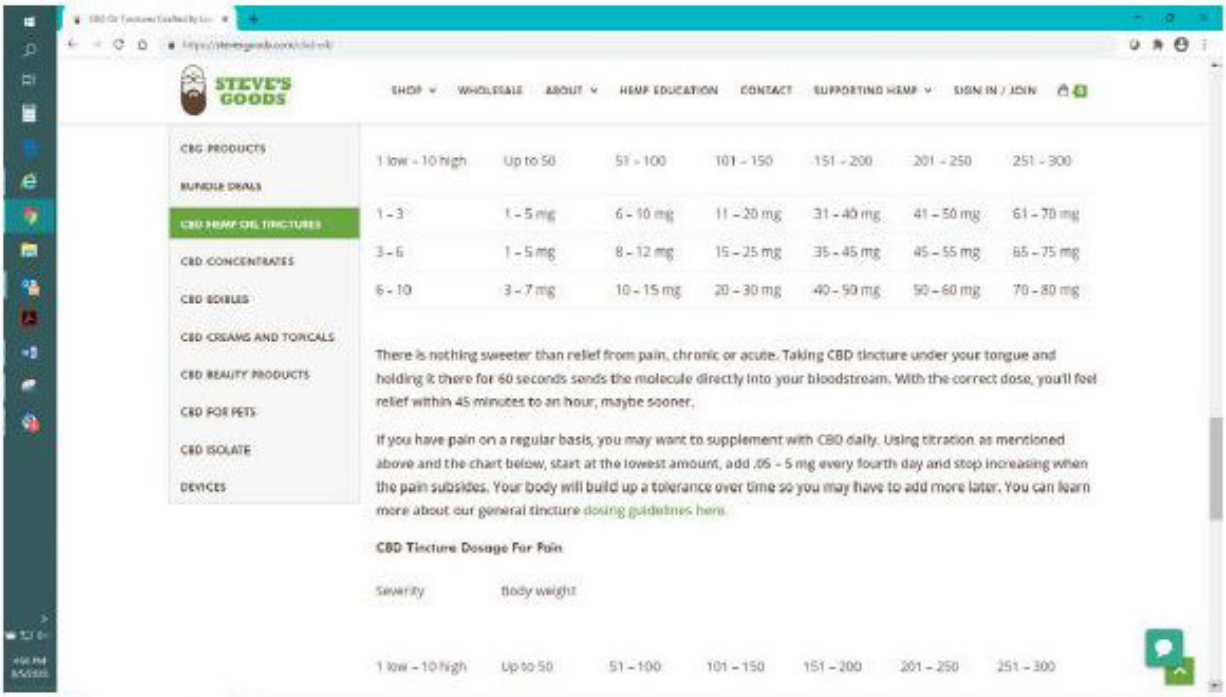
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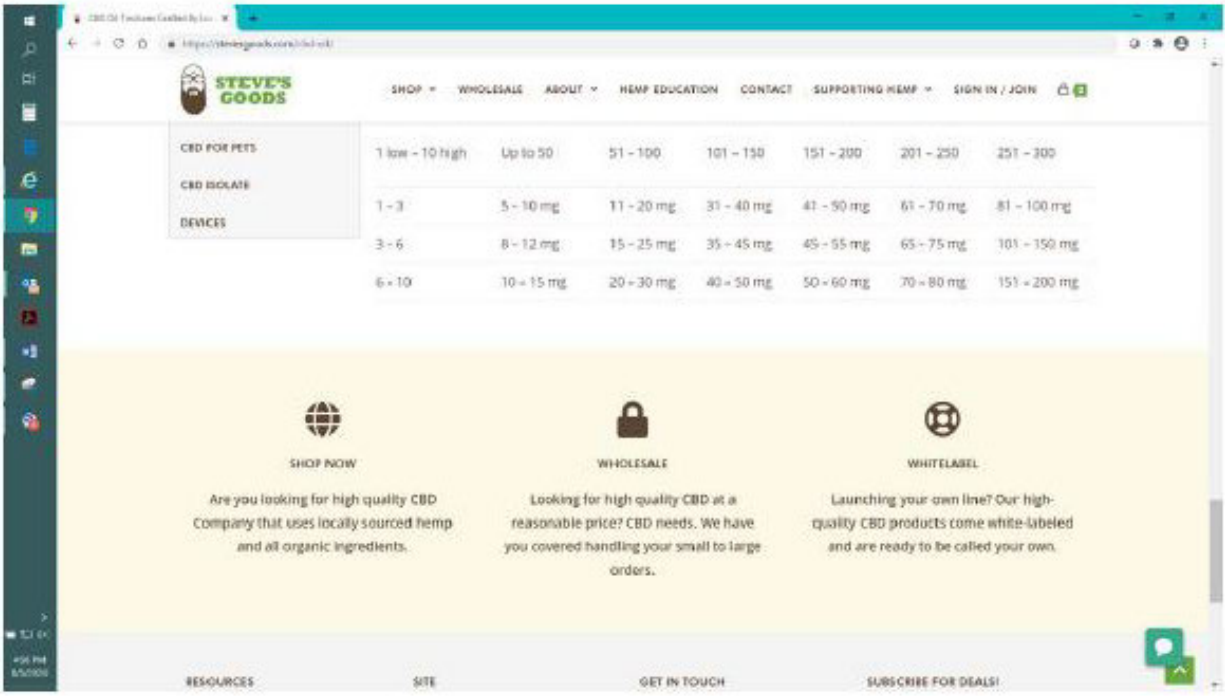
CBD FOR PETS
CBD ISOLATE
DEVICES
1 low - 10 high
Up to 50
51 - 100
101 - 150
151 - 200
201 - 250
251 - 300
1 - 3
1 - 5 mg
6 - 10 mg
11 - 20 mg
31 - 40 mg
41 - 50 mg
61 - 70 mg
3 - 6
1 - 5 mg
8 - 12 mg
15 - 25 mg
35 - 45 mg
45 - 55 mg
65 - 75 mg
6 - 10
3 - 7 mg
10 - 15 mg
20 - 30 mg
40 - 50 mg
50 - 60 mg
70 - 80 mg
There is nothing sweeter than relief from pain, chronic or acute. Taking CBD tincture under your tongue and holding it there for 60 seconds sends the molecule directly into your bloodstream. With the correct dose, you'll feel relief within 45 minutes to an hour, maybe sooner.
If you have pain on a regular basis, you may want to supplement with CBD daily. Using titration as mentioned above and the chart below, start at the lowest amount, add .05 - 5 mg every fourth day and stop increasing when the pain subsides. Your body will build up a tolerance over time so you may have to add more later. You can learn more about our general tincture dosing guidelines here.
CBD Tincture Dosage For Pain
Severity
Body weight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CBD ISOLATE
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151 - 200
201 - 250
251 - 300
1 - 3
5 - 10 mg
11 - 20 mg
31 - 40 mg
41 - 50 mg
61 - 70 mg
81 - 100 mg
3 - 6
8 - 12 mg
15 - 25 mg
35 - 45 mg
45 - 55 mg
65 - 75 mg
101 - 150 mg
6 - 10
10 - 15 mg
20 - 30 mg
40 - 50 mg
50 - 60 mg
70 - 80 mg
151 - 200 mg
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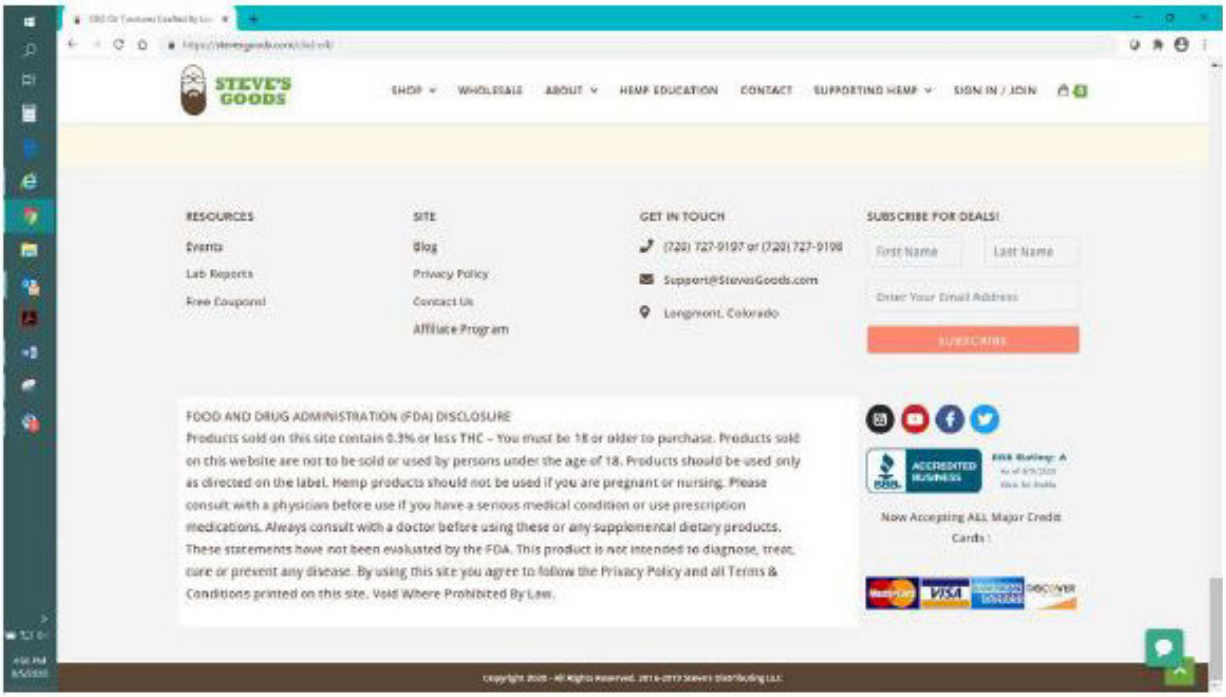
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FOOD AND DRUG ADMINISTRATION (FDA) DISCLOSURE
Products sold on this site contain 0.3% or less THC – You must be 18 or older to purchase. Products sold on this website are not to be sold or used by persons under the age of 18. Products should be used only as directed on the label. Hemp products should not be used if you are pregnant or nursing. Please consult with a physician before use if you have a serious medical condition or use prescription medications. Always consult with a doctor before using these or any supplemental dietary products. These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease. By using this site you agree to follow the Privacy Policy and all Terms & Conditions printed on this site. Void Where Prohibited By Law.
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Exhibit G

What is CBG, How Does it Work, & What Are the Potential Benefits?

Amy Glin

What is Steve's Goods CBG Oil?

CBG, short for cannabigerol, is at the forefront of cannabinoid research. It's an important cannabinoid to learn about and add to your daily routine.

Here's why...

It's been known since the early 1990's that humans and animals have an endocannabinoid system regulating all body functions including digestion, sleep, and nerves. It's the body's largest receptor system and maintains homeostasis. There are two main types; CB_1 and CB_2.

CB_1 receptors are mostly in the brain and organs. CB_2 receptors live on cells.

This system needs Omega Fatty acids, in the proper ratio, to produce and uptake its own cannabinoids. Unfortunately, today's diet is severely lacking in Omega-3's, and that can lead to an endocannabinoid deficiency, causing unrest, imbalance, and dis-ease. Once that happens it's easy to feel helpless and seek traditional pharmaceutical medicine paths with all the nasty effects besides the one you're looking for.

But it doesn't have to go that way. Fortunately, the hemp plant's important medicinal properties and multipurpose uses are becoming more known and accepted. And the technology is well-developed for extracting both isolates and full-spectrum cannabinoids for human and animal use. You can feed your endocannabinoid system with phytocannabinoids from the hemp plant and return your body to balance. Hallelujah!

How it Works

CBGa is considered the stem cell molecule of cannabinoids, where it all began! It's the precursor to three different cannabinoids, THCa, CBDa, CBNa, acid forms of the compounds found when in raw states. Ingenious as nature is, the cannabis/hemp plant has a natural enzyme, called synthase, that uses heat or UV light to break the CBGa down into one of the three paths, making it bioavailable.

You could call CBG the mother of all cannabinoids. And as a mother, CBG works with its offspring to enhance performance. When CBG is present, then combined with CBD, it increases the effectiveness. But it also has its own beneficial properties.

Benefits of CBG Oil

CBG helps your body is so many ways. It's good for stress, anxiety, sleep relief, and pain reduction. It helps regulate mood and behavior and keeps your body in balance, running like the fine machine it is. It's been found in research, by the US National Institute of Health, to inhibit the growth of colon cancer, and has positive effects on glaucoma and irritable bowel syndrome knows as IBS.

CBG is non-psychoactive, meaning it will not get you high. Truthfully, it's an antagonist to the high produced by THC, and we've experimented!

CBG Ceremonies

The best way to understand the benefits of the product is to use them, so here at Steve's Goods we host CBG ceremonies. We invite members of the industry to join us, ingest CBG in different ways, and compare notes. We help each other get further in tune with our bodies, and it's usually followed by a yoga session.

We wanted to experience the effect CBG has on THC so at one of the ceremonies we smoked uber amounts of THC then each took a dab of CBG isolate. Within moments, clarity and focus. It was as if the CBG literally kicked the THC off of the receptor. The shift is epic. You can try this at home!

This Saturday, July 28, we're celebrating Steve's Goods new Watermelon CBG, with a ceremony and big bash! Reach out if you're interested in joining, we'd love to meet you!

EXHIBIT G Page 2 of 4

What Sets us Apart?

Steve's Goods formulates award winning full spectrum CBG oil, the strongest and best-tasting on the market. In addition to the purest ingredients available, it's made with intention, love, and passion. Purity and soul in one sweet package.

CBG oil is currently available in two terpene profiles, our name for flavor. Terpenes are unique compounds found in a large variety of plants and even in some insects. Botanists refer to them as a plant's essential oils, the building blocks of plant resin. They're responsible for the color, scents, and flavors of plants and each has distinguishing values.

The terms terpene and terpenoids are often used interchangeably but there is a slight difference between the two. Raw terpenes are hydrocarbons and terpenoids have been denatured by drying and curing the flowers.

Blueberry Blast is made with our Blueberry OG Flavor profile/CBG Distillate Wax. This terpene profile features limonene, known for being anti-fungal, antibacterial and anti-carcinogenic. It relieves pain and is known for its mood elevating and stress-reducing qualities. It also helps ease insomnia, fatigue, and lack of appetite.

NEW! Watermelon Kush is made with Watermelon OG Flavor profile/CBG Distillate Wax. It offers the active terpene compounds Alpha and Beta-Pinene, known for their antibacterial and anti-inflammatory qualities. These terpenes also aid in memory and work as a bronchodilator. This compound has been used in traditional medicine for centuries.

Steve's Goods CBG oil comes in 30 ml. bottles. We offer three strengths, 500 mg. 1000 mg. or 2500 mg. We're happy to discuss the best strength for your personal needs.

Coming Soon!!! Keep on the lookout for our soon-to-be-released new terpene profiles Pineapple Express, Terpene Gorilla, and Girl Scout Cookies. We pride ourselves on having something for everyone!

The Entourage Effect

When you begin using CBG, CBD and hemp-based products, and as you become more in balance and begin to exude joy and glow, people gather around you and follow you everywhere. This is known as The Entourage Effect. Okay, not really. But it could happen!

Silliness aside, when you combine CBD with CBG it enhances the CBD's performance. When you add terpenes to that combo, benefits are amplified. The interactive synergy between compounds is known as The Entourage Effect and explains why some compounds work better for individuals than others, and why adding CBG to your CBD intake increases its efficacy.

The facts:

Our distillate oil is 4% – 8% CBG, we have the lab reports. Others weigh in at much less. Our ingredients are simple, in addition to the oil we add monk fruit and agave for sweetness, and the terpene profile based its name, giving each tincture its unique

quality and targeted wellness.

Remember! Every time you take it, you gotta shake it!!! Shake it, take it! Might as well shake your booty at the same time. Why the hell not?

Complaint

Exhibit H

Exhibit I

The ABCs of CBG - Steves Goods

Jordan Turner

It's 2019, and CBG oil is the new buzz word. Cannabis has become near commonplace in American pop culture. Advancements in legalization have blanketed participating states with new wealth. In the same ways, technology and science have kept pace: concentrates, tinctures, inhalers, battery atomizers, e-nails... the list goes on. As innovation continues, more is being revealed about the other 112 cannabinoids that comprise the full-spectrum. Though we are still gathering data on THC and CBD, Cannabigerol (CBG) is growing in both awareness and popularity, and Steve's Goods is leading the charge.

What is cannabigerol?

Cannabigerol is the chemical mother of all other cannabinoids. Hemp & marijuana plants produce it naturally in the form of cannabigerolic acid, but it is considered to be a minor cannabinoid in lieu of the fact that it appears in low readings on lab tests of mature cannabis plants. The major cause of this? Most CBG is immediately converted into one of the other major cannabinoids during photosynthesis. That means it is not plentiful, and that it takes a lot of cannabis to isolate or distill a considerable amount of CBG, making it expensive to come by. In bulk, it can be obtained in the form of isolate powder, and in the form of distillate liquid (more to come on those later).

Steve's Goods Blueberry flavored CBG Oil (30mL, 2500mg bottle)

How is cannabigerol used?

Our bodies have a built-in endocannabinoid system which aids in the balance of our mental and physical equilibrium. Every cannabinoid has varying effects on the body and on the endocannabinoid system, and CBG has been found to be one of the more universally beneficial. Various scientific studies have revealed use cases for ailments ranging from ocular diseases to inflammatory bowel conditions. Other studies have shown CBG to carry antibacterial and anti-inflammatory effects on the body. There are dozens of other ailments and conditions that CBG has been rumored to treat, and simply not enough data to render an opinion as to its effectiveness. One way or another, Steve's Goods is excited to be at the forefront of the CBG movement.

Will CBG get a user high?

Perhaps one of the most interesting observations from studies on CBG noted that in larger doses, CBG actually interferes with the psychoactive feelings THC causes the body, overpowering the neuro-inhibiting effects that THC produces when consumed in high-doses. Since the amount of CBG needed for a human overdose would be all but impossible to consume, the answer to the question, "will CBG get a user high," is not only a firm no, but quite the opposite; it stops the high and the feelings associated

with it.

What are the best ways to buy CBG?

Though we anticipate a wave of high-CBG flower strains emerging to satisfy demand from the market, there are few to no such strands in circulation presently. Again, cannabigerol is almost always biosynthesized into another cannabinoid while plants grow and flower, meaning someone would have to interrupt such biosynthesis to retain the maximum levels of CBG produced by a particular strain or plant. That is not to say CBG cannot be attained in bulk volume. Steve's Goods deals in three major bulk forms of CBG: CBG isolate powder, CBG distillate, and CBG oils and tinctures.

Steve's Goods CBG Isolate Slab

CBG Isolate Explained

CBG isolate powder is utilized in the manufacturing of other concentrate products, Including including CBG isolate slab. It looks and feels similar to powdered sugar, and comes in a concentration of 99% purity. CBG isolate powder could theoretically be utilized to make gummies, capsules, topicals, and other forms of concentrates, including shatter, and any other product for which CBD isolate powder is a base product. This powder is commonly isolated from the other cannabinoids among the full spectrum through refinement from hemp or marijuana.

CBG Super Distillate

CBG super distillate is utilized in the formulation of oils and tinctures. This distillate is the key ingredient in Steve's Goods CBG oils, and could theoretically be used in the formation of several other products, including wax concentrates, similar to the products Steve's Goods offers among their CBD wax concentrates. CBG super distillate is made via chromatography. This process passes evaporated hemp distillate into a medium in which all the different cannabinoids (CBG, THC, etc.) are isolated to be separated manually with no error. This is one of the most advanced methods for generating pure cannabinoid concentrates and is certainly one of the cleanest methods.

CBG Oils & Tinctures

If you enjoy a tasty, smoke-free means of getting your controlled dose of CBG daily, Steve's Goods CBG oils are a fantastic option. They are available in Watermelon, Blueberry, and OG Hemp flavors, achieved by blending our CBG super distillate with the appropriate terpene profile to offer the ideal formula to satisfy just about any taste pallet. Every flavor is sold in 15mL bottles with 250mg, 500mg, and 1250mg concentrations, and in 30mL bottles with 500mg, 1000mg, and 2,500mg concentrations, ensuring Steve's Goods is also ready with every size and strength refill one could possibly need for home use. These tinctures are also available for private labeling.

CBG Slab?!

If you enjoy Steve's Goods CBD concentrates, you will love their state-of-the-art CBG isolate slab. Made from CBG isolate powder, and via Steve's proprietary process, Steve's is offering a terpene-free, 99%-

pure CBG concentrate that tastes like unexplainable citrus flavor, and a feeling of total renewal that rushes over you as quickly as you inhale it. We don't know of another company offering anything similar, and it is our true pleasure to be among the first to take the step and create something this rare and incredibly healthy.

Our hope is that this post resources you with enough background knowledge on what CBG is, why it is important for the human body, the different benefits of using it, and the types of CBG on the market. We sincerely hope you will consider CBG for your diet and health (if you have not already done so), and that you will strongly consider Steve's Goods CBG products to fill that need.

Steve from Steve's Goods using Dipper to enjoy CBG Isolate Slab.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

    a. Respondent Steves Distributing, LLC, also doing business as Steve's Goods, is a Colorado corporation, with its principal office or place of business at 1500 Kansas Avenue, Suite 2C, Longmont, CO 80501.

    b. Respondent Steven Taylor Schultheis is Chief Executive Officer, President, and principal shareholder of Steves Distributing, LLC. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of Steves Distributing, LLC. His principal office or place of business is the same as that of Steves Distributing, LLC.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "CBD Product" means any Dietary Supplement, Food, or Drug containing cannabidiol.

B. "CBG Product" means any Dietary Supplement, Food, or Drug containing cannabigerol.

C. "Covered Product" means any Dietary Supplement, Food, or Drug, including but not limited to CBD Products or CBG Products.

D. "Dietary Supplement" means: (1) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional Food or as a sole item of a meal or the diet.

E. "Drug" means: (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans; (3) articles (other than Food) intended to affect the structure or any function of the body of humans; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

F. "Essentially Equivalent Product" means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients are unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

G. "Food" means: (1) any article used for food or drink for humans; (2) chewing gum; and (3) any article used for components of any such article.

H. "Respondents" means the Corporate Respondent and the Individual Respondent, individually, collectively, or in any combination.

1. "Corporate Respondent" means Steves Distributing, LLC, a limited liability company, also doing business as Steve's Goods, and its successors and assigns.

2. "Individual Respondent" means Steven Taylor Schultheis.

Provisions

I. PROHIBITED REPRESENTATIONS: REGARDING HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Respondents, Respondents' officers, agents, and employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, or assist others in making, expressly or by implication, any representation that such product:

A. treats, alleviates, or cures overactive bladder;

B. reduces blood sugar levels;

C. stimulates bone formation and healing;

D. treats, alleviates, or cures any disease, including but not limited to Alzheimer's disease, amyotrophic lateral sclerosis, anal fissures, asthma, cancer, chronic inflammation, chronic traumatic encephalopathy, Crohn's disease, depression, diabetes, epilepsy, fibromyalgia, glaucoma, glioblastoma, heart disease, hemorrhoids, hypertension, inflammatory bowel conditions, inflammatory bowel syndrome ("IBS"), migraines, multiple sclerosis, neurological disorders, ocular diseases, osteoporosis, pain, Parkinson's disease, post-traumatic stress disorder, psoriasis, rheumatoid arthritis, or seizures; or

E. treats, alleviates, or cures diseases and other health conditions as effectively as most over-the-counter medications, or is an effective alternative to prescription medications,

unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Provision, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when

considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, and employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product must not make, or assist others in making, expressly or by implication, any representation, other than representations covered under the Provision of this Order entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product or of an Essentially Equivalent Product when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Corporate Respondents' size and complexity, the nature and

scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

IV. PROHIBITED MISREPRESENTATIONS REGARDING TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, and employees, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product must not misrepresent, in any manner, expressly or by implication:

A. That any Covered Product is scientifically proven to have antibacterial properties, stimulate bone formation or healing, have neuroprotective effects, or cure, mitigate, or treat anxiety, cancer, depression, glaucoma, inflammation, inflammatory bowel conditions, IBS, neurological disorders, ocular diseases, overactive bladder, pain, or psoriasis;

B. That the performance or benefits of any product are scientifically or clinically proven or otherwise established; or

C. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V. FDA-APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, Respondents' officers, agents, and employees, and all other persons in active concert or participation with any of them from:

A. For any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. For any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI. MONETARY RELIEF

IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $75,000, which Respondents stipulate their undersigned counsel holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

VII. ADDITIONAL MONETARY PROVISIONS

IT IS FURTHER ORDERED that:

A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondents have no right to challenge any activities pursuant to this Provision.

E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that payment is due, the entire amount will immediately become due and payable.

F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.

G. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers), which Respondents have previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

VIII. CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Respondents must directly or indirectly provide sufficient customer information, including sufficient identification of all resellers, to enable the Commission to efficiently administer consumer redress to all purchasers of Respondents' CBD Products and CBG Products. If a representative of the Commission requests in writing any information related to redress, Respondents must provide it, in the form prescribed by the Commission representative, within 14 days.

IX. NOTICES TO CUSTOMERS

IT IS FURTHER ORDERED that Respondents must notify customers as follows:

A. Respondents must identify all consumers who purchased CBD Products or CBG Products on or after January 1, 2018 ("eligible customers").

1. Such eligible customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody or control, including from third parties such as resellers;

2. Eligible customers include those identified at any time, including after Respondents' execution of the Agreement through the eligibility period, which runs for 1 year after the issuance date of the Order.

B. Respondents must send a notice via electronic mail to all identified eligible customers:

1. The notice must be in the form shown in Attachment A.

2. The subject line of the email must state: "About Your Purchase of Steve's Goods' CBD or CBG Products."

3. The email of the notice must not include any other enclosures.

C. Respondents must notify all eligible customers within 180 days after the issuance date of this Order and any eligible customers identified thereafter within 30 days of their identification.

D. Respondents must provide a notice on all of their social media accounts (including any Facebook, Twitter, Instagram, or YouTube accounts) and on the first page of their websites. Such notice must link to a copy of the Order, along with a toll-free telephone number and an email address for the redress administrator. The notice must be posted not later than 3 days after the effective date of the Order and for at least 1 year after the redress period ends.

E. Respondents must report on their notification program under penalty of perjury:

1. Respondents must submit a report annually and at the conclusion of the program summarizing their compliance to date, including the total number of eligible customers identified and notified.

2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Respondents must submit it within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

X. NOTICE TO AFFILIATES AND OTHER RESELLERS

IT IS FURTHER ORDERED that within 30 days of the effective date of this Order, Respondents must notify all affiliates and other resellers by sending each via electronic mail the notification letter attached as Attachment A. Respondents must include a copy of this Order, but no other document or enclosure.

XI. ACKNOWLEDGMENTS OF THE ORDER

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 5 years after the issuance date of this Order, the Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is the majority owner or controls directly or indirectly, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for labeling, manufacturing, advertising, marketing, promotion, distribution, offering for sale, or sale of CBD or CBG Products; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10

days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

XII. COMPLIANCE REPORTS AND NOTICES

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. Sixty days after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which the Individual Respondent must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, the Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. Each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or

indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, the Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Steves Distributing, LLC, FTC File No. 202-3065.

XIII. RECORDKEEPING

IT IS FURTHER ORDERED that Respondents must create certain records for 7 years after the issuance date of the Order, and retain each such record for 5 years, unless otherwise specified below. Specifically, the Corporate Respondent and the Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. Personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name;

addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. Copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. A copy of each unique advertisement or other marketing material making a representation subject to this Order;

F. For 5 years from the date of the last dissemination of any representation covered by this Order:

1. All materials that were relied upon in making the representation; and

2. All tests, studies, analysis, other research, or other such evidence in Respondents' possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

XIV. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning the Individual Respondent, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XV. ORDER EFFECTIVE DATES

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ATTACHMENT A TO THE ORDER

CLAIMS ABOUT PRODUCTS CONTAINING CBD/CBG

In the Matter of Steves Distributing, LLC et al

Dear <Name of customer>:

We are writing to you because our records show that you bought CBD and/or CBG products from our company, Steve's Goods. The Federal Trade Commission (FTC) has settled claims against us relating to certain advertising practices. While we deny that we violated the law, we have agreed to stop making certain claims about our products as follows:

- Unless we have scientific proof, we will not say that our CBD and CBG products can effectively treat or ease serious diseases and health conditions, such as Alzheimer's disease, cancer, Crohn's disease, diabetes, and irritable bowel syndrome (IBS);

- Unless we have scientific proof, we will not say that we have studies or scientific research that prove that our CBD or CBG products have antibacterial properties, stimulate bone formation or healing, have neuroprotective effects, or cure, mitigate, or treat anxiety, cancer, depression, glaucoma, inflammation, inflammatory bowel conditions, IBS, neurological disorders, ocular diseases, overactive bladder, pain, or psoriasis.

For a full list of the health claims covered by the settlement, and to learn more about the settlement, please visit [add URL].

Talk to your doctor before you stop any prescriptions or take CBD, CBG, or any other treatments to treat health conditions. For more information about health product claims, visit ftc.gov/health.

Sincerely,

[signature]

[identify Respondent or other person responsible for signing the notification letter]

Concurring Statement

STATEMENT OF COMMISSIONER ROHIT CHOPRA

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish – and unlawful – claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine "a competitor's ability to compete" on honest attributes.[1]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID-19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[2] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer

1 *In re Pfizer, Inc.*, 81 F.T.C. 23, 62 (1972).

2 *See, e.g.*, Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic*, WALL STREET J. (Sept. 8, 2020), https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; *Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic*, AMERICAN MEDICAL ASSOCIATION (last updated on Oct. 31, 2020), https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.

Americans into high-cost, subpar treatment centers, and some even hire intermediaries – so-called "body brokers" – who collect kickbacks from this harmful practice.[3]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[4] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[5]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[6] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[7] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[8] Under the Penalty Offense

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3 For example, recent reporting describes the "Florida Shuffle," where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America*, VOX (Mar. 2, 2020), https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-brijayne. *See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), https://www ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid (calling on the FTC to do more to tackle this problem).

4 Pub. L. No. 115-271 §§ 8021-8023 (codified in 15 U.S.C. § 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

5 Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.

6 Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.

7 In one of these matters, the respondents are paying nothing.

8 15 U.S.C. § 45(m)(1)(b).

Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[9] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[10] and apprising firms of these findings – along with a warning that noncompliance can result in penalties – makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a "high level of voluntary compliance achieved quickly and at a low cost."[11] Going forward, we should pursue this strategy.[12]

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.

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9 *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256. Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

10 This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that "[f]airness to the consumer, as well as fairness to competitors" compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.*, 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that "a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act." *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.*, 155 F.T.C. 1, 6 (2013).

11 Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an "extremely effective and efficient way to enforce the law." Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.

12 My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

CONCURRING STATEMENT OF COMMISSIONER CHRISTINE S. WILSON

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication.

The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters[1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo- controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions – specifically, the FDA has approved a drug containing CBD as an active ingredient

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1 Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions*, Oct. 22, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims; Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis*, Sept. 10, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused; Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases*, Apr. 2, 2019, available at https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.

2 Press Release, *FTC Order Stops the Marketer of "Thrive" Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID-19*, July 10, 2020, available at https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.

3 *See, e.g.*, Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that "[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes."[6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

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4 *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.

5 *See, e.g.*, Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC v. Avrom Boris Lasarow, et al.* (Feb. 2015), https://www ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health; Statement of Commissioner Joshua D. Wright, *FTC v. Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin; Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), https://www ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru; Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part; Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC v. Springtech 77376, et al.* (July 2013), https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; *see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12-49 (May 2012), available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.

6 *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order with Steves Distributing, LLC, a limited liability company doing business as "Steves Goods," and Steven Taylor Schultheis, individually and as an officer and owner of Steves Distributing, LLC (collectively, "Respondents").

The proposed consent order ("Order") has been placed on the public record for 30 days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Order and the comments received, and will decide whether it should withdraw the Order or make it final.

This matter involves the Respondents' advertising of cannabidiol ("CBD") and cannabigerol ("CBG"), cannabinoid compounds found in hemp and cannabis. The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) CBD and CBG products can effectively prevent, treat, or mitigate multiple diseases and other health conditions; and (2) studies or scientific research prove that CBD and CBG products effectively prevent, treat, or mitigate multiple diseases and other health conditions.

The Order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food the respondent sells, markets, promotes, or advertises.

Provision I requires randomized, double-blind, placebo-controlled clinical testing for the challenged claims or any disease treatment, mitigation, or cure claim for a Covered Product. The Order defines "Covered Product" as any dietary supplement, food, or drug including but not limited to CBD products or CBG products.

Provision II prohibits other misleading or unsubstantiated representations about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or essentially equivalent product. It also covers prevention claims not specifically included in Provision I.

Provision III requires the preservation of certain records for any testing Respondents rely upon as competent and reliable scientific evidence.

Provision IV addresses Respondents' false establishment claims and generally prohibits misrepresentations regarding the scientifically or clinically proven benefits of any product.

Provision V provides a safe harbor for FDA-approved claims.

Provisions VI and VII contain monetary payment provisions.

Provisions VIII, IX, and X require Respondents to provide customer information to the Commission and to provide notice of the Order to customers, affiliates and other resellers.

Provision XI requires an acknowledgement of receipt of the Order. It also requires the individual Respondents to deliver a copy of the Order to certain individuals in any business for which they are the majority owner or which they control directly or indirectly.

Provisions XII, XIII, and XIV provide the required reporting, recordkeeping, and compliance monitoring programs that must be put in place.

Provision XV explains when the Order is final and effective.

The purpose of this analysis is to facilitate public comment on the Order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

Complaint

IN THE MATTER OF

TAPJOY, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4740; File No. 172 3092
Complaint, March 9, 2021 – Decision, March 9, 2021

This consent order addresses Tapjoy, Inc.'s operation of an advertising platform within mobile gaming applications. The complaint alleges that Tapjoy has violated Section 5 of the Federal Trade Commission Act by representing that consumers will receive a reward of virtual currency upon completion of a specific action when, in many instances, that representation was false, misleading, or not substantiated at the time the representation was made. The consent order requires Tapjoy to disclose that its advertisers determine whether rewards are likely to issue, and when consumers are likely to receive rewards; and prohibits Tapjoy from making the misrepresentations alleged in the complaint.

Participants

For the *Commission*: *Matthew G. Schiltz* and *Matthew H. Wernz.*

For the *Respondents*: *Travis LeBlanc* and *David Mills, Cooley LLP; Christopher N. Olsen* and *Lydia B. Parnes, Wilson Sonsini Goodrich & Rosati.*

COMPLAINT

The Federal Trade Commission ("FTC" or "Commission"), having reason to believe that Tapjoy, Inc., a corporation, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Tapjoy, Inc. ("Tapjoy" or "Respondent") is a Delaware corporation with its principal place of business at 353 Sacramento Street, 6th Floor, San Francisco, CA 94111.

2. Tapjoy has advertised, marketed, or distributed virtual currency to consumers throughout the United States.

3. The acts and practices of Tapjoy alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Tapjoy's Business Practices

4. Tapjoy operates an advertising platform within mobile gaming applications ("apps"). On the platform, Tapjoy promotes offers of in-app rewards (e.g., virtual currency) to consumers who complete an action, such as taking a survey or otherwise engaging with third-party advertising. Often, these consumers must divulge personal information or spend money.

In many instances, Tapjoy never issues the promised reward to consumers who complete an action as instructed, or only issues the currency after a substantial delay. Consumers who attempt to contact Tapjoy to complain about missing rewards find it difficult to do so, and many consumers who complete an action as instructed and are able to submit a complaint nevertheless do not receive the promised reward. Tapjoy has received hundreds of thousands of complaints concerning its failure to issue promised rewards to consumers. Tapjoy nevertheless has withheld rewards from consumers who have completed all required actions.

Tapjoy's Rewards Platform

5. Tapjoy's advertising platform appears in certain mobile games, including, for example, games related to war, shopping, sports, and home improvement. Tapjoy receives network fees and commissions from third-party advertisers that engage with consumers through Tapjoy's platform. Advertisers pay Tapjoy for each consumer who Tapjoy induces to, for example:

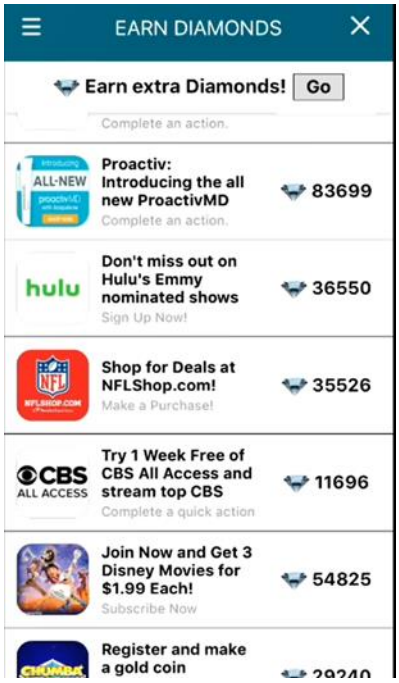
- purchase a product;
- enroll in a free trial of a magazine subscription, video streaming service, or other continuity program;
- disclose personally identifiable information;
- download an additional app;
- complete a survey; or
- watch a short video.

Tapjoy then pays a portion of each commission to the game developer, known as the "publisher," through whose game the consumer engaged with Tapjoy's platform.

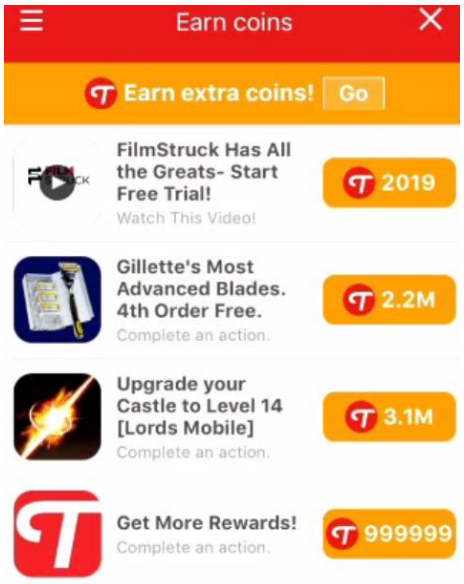
6. To induce consumers to engage with the advertisers, Tapjoy offers in-app rewards in the form of a specified amount of virtual currency that can be used in the publishers' games. These games require or allow consumers to obtain and use virtual currency, such as diamonds, gold bars, coins, or cash, to facilitate game play, unlock special features, or reach higher game levels.

7. Consumers typically are able to obtain virtual currency in two ways: (i) through the game in which Tapjoy's platform appears, or (ii) through Tapjoy's platform. When obtained directly through the game, as demonstrated by the offer below, virtual currency is available immediately upon purchase.

8. Consumers also can attempt to obtain currency by completing actions associated with third-party advertisements that Tapjoy displays to consumers on their in-game platform, known as their "offerwall." Consumers can access Tapjoy's offerwall by clicking on buttons within the game. Tapjoy's offerwall lists a series of third-party advertisements, arranged for each consumer according to an algorithm Tapjoy developed. Next to each ad, Tapjoy represents the amount of virtual currency associated with completing that offer by displaying a number adjacent to or below the image of a diamond, gold bar, coin, or other symbol. For example, in the screenshot below, Tapjoy's offerwall presents several third-party advertisements and claims that consumers can "earn" tens of thousands of virtual diamonds by completing the corresponding actions:



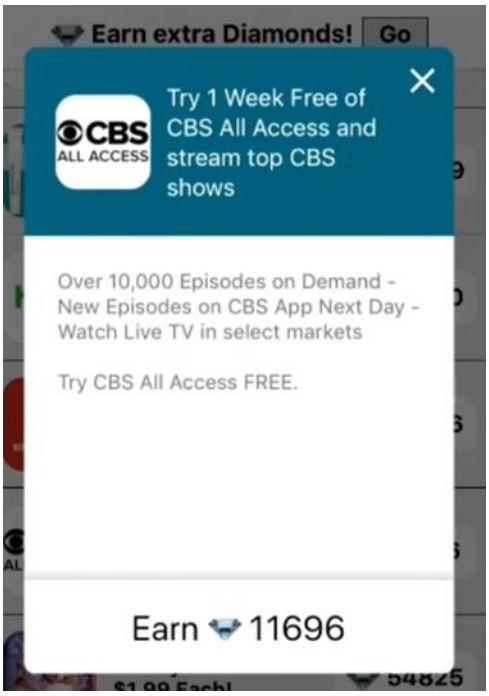
9. In some apps, the "T" from Tapjoy's logo has appeared next to the amount of virtual currency offered for each advertiser-related action, as shown below:



10. Additionally, Tapjoy's offerwall has contained a link that instructs users to "Get More Rewards!" The icon associated with this link also has been the "T" from Tapjoy's logo. Clicking on this link has caused a pop-up window to overlay the offerwall. This pop-up window has repeated the instruction to "Get More Rewards!" and further has instructed users, "Earn more rewards for your app! Tap below to see all the amazing ways you can increase your currency." A link to "Earn [currency]" has appeared below these instructions. Clicking on this link has taken the user to a page on Tapjoy's website, more.tapjoy.com, where users have been able to review additional virtual currency offers. These offers have appeared identically to the offers on Tapjoy's in-app offerwall.

11. In addition to incorporating into the offerwall text indicating that consumers will "earn" virtual currency by completing a particular action, Tapjoy also creates and publishes text that appears in conjunction with each advertisement describing what a consumer must do to complete the virtual currency offer. Tapjoy refers to this text as the "Call to Action," or "CTA summary." In default Calls to Action, Tapjoy instructs consumers that they must "complete an action," "watch this video," or "download and run this app" in order to obtain the associated virtual currency reward.

12. Clicking on an ad on Tapjoy's offerwall causes a pop-up window to overlay the offerwall. In this pop-up window, Tapjoy again represents that consumers will "earn" the specified amount of virtual currency in exchange for completing the specified action. Additional information also is provided in the pop-up window about the offer's requirements. As shown in the screenshot below of a pop-up window, for example, Tapjoy prominently claims that consumers would "earn" virtual currency by registering for a free trial of a video streaming service.



13. In some instances, Tapjoy promises a small reward of virtual currency to consumers who complete a discrete action, such as watching a short video. In many such instances, consumers who click on the image of the virtual currency have been able to complete that action and receive their reward immediately.

14. In many other instances, however, Tapjoy promises a large reward of virtual currency to consumers who complete actions more significant than simply watching a video — for example, purchasing a good or service, registering for a free trial followed by recurring charges, submitting personal information, or downloading and operating another app. In these instances, clicking on the image of the virtual currency within the pop-up window takes consumers outside Tapjoy's offerwall to the third-party advertiser's website. When Tapjoy's virtual currency offer involves downloading or using third-party apps, consumers typically are taken to a mobile app store to complete those offers.

Tapjoy's Virtual Currency Offers Often Require Consumers to Incur Charges or Divulge Personal Information

15. To obtain the rewards Tapjoy promises, consumers frequently must incur charges or reveal personal information. For example, Tapjoy's offers often require consumers to pay for products or services sold by the third-party advertisers. Frequently, these products involve recurring payment obligations, such as magazine subscriptions or video streaming services that require the payment of some amount each week or month. Consumers frequently complain that they spent a significant amount — often more than $100 — in completing various Tapjoy offers. As one consumer put it, "These offers aren't cheap and . . . the incentive to purchase them primarily is due to the gaming rewards."

16. In other instances, to obtain the promised reward, consumers must sign up for a short-term free trial, frequently of one week or less, of a product or service offered by the advertiser. Once these trials expire, consumers are charged on a recurring basis for the product or service.

17. Finally, in many instances, consumers have been required to disclose personal information, including contact information and medical history to third-party advertisers, to complete an offer. Consumers who have pursued these offers have been required to disclose, for example, email addresses, telephone numbers, full names, and addresses. In many instances, however, consumers who have submitted the requested information do not receive the promised rewards.

18. Rather, those consumers have been presented with requests for additional personal information, including personally identifiable information and sensitive health information. For example, in one such offer, Tapjoy represented that it would reward consumers who submitted their email address to an advertiser. However, consumers who submitted their email addresses did not receive a reward. Instead, such consumers were presented with a survey that included questions about "whether you or a loved one" had various health conditions, including cancer, diabetes, or arthritis.

19. In other instances, consumers who have submitted the personal information requested by advertisers are presented with a seemingly endless series of additional advertising offers that require consumers to spend money or sign up for limited-time free trials.

20. Consumers who have completed the actions as instructed do not receive rewards from Tapjoy, but instead have found that the personal information that they submitted was sold by Tapjoy's advertisers to third-party marketers. One consumer complained that she almost never received rewards from Tapjoy — instead, "All I ever get from completing any TapJoy offers are SPAM emails and Telemarketers calling my cellphone." Another consumer reported, "Frequently after completing these offers [I] have not received compensation for this. . . . [Y]ou have these people calling and it is doubly annoying to get nothing for this."

Tapjoy's Failure to Reward Completed Offers

21. Many consumers complete offers through Tapjoy's offerwall but do not receive the promised reward.

22. Indeed, Tapjoy recognized as far back as July 2016 that "too many users [were] simply not getting rewarded," that Tapjoy "clearly [had] a problem," and that "there are a number of scenarios where we fail to reward people."

23. An internal presentation over six months later, at the end of February 2017, similarly identified "poor customer experience," "inconsistent user rewarding," and "waning reputation" among the "hurdles" the company was facing.

24. Tapjoy's virtual currency rewarding "problem" has had significant consequences for consumers. Over the past several years, people have filed hundreds of thousands of complaints with Tapjoy, nearly all of which relate to Tapjoy's failure to issue virtual currency to consumers who completed the offers as instructed.

25. Many consumers who spent money in completing the offers through Tapjoy's offerwall never receive the promised reward. Tapjoy has received tens of thousands of complaints from consumers who spent money or signed up for limited-time free trials through Tapjoy's offerwall but have not received promised virtual currency.

26. In many instances in which Tapjoy has represented that it will issue rewards of virtual currency to consumers who disclose specified personal information, consumers have not received their reward.

27. Tapjoy has acknowledged in internal emails that it was "not news" that consumer complaint rates related to offers that purported to request personal information were "out of control."

28. Nevertheless, Tapjoy has continued to prominently and falsely claim that it will always issue rewards to consumers who simply submit personal information or perform other actions.

29. In numerous instances, even when Tapjoy issues promised rewards, it does not issue them for several days or more after consumers complete the offers. However, nowhere on Tapjoy's offerwall does it reveal that rewards will not be fulfilled for multiple days.

Tapjoy Often Withholds Rewards Despite Consumer Complaints about Uncompensated Offers

30. Many consumers who do not receive the promised virtual currency from Tapjoy despite having completed the actions associated with an offer seek to contact Tapjoy to request the reward. In many instances, however, consumers find that they cannot contact Tapjoy, or that Tapjoy does not respond to their communications, wrongfully "closes" their complaint, or delays responding until consumers have incurred additional charges or other obligations related to the third-party advertisement.

31. Despite these failures in responding to consumer complaints, and even though consumers frequently must resort to filing consumer complaints in an effort to obtain the virtual rewards promised by Tapjoy, Tapjoy continues to represent on its offerwall, without qualification, that consumers will earn virtual rewards by performing certain actions.

Tapjoy's Practice of Discouraging Customer Service Inquiries

32. Because of a high volume of consumer complaints, Tapjoy has adopted policies that serve to discourage contacts from consumers who have not received their rewards. Beginning in or around March 2017, Tapjoy prohibited consumers from submitting complaints

regarding unrewarded virtual currency within 24 hours after completing an offer. Tapjoy has failed to disclose to consumers in making the offer of virtual currency that they must wait any amount of time after completing the required action to receive it, or that they will be unable to contact Tapjoy for 24 hours after completing the action. Indeed, Tapjoy understood that, before March 2017, half of all consumer complaints were filed within 15 minutes after consumers completed Tapjoy's offer but did not receive the promised reward.

33. Additionally, in or around November 2017, Tapjoy removed a link from its offerwall, labeled "Missing [Currency]?," that previously allowed consumers to contact customer support to submit complaints regarding missing rewards.

34. Beginning in or around November 2017, consumers have been able to submit a customer support complaint to Tapjoy only after waiting 24 hours, returning to the offerwall, and finding an obscurely located link.

Tapjoy's Failure to Respond to Customer Service Complaints

35. Consumers who are able to submit a complaint often find that they nevertheless are unable to obtain the reward promised by Tapjoy. Until at least 2018, Tapjoy sent consumers who filed complaints regarding unrewarded virtual currency an automated email that requested proof that the consumer completed the offer, such as a confirmation email or billing invoice. Unbeknownst to consumers, they had to respond to this email within 72 hours to avoid having their complaints closed and marked as "solved."

36. Consumers who did not respond to Tapjoy's automated email within 72 hours received another automated email from Tapjoy stating that it "marked your case . . . as Solved because we haven't heard from you in at least 72 hours." Tapjoy then promised that consumers who would like assistance could "simply reply to this email to reopen the case."

37. However, in many instances, consumers who sent the requested proof to Tapjoy, including within 72 hours, received no response from the company. As one consumer complained, "they requested my screenshots as proof that I have done the offer so I sent it to them and I haven't heard anything from them since. . . . I just want my diamonds . . . ."

38. Similarly, many consumers who sent the requested proof nevertheless received an email stating that Tapjoy has "marked your case . . . as Solved because we haven't heard from you in at least 72 hours." As one consumer complained, "I email them and they ignore me and then days later send an email saying 'since they haven't heard from me in 72 hours, they mark the case closed!'"

39. Moreover, many consumers who attempted to respond to Tapjoy's "Solved" email—including consumers who previously submitted proof of completion of an offer—did not receive any reward, or any other response from Tapjoy, despite sending repeated emails to Tapjoy in an attempt to "reopen the case."

40. In many instances in which Tapjoy delays issuing a reward, or incorrectly closes a complaint as "Solved," consumers have been required to purchase limited-time free trials or other recurring subscriptions of Tapjoy's advertisers' goods and services to earn the promised reward. When consumers attempt to contact Tapjoy to inquire about the status of their rewards, Tapjoy often fails to respond or delay responding until after the free or limited-time free trial offer has expired. As a result, consumers are charged the full cost of advertisers' goods and services while awaiting the reward of virtual currency from Tapjoy.

Count I
Deceptive Acts and Practices

41. In connection with Tapjoy's advertising, marketing, promotion, or display of offers of virtual currency, Tapjoy has represented, directly or indirectly, expressly or by implication, that consumers will receive a reward of virtual currency upon completion of a specific action.

42. The representation set forth in Paragraph 41 is false and misleading or was not substantiated at the time the representation was made.

Violations of Section 5 of the FTC Act

43. The acts and practices of Tapjoy as alleged in this complaint constitute deceptive acts or practices, in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this ninth day of March, 2021, has issued this Complaint against Tapjoy.

By the Commission.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondent named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violations of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondent that it

neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondent is Tapjoy, Inc., a Delaware corporation with its principal office or place of business at 353 Sacramento Street, 6th Floor, San Francisco, CA 94111.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "Advertiser" means any third-party person, company, or entity that advertises, markets, promotes, offers for sale, or sells any good or service in connection with the promotion or offer of a Reward.

B. "Clearly and Conspicuously" means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

   1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure ("triggering representation") is made through only one means.

2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.

5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the triggering representation appears.

6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.

7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.

8. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

C. "Gameplay Reward" means a Reward issued after and only in exchange for completing a specified level or challenge within the gameplay of a mobile application.

D. "Respondent" means Tapjoy, Inc., a corporation, and its successors and assigns.

E. "Reward" means virtual currency usable within a mobile application.

F. "Video Reward" means a Reward automatically issued immediately after and in exchange only for viewing a promotional video.

Provisions

I. Prohibited Business Practices

IT IS ORDERED that Respondent, and Respondent's officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the promotion or display of any offer of a Reward, must not:

A. misrepresent expressly or by implication:

1. That consumers will receive a Reward;

2. The requirements for consumers to receive a Reward;

3. When consumers will receive a Reward; or

4. Any other fact material to consumers concerning the receipt of a Reward.

B. fail to disclose, Clearly and Conspicuously, and in close proximity to such promotion or display of any offer of a Reward (other than a Video Reward):

1. that an Advertiser determines whether a Reward shall issue; and

2. when consumers are likely to receive the Reward;

C. before the initial promotion or offer of any Reward (other than a Video Reward) in conjunction with any Advertiser, fail to obtain the Advertiser's express written agreement that it will prominently disclose all material terms and conditions applicable to any promotion or offer of a Reward, notify Respondent in writing of any material change to those terms and conditions, not misrepresent any material aspect of those terms and conditions, and will comply with all applicable laws in connection with the promotion or offer of a Reward;

D. before the initial promotion or offer of any Reward (other than a Video Reward), and upon notice of any material change to any of the items listed in Paragraph D(1) of this Provision for such Reward, fail to:

1. obtain (i) all materials to be used in connection with the promotion or offer of the Reward, including text, graphic, video, audio, and photographs; (ii) the URL of any hyperlink contained in the promotion or offer of the Reward; (iii) all terms and conditions applicable to the promotion or offer of the Reward; and (iv) the instructions that state what a consumer must do to obtain the Reward;

2. use the information described in Paragraph D(1) of this Provision to attempt to obtain the Reward; and

3. validate based on successfully obtaining the Reward sought in Paragraph D(2) of this Provision that (i) all material terms and conditions applicable to the promotion or offer of the Reward, and all instructions to obtain the Reward, are Clearly and Conspicuously disclosed and non-misleading; and (ii) the offered Reward is delivered upon completion of the required actions or, if the promotion or offer specifies a time period within which the Reward will likely be delivered, within such specified time;

E. fail to provide a prominently disclosed and easy-to-use method by which consumers may submit support requests to Respondent; or

F. fail to promptly investigate any pattern of consumer support requests, offer-conversion data, or other information indicating that, for a particular promotion or offer of a Reward, the requirements of Paragraph D(3)(i) or (ii) of this Provision are not being satisfied, which investigation shall be documented in writing and at minimum entail:

1. repeating the steps described in Paragraphs D(1)-(3) of this Provision for the promotion or offer of the Reward (other than a Video Reward), *provided, however,* that repeating such steps shall be required for Gameplay Rewards only as necessary to confirm that Paragraphs D(3)(i) and (ii) of this Provision are satisfied;

2. promptly ceasing the promotion or offer of a Reward upon any finding by Respondent that Paragraph D(3)(i) or (ii) of this Provision and the terms of this Order are not satisfied for that particular promotion or offer, until Respondent confirms such promotion or offer of a Reward is corrected to bring it into compliance with Paragraphs D(3)(i) and (ii) of this Provision and the terms of this Order;

3. promptly and permanently ceasing to do business with any Advertiser if the findings of any investigation by Respondent indicate that the Advertiser has committed fraud; and

4. promptly and permanently ceasing to do business related to Rewards with an Advertiser if the findings of any investigation by Respondent indicate a pattern of violations by that Advertiser of the requirements imposed under Paragraph D(3)(i) of this Provision with respect to more than one promotion or offer of a Reward.

II. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondent obtain acknowledgments of receipt of this Order:

A. Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 5 years after the issuance date of this Order, Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any

business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

III. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondent make timely submissions to the Commission:

A. One year after the issuance date of this Order, Respondent must submit a compliance report, sworn under penalty of perjury, in which Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales; (d) describe in detail whether and how Respondent is in compliance with each Provision of this Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

B. For 10 years after the issuance date of this Order, Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following: (a) any designated point of contact; or (b) the structure of Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

C. Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re *Tapjoy, Inc.*, FTC File No. 1723092.

IV. Recordkeeping

IT IS FURTHER ORDERED that Respondent must create certain records for 10 years after the issuance date of the Order, and retain each such record for 5 years. Specifically, Respondent must create and retain the following records:

A. accounting records showing the revenues from all goods or services sold;

B. personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. records of all consumer complaints and customer support requests related to a Reward, whether received directly or indirectly, such as through a third party, and any response;

D. records obtained or created pursuant to Provision I(F) of this Order, including all information obtained to conduct any investigation and the outcome of each such investigation;

E. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission; and

F. a copy of each unique advertisement or other marketing material making a representation subject to this Order.

V. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondent's compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit

representatives of the Commission to interview anyone affiliated with Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

VI. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Concurring Statement

STATEMENT OF COMMISSIONER ROHIT CHOPRA JOINED BY COMMISSIONER REBECCA KELLY SLAUGHTER

Summary

- The explosive growth of mobile gaming has led to mounting concerns about harmful practices, including unlawful surveillance, dark patterns, and facilitation of fraud.
- Tapjoy's failure to properly police its mobile gaming advertising platform cheated developers and gamers out of promised compensation and rewards.
- The Commission must closely scrutinize today's gaming gatekeepers, including app stores and advertising middlemen, to prevent harm to developers and gamers.

The video game business has solidified its place as a fixture of America's entertainment industry. During the pandemic, revenues in the sector have reportedly eclipsed those of the sports and film businesses combined.[1] This period has brought about a massive increase in mobile gaming app installs and spending, cementing gaming as a major magnet for Americans' attention.[2] The latest industry offerings rely on deeper social connectivity features and facilitate content creation by players. Americans are hosting birthday parties through gaming apps, and tens of millions have attended concerts by major artists on Fortnite and Roblox.[3]

Mobile gaming is the fastest growing segment of the market, where revenues are primarily generated through in-app purchases and advertising. Importantly, this segment is characterized by a unique market structure dominated by new gatekeepers, particularly app stores and advertising middlemen. This structure is rightfully under more intense scrutiny, given the challenges facing developers and the downstream practices that can harm gamers.

It is against this backdrop that the Federal Trade Commission evaluates an appropriate remedy to address the conduct of Tapjoy, a mobile advertising platform that connects gamers, game developers, and advertisers. As detailed in the Commission's complaint, Tapjoy's practices allowed users to be cheated of promised rewards, and developers to be cheated of promised

1 Ben Gilbert, *Video-game industry revenues grew so much during the pandemic that they reportedly exceeded sports and film combined*, BUSINESS INSIDER (Dec. 23, 2020), https://www.businessinsider.com/video-game-industry-revenues-exceed-sports-and-film-combined-idc-2020-12.

2 Robert Williams, *Mobile gaming surges as pandemic drives 45% jump in app installs*, MARKETING DRIVE (Dec. 2, 2020), https://www marketingdive.com/news/mobile-gaming-surges-as-pandemic-drives-45-jump-in-app-installs/591417/. Gaming expert Joost van Dreunen recently offered helpful analysis about emerging trends in this growing industry. The Prof G Show with Scott Galloway, *Pandemic Learnings with Dr. Abdul El-Sayed* (Dec. 15, 2020), https://westwoodonepodcasts.com/pods/the-prof-g-show-with-scott-galloway/.

3 *See, e.g.*, Gil Kaufman, *Here's How Many People Tuned Into Lil Nas X's Roblox Show*, BILLBOARD (Nov. 17, 2020), https://www.billboard.com/articles/columns/hip-hop/9485495/lil-nas-x-roblox-show-viewers; *see also* Joost van Dreunen, *The future is user-generated*, SUPERJOOST PLAYLIST (Nov. 23, 2020), https://superjoost.substack.com/p/the-future-is-user-generated.

compensation. The proposed settlement does not remedy these past harms, but will require Tapjoy to better police its platform to prevent abuses going forward.[4]

Tapjoy's Middleman Misconduct

Tapjoy is a major mobile advertising platform that acts as a middleman between advertisers, gamers, and game developers. The platform woos developers into integrating its technology by promising payments for user activity. In a mobile gaming experience where developers use Tapjoy's advertising platform, Tapjoy displays "offers." When gamers complete these "offers," such as by signing up for subscriptions or making purchases, Tapjoy credits the user's account with coins or other currency for use in the game, and developers receive a percentage of Tapjoy's advertising revenue.[5]

However, according to the FTC's complaint, many players jumped through hoops – and even spent money and turned over sensitive data – to complete Tapjoy's offers, only to receive nothing in return.[6] It appears that Tapjoy amplified false offers by its business partners, who baited gamers with big rewards only to cheat them when it was time to pay up.[7] Tapjoy did little to clean up the mess, even when hundreds of thousands of gamers filed complaints.[8] This also harmed developers of mobile games, who were cheated of advertising revenue they were entitled to.

In my view, Tapjoy's conduct violated the FTC Act's prohibition on unfair practices, as well as the prohibition on deceptive practices.[9] The FTC's proposed settlement requires the platform to implement screening and testing procedures to weed out advertisers that cheat gamers and developers. This provision will help ensure Tapjoy takes more responsibility for fraud, rather than facilitating it.[10]

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4 This matter is another example where the lack of clarity regarding the scope of immunities conferred by Section 230 of the Communications Decency Act has given legal ammunition to platforms seeking to shirk responsibility for their commercial activity, including sales and advertising practices. This lack of clarity undermines the ability of the FTC and other regulators to obtain adequate monetary relief for misconduct.

5 In other instances, users can receive rewards directly through the game.

6 Compl. In the Matter of Tapjoy, Inc., ¶¶ 21-29.

7 Compl., *id.* ¶¶ 8, 15-29.

8 Compl., *id.* ¶¶ 30-40.

9 The Commission's proposed complaint charges Tapjoy with deception, but fails to include a charge of unfairness. However, the settlement includes injunctive relief that addresses Tapjoy's failure to police fraud.

10 I respectfully disagree with the proposed order provision requiring Tapjoy to disclose that advertisers are responsible for issuing rewards. This disclaimer undermines the goal of ensuring that Tapjoy takes adequate responsibility for its business partners' practices.

Gaming Gatekeepers and Trickle-Down Abuse

Tapjoy is not the only platform squeezing developers. In fact, the firm is a minnow next to the gatekeeping giants of the mobile gaming industry, Apple and Google. By controlling the dominant app stores, these firms enjoy vast power to impose taxes and regulations on the mobile gaming industry, which was generating nearly $70 billion annually even before the pandemic.[11]

We should all be concerned that gatekeepers can harm developers and squelch innovation. The clearest example is rent extraction: Apple and Google charge mobile app developers on their platforms up to 30 percent of sales, and even bar developers from trying to avoid this tax through offering alternative payment systems.[12] While larger gaming companies are pursuing legal action against these practices, developers and small businesses risk severe retaliation for speaking up, including outright suspension from app stores – an effective death sentence.[13]

This market structure also has cascading effects on gamers and consumers. Under heavy taxation by Apple and Google, developers have been forced to adopt alternative monetization models that rely on surveillance, manipulation, and other harmful practices.

For example, many developers are turning to "loot boxes" to squeeze more revenue out of gamers. These loot boxes deploy dark patterns and other deceptions to lure gamers – often children – into purchasing in-app rewards of randomly assigned value, turning videogames into virtual casinos. As detailed in a recent FTC report, this addictive phenomenon emerged as a direct consequence of changing monetization models in the industry, as developers increasingly rely on recurring revenue, such as through in-app purchases, rather than upfront sales.[14]

Mobile gaming's market structure is also forcing developers to create revenue streams that are not subject to app store taxation, including through intrusive behavioral advertising. Last year, for example, the FTC brought an action against Hyperbeard, a developer of child-directed games charged with allowing major ad networks to surveil users – including children – in order

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11 *See* Omer Kaplan, *Mobile gaming is a $68.5 billion global business, and investors are buying in*, TECHCRUNCH (Aug. 22, 2019), https://techcrunch.com/2019/08/22/mobile-gaming-mints-money/.

12 *See* STAFF OF H. COMM. ON THE JUDICIARY, 116TH CONG., INVESTIGATION OF COMPETITION IN DIGITAL MARKETS: MAJORITY STAFF REPORT AND RECOMMENDATIONS at 221 (Google); 339 (Apple). Although Google allows users to "sideload" apps from outside the Play Store, it has been alleged that Google makes this process "technically complex, confusing and threatening[.]" *Id.* at 220 (quoting Epic lawsuit).

13 Developers have alleged retaliatory practices by both Google and Apple, such as when they have tried to circumvent these gatekeepers' preferred monetization tools. *Id.* at 222, 348-349.

14 Press Release, Fed. Trade Comm'n, FTC Staff Issue Perspective Paper on Video Game Loot Boxes Workshop (Aug. 14, 2020), https://www.ftc.gov/news-events/press-releases/2020/08/ftc-staff-issue-perspective-paper-video-game-loot-boxes-workshop.

to serve behavioral advertising.[15] This type of conduct violates the Children's Online Privacy Protection Act, but Hyperbeard's surveillance practices are not unique. In fact, Google encourages game developers on its platform to adopt this monetization model, claiming "users expect free games."[16]

Today's action against Tapjoy reveals another monetization model that developers are turning to in the face of fees and restrictions imposed by app stores. By offering a platform connecting advertisers, gamers, and game developers, Tapjoy allows these developers to generate advertising revenue that Apple and Google do not tax. But this monetization model also creates opportunities for fraud, and the Commission's complaint details how Tapjoy allowed this fraud to fester.

Monitoring the Middlemen

Developers of mobile games are delivering creative content that keeps Americans entertained and engaged, but face many middlemen, even beyond the dominant app stores. Game developers relied on Tapjoy to generate revenue for themselves and offer gamers a way to earn currency to enhance their play. However, Tapjoy's failure to screen fraudulent offers left both gamers and developers holding the bag.

The settlement proposed today should help reverse the lax policing practices that led hundreds of thousands of gamers to file complaints. But when it comes to addressing the deeper structural problems in this marketplace that threaten both gamers and developers, the Commission will need to use all of its tools – competition, consumer protection, and data protection – to combat middlemen mischief, including by the largest gaming gatekeepers.

15 Press Release, Fed. Trade Comm'n, Developer of Apps Popular with Children Agrees to Settle FTC Allegations It Illegally Collected Kids' Data without Parental Consent (June 4, 2020), https://www ftc.gov/news-events/press-releases/2020/06/developer-apps-popular-children-agrees-settle-ftc-allegations-it.

16 *Mobile ads: the key to monetizing gaming apps*, GOOGLE ADMOB, https://admob.google.com/home/resources/monetize-mobile-game-with-ads/ (last visited on Jan. 5, 2021).

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order from Tapjoy, Inc. ("Tapjoy"). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

Tapjoy operates an advertising platform within mobile gaming applications. On the platform, Tapjoy promotes offers of in-app rewards (e.g., virtual currency) to consumers who complete an action, such as taking a survey or otherwise engaging with third-party advertising. To induce consumers to engage with third-party advertisers, Tapjoy offers in-app rewards in the form of a specified amount of virtual currency that can be used in the in-app games. However, in many instances, Tapjoy never issued the promised reward to consumers who complete an action as instructed, or only issued the currency after a substantial delay. Consumers who attempt to contact Tapjoy to complain about missing rewards have found it difficult to do so, and even consumers who have been able to submit a complaint nevertheless did not receive the promised reward.

The Commission's proposed complaint alleges that Tapjoy has violated Section 5 of the FTC Act. In particular, the proposed complaint alleges that Tapjoy has represented that consumers will receive a reward of virtual currency upon completion of a specific action when, in many instances, that representation was false, misleading, or not substantiated at the time the representation was made.

The proposed order contains injunctive provisions addressing the alleged deceptive conduct. Part I.A of the proposed order prohibits Tapjoy from making the misrepresentations alleged in the complaint. Part I.B of the proposed order requires Tapjoy to make certain disclosures, specifically that its advertisers determine whether rewards are likely to issue, and when consumers are likely to receive rewards. Part I.C requires Tapjoy to obtain specified agreements from the associated advertiser before a reward is promoted or offered. Part I.D. requires Tapjoy, before a reward is promoted or offered, to obtain the materials used to promote or offer the reward, to use those materials to attempt to obtain the reward, to validate the accuracy of those materials, and to validate that the reward is delivered promptly or that any delay is disclosed. Part I.E requires Tapjoy to provide a prominently disclosed and easy-to-use method by which consumers may submit support requests. Part I.F requires Tapjoy to investigate patterns of customer support requests or other information indicating that a particular promotion or offer of a reward has inaccurate instructions or is failing to deliver the reward.

Parts II through V of the proposed order are reporting and compliance provisions. Part II requires acknowledgments of the order. Part III requires Tapjoy to notify the Commission of changes in corporate status and mandates that the company submit an initial compliance report to the Commission. Part IV requires the company to create certain documents relating to its compliance with the order for 10 years and to retain those documents for a 5-year period. Part V

mandates that the company make available to the Commission information or subsequent compliance reports, as requested.

Finally, Part VI states that the proposed order will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

Complaint

IN THE MATTER OF

THOMAS JEFFERSON UNIVERSITY
AND
ALBERT EINSTEIN HEALTHCARE NETWORK

FINAL ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

Docket No. 9392; File No. 181 0128
Complaint, February 27, 2020 – Decision, [Date]

This order addresses the $[redacted] acquisition by Thomas Jefferson University of certain assets of Albert Einstein Healthcare Network. The complaint alleges that the acquisition, if consummated would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by significantly reducing competition in the market for inpatient general acute care hospital services and inpatient acute rehabilitation services in Philadelphia and Montgomery counties. The U.S. District Court for the Eastern District of Pennsylvania denied a preliminary injunction barring the Proposed Transaction until completion of the administrative proceeding finding the testimony of the insurance company witnesses not credible and rejecting the proposed geographic markets. The Order returns the matter to adjudication and dismisses the complaint.

Participants

For the *Commission*: *Ryan Andrews, Emily Bowne, Gustav Chiarello, Charles Dickinson, Jamie France, Christopher Harris,* and *Albert Teng.*

For the *Respondents*: *Ken Vorrasi, Drinker Biddle & Reath LLP; Leigh Oliver* and *Bob Leibenluft, Hogan Lovells US LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by the virtue of the authority vested in it by the FTC Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents Thomas Jefferson University ("Jefferson") and Albert Einstein Healthcare Network ("Einstein") have executed a system integration agreement in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, which if consummated would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

I.

NATURE OF THE CASE

1. Jefferson and Einstein are two of the leading providers of inpatient general acute care ("GAC") hospital services and inpatient acute rehabilitation services in Philadelphia and

Montgomery counties. Jefferson and Einstein entered a System Integration Agreement dated September 14, 2018 ("Integration Agreement"), whereby Jefferson will become the sole member of Einstein and the ultimate parent entity of Einstein (the "Transaction"). The proposed Transaction would combine the Jefferson and Einstein systems to create the largest hospital system in Philadelphia County and by far the largest hospital system in Montgomery County and in the greater Philadelphia region.

2. Einstein and Jefferson hospitals offer a broad range of medical and surgical diagnostic and treatment services that require an overnight hospital stay. Today, Respondents compete to sell these inpatient GAC hospital services to commercial insurers and to provide inpatient GAC hospital services to those insurers' members.

3. Einstein operates GAC hospitals that compete directly and significantly with Jefferson's GAC hospitals. Located in North Philadelphia, Einstein's flagship hospital, Einstein Medical Center Philadelphia ("EMCP"), significantly competes with Jefferson's Abington Hospital ("Abington"), located in eastern Montgomery County, and Jefferson Frankford Hospital, located in northeast Philadelphia. Einstein Medical Center Elkins Park ("EMCEP"), a GAC hospital inside a larger inpatient rehabilitation facility in eastern Montgomery County, likewise significantly competes with Jefferson's Abington Hospital and Jefferson Frankford Hospital. In Montgomery County, Einstein Medical Center Montgomery ("EMCM") significantly competes with both Jefferson's Abington Hospital and Jefferson's Abington-Lansdale Hospital ("Lansdale"). The relevant geographic markets to assess the competitive impact of the Transaction include GAC hospitals in the area around EMCP in North Philadelphia (the "Northern Philadelphia Area") and GAC hospitals in the area around EMCM in Montgomery County (the "Montgomery Area").

4. Jefferson and Einstein are close competitors for inpatient GAC hospital services. Einstein's internal documents identify Jefferson as the "market leader" for inpatient GAC hospital services in the greater Philadelphia region. Jefferson is "1st in the [Einstein] service area and ahead of [Einstein]." [redacted] Likewise, Jefferson recognizes that Einstein "competes closely" with Jefferson and that Jefferson's GAC hospitals are "Einstein's major competitors in the Einstein [primary service area]."

5. Post-Transaction, Respondents would control at least 60% of the inpatient GAC hospital services market, as measured by commercially insured patient admissions in the Northern Philadelphia Area, with only one other hospital system providing inpatient GAC hospital services with any meaningful presence. Post-Transaction, Respondents also would become the market leader in the Montgomery Area, controlling at least 45% of the inpatient GAC hospital services market, as measured by commercially insured patient admissions, in the Montgomery Area.

6. Under the 2010 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines ("Merger Guidelines"), a post-acquisition market concentration

level above 2,500 points, as measured by the Herfindahl-Hirschman Index ("HHI"), and an increase in market concentration of more than 200 points renders an acquisition presumptively unlawful. Based on commercially insured patient admissions, the Transaction would significantly increase concentration in already highly concentrated markets for inpatient GAC hospital services, well beyond the thresholds set forth in the Merger Guidelines. Thus, under the Merger Guidelines, the Transaction is presumptively unlawful in the inpatient GAC hospital services product market in both the Northern Philadelphia Area and the Montgomery Area.

7. In addition to providing inpatient GAC hospital services, Respondents also operate nationally renowned inpatient rehabilitation facilities ("IRFs") that compete against each other today. Einstein operates several IRFs under the name MossRehab ("Moss") throughout the greater Philadelphia region, and Jefferson operates Magee Rehabilitation Hospital ("Magee") in the Center City neighborhood of Philadelphia and two other IRFs in the greater Philadelphia region.

8. Einstein and Jefferson IRFs provide advanced post-acute rehabilitation care for patients treated at GAC hospitals for conditions such as stroke, traumatic brain injury, or spinal cord injury. IRFs provide such inpatient acute rehabilitation services to only those patients who can withstand and benefit from them. The relevant geographic market in which to analyze the effects of the Transaction for inpatient acute rehabilitation services is the area around Einstein's Moss at Elkins Park (the "Philadelphia Area"). Together, Respondents operate six of the eight IRFs in the Philadelphia Area.

9. Both Einstein and Jefferson compete vigorously for rehabilitation patients. Magee "compete[s] head to head with [Moss] for everything." Magee identifies Moss IRFs as its "Primary Competitor(s)" for post-acute "Services" and "Reputation/brand." And from Einstein's perspective, "Magee is a threat."

10. The Transaction will substantially lessen competition in the market for inpatient acute rehabilitation services in the Philadelphia Area. Respondents are the largest providers of inpatient acute rehabilitation services in the Philadelphia Area. Post-Transaction, Respondents would control at least 70% of the inpatient acute rehabilitation services market by commercially insured patient admissions in the Philadelphia Area, with only one other IRF providing inpatient acute rehabilitation services with any meaningful presence.

11. In the Philadelphia Area, the Transaction would significantly increase market concentration in an already highly concentrated market for inpatient acute rehabilitation services such that the Transaction is presumptively unlawful under the Merger Guidelines.

12. Today, Jefferson and Einstein compete for inclusion in commercial insurers' hospital networks. A commercial insurer would find it difficult to market a health plan to employers and their employees living or working in the Northern Philadelphia Area or the Montgomery Area that excluded all of the GAC hospitals owned by Einstein and Jefferson. Likewise, a commercial insurer would find it difficult to market a health plan to employers and their employees living or working in the Philadelphia Area that excluded all of the IRFs owned by Respondents.

13. Hence, by eliminating competition between Respondents, the Transaction is likely to increase Respondents' bargaining leverage with commercial insurers and enhance Respondents' ability to negotiate more favorable reimbursement terms, including reimbursement rates (i.e., prices). Faced with higher reimbursement rates and other less favorable terms, commercial insurers will have to pass on at least some of those higher healthcare costs to employers and their employees in the form of increased premiums, co-pays, deductibles, and other out-of-pocket expenses. "Self-insured" employers that pay the cost of their employees' healthcare claims directly will bear the full and immediate burden of higher reimbursement rates and other less favorable terms.

14. Jefferson and Einstein have a history of upgrading medical facilities, improving patient access, and offering more competitive reimbursement rates and terms to commercial insurers because of competition from each other that will be lost if the Transaction goes forward.

15. The Transaction will substantially lessen competition and cause significant harm to consumers. If Respondents consummate the Transaction, healthcare costs will rise, and the incentive for Respondents to increase service offerings and improve the quality of healthcare will diminish.

16. Entry or expansion by other GAC hospitals or IRFs will not be likely, timely, or sufficient to offset the adverse competitive effects that likely will result from the Transaction. Potential entrants would need to devote significant time and resources to conduct studies, develop plans, acquire land or repurpose a facility, and construct and open a competitive GAC hospital or IRF. Respondents' reputations, size, and the breadth and depth of the inpatient GAC hospital services and inpatient acute rehabilitation services they provide make it unlikely that there will be entry on a sufficient scale to counteract or constrain post-Transaction price increases.

17. Respondents have not substantiated any verifiable, merger-specific efficiencies. Even if Respondents could identify some cognizable efficiencies resulting from the Transaction, any savings likely to be passed on to patients are far outweighed by the Transaction's potential harm and thus would not be sufficient to justify the Transaction.

II.

JURISDICTION

18. Respondents, and each of their relevant operating entities and subsidiaries are, and at all relevant times have been, engaged in commerce or in activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

19. The Transaction constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

III.

BACKGROUND

A.

Respondents

20. Respondent Jefferson, a Pennsylvania not-for-profit corporation, operates an academic health system headquartered in Philadelphia that is the largest health system by hospital beds in the greater Philadelphia region. It is also the second-largest employer in Philadelphia, employing over 30,000 people, including approximately 6,100 physicians and practitioners and 7,400 nurses. For fiscal year 2019, Jefferson generated $5.2 billion in revenues.

21. Jefferson operates 11 GAC hospitals in Pennsylvania and New Jersey and three IRFs in Pennsylvania. Across all of its inpatient facilities, Jefferson discharges approximately 130,000 inpatients a year. Jefferson also operates over 50 outpatient and urgent care locations in Pennsylvania and New Jersey.

22. Jefferson operates four GAC hospitals in the City of Philadelphia—Thomas Jefferson University Hospital ("TJUH"), Methodist Hospital, Jefferson Frankford Hospital (f/k/a Aria Frankford Hospital), and Jefferson Torresdale Hospital (f/k/a Aria Torresdale Hospital)—and two GAC hospitals in Montgomery County—Abington and Lansdale (together, f/k/a Abington Health).

23. Jefferson has acquired a number of hospital systems and IRFs in recent years. Since 2015, Jefferson has merged with Abington Health, Aria Health System, Kennedy Health, and Magee. By virtue of its merger with Aria Health System, Jefferson also has a partial ownership stake in Health Partners Plans, a not-for-profit health maintenance organization that offers managed government insurance, including Medicaid and Medicare plans, to members in Southeastern Pennsylvania. In December 2019, Jefferson signed definitive agreements to acquire Temple University's Fox Chase Cancer Center, Temple's Bone Marrow Transplant program, and Temple's partial ownership interest in Health Partners Plans. Jefferson operates 12 colleges, schools, and institutes, including Sidney Kimmel Medical College, the fifth-largest medical school in the country.

24. After merging with Abington Health in 2015, Jefferson now owns and operates two hospitals in Montgomery County. Abington is a 665-bed regional referral center and teaching hospital located in Abington Township in eastern Montgomery County, near the border with Philadelphia County.[1] Lansdale is a 140-bed hospital in Lansdale, which is located in the northern part of central Montgomery County. Subsequent to its merger with Aria Health System

1 This includes 23 hospital beds for inpatient acute rehabilitation services, as discussed *supra*.

in 2016, Jefferson gained control over three additional hospitals in the greater Philadelphia region, including Jefferson Frankford, a 115-bed hospital in northeast Philadelphia.

25. Jefferson merged with Magee in 2018. Magee is located in the City of Philadelphia and is currently undergoing a renovation that will bring its hospital beds down from 96 to 82. Jefferson also operates two IRF units within larger GAC hospitals—one at TJUH named the Jefferson Acute Rehabilitation Unit and one at Abington named the Abington Acute Rehabilitation Unit. Both have 23 beds.

26. Respondent Einstein, a Pennsylvania not-for-profit corporation, operates an academic health system headquartered in North Philadelphia. Einstein operates three GAC hospitals—one in Philadelphia and two in Montgomery County—and five IRFs. Einstein also operates 15 outpatient centers. Einstein discharges over 30,000 inpatients a year and employs over 8,800 people, including over 500 physicians. Like Jefferson, Einstein has a partial ownership stake in Health Partners Plans. For fiscal year 2019, Einstein generated $1.2 billion in revenues.

27. Einstein provides inpatient GAC hospital services at two main locations. EMCP, Einstein's largest GAC hospital with 485 licensed acute care beds, is located in North Philadelphia. EMCP is a tertiary care teaching hospital and a Level 1 Trauma Center. EMCP is the largest independent academic medical center in the greater Philadelphia region and trains more than 400 residents and fellows each year in graduate medical education programs. Einstein's second GAC hospital is EMCM, a 191-bed hospital in East Norriton in central Montgomery County. Einstein also owns and operates EMCEP, a 67-bed GAC hospital in eastern Montgomery County that is located inside the larger Moss at Elkins Park IRF.

28. Einstein's Moss provides inpatient acute rehabilitation services at five IRFs in the greater Philadelphia region. Moss at Elkins Park is a freestanding IRF with 130 licensed beds. Moss also owns and operates an IRF unit at EMCP with 19 beds. Moss currently operates three 12-bed IRF units at non-Einstein hospitals. Two are at Jefferson hospitals—Jefferson Frankford Hospital and Jefferson Bucks Hospital—and one is at Doylestown Hospital.

B.

The Transaction

29. After several years of discussions between Jefferson and Einstein, Respondents entered into the Integration Agreement on September 14, 2018, whereby Jefferson would become the sole member and ultimate parent entity of Einstein. The Respondents value the Transaction at [redacted]. The combined entity would operate 14 GAC hospitals, including 11 in Pennsylvania, and eight IRFs in Pennsylvania. The Transaction would make Jefferson—already the largest health system by hospital beds in the greater Philadelphia region—even larger, with over 1,000 more hospital beds than the next largest health system in the greater Philadelphia region.

IV.

THE RELEVANT SERVICE MARKETS

30. The Transaction threatens substantial harm to competition in two service markets: (i) inpatient GAC hospital services sold and provided to commercial insurers and their insured members; and (ii) inpatient acute rehabilitation services at IRFs sold and provided to commercial insurers and their insured members. For each service market, a hypothetical monopolist could profitably impose a small but significant and non-transitory increase in price ("SSNIP"). Because commercial insurers would accept a SSNIP rather than market a network that omitted inpatient GAC hospital services, and would accept a SSNIP rather than market a network that omitted inpatient acute rehabilitation services at IRFs, each of these service markets constitutes a relevant market for analyzing the Transaction.

A.

Inpatient GAC Hospital Services

31. Inpatient GAC hospital services sold and provided to commercial insurers and their insured members is a relevant service market for assessing the Transaction's effects on competition. This service market encompasses a broad cluster of medical and surgical diagnostic and treatment services offered by both Einstein and Jefferson that require an overnight hospital stay. Inpatient GAC hospital services include, but are not limited to, many emergency services, internal medicine services, and surgical procedures offered by both Respondents under similar competitive conditions.

32. Although the Transaction's likely effect on competition could be analyzed separately for each individual inpatient service, it is appropriate to evaluate the Transaction's likely effects across this cluster of inpatient GAC hospital services because these services are offered to patients in the Northern Philadelphia Area and the Montgomery Area under similar competitive conditions. Thus, grouping the hundreds of individual inpatient GAC hospital services into a cluster for analytical convenience enables the efficient evaluation of competitive effects with no loss of analytic power.

33. Outpatient services are not included in the inpatient GAC hospital services market because commercial insurers and patients cannot substitute outpatient services in response to a price increase for inpatient GAC hospital services. Additionally, outpatient services are offered by a different set of competitors under different competitive conditions than inpatient GAC hospital services.

34. Finally, the inpatient GAC hospital services market does not include services related to psychiatric care, substance abuse, and rehabilitation services. These services also are offered by a different set of competitors under different competitive conditions than, and are not substitutes for, inpatient GAC hospital services.

B.

Inpatient Acute Rehabilitation Services

35. Inpatient acute rehabilitation services at IRFs sold and provided to commercial insurers and their insured members also is a relevant service market for assessing the Transaction's effects on competition. This service market encompasses a cluster of acute rehabilitation services provided under similar competitive conditions to patients that require an overnight stay and were previously treated at a GAC hospital (i.e., post-acute patients). Inpatient acute rehabilitation services include, at a minimum, intensive multi-disciplinary rehabilitation therapies at least three hours a day for five days per week, three face-to-face visits with a physician per week, and 24-hour nursing care, *inter alia*.

36. Although the Transaction's likely effect on competition could be analyzed separately for each inpatient acute rehabilitation service, it is appropriate to evaluate the Transaction's likely effects across this cluster of inpatient acute rehabilitation services because these services are offered to patients in the Philadelphia Area under similar competitive conditions.

37. IRFs, which operate under a hospital license, provide inpatient acute rehabilitation services. IRFs can exist either as units housed in larger hospitals providing inpatient GAC hospital services ("IRF units") or as standalone hospitals ("freestanding IRFs"). Freestanding IRFs may house departments providing other services as well. For instance, a freestanding IRF like Moss at Elkins Park can have a department—in this case, EMCEP—that offers inpatient GAC hospital services. To obtain certification for reimbursement as an IRF by the Centers for Medicare and Medicaid Services, 60% of all patient discharges (Medicare or other) must have as a primary diagnosis or comorbidity one of 13 specified conditions that typically require inpatient acute rehabilitation services.

38. Other post-acute care services like subacute rehabilitation services provided at skilled nursing facilities are not included in the market for inpatient acute rehabilitation services because commercial insurers and patients cannot substitute these services for inpatient acute rehabilitation services. Subacute rehabilitation services are offered by a different set of competitors under different competitive conditions than inpatient acute rehabilitation services. In fact, subacute rehabilitation services are often complementary to inpatient acute rehabilitation services.

V.

THE RELEVANT GEOGRAPHIC MARKETS

39. The relevant geographic markets in which to analyze the effects of the Transaction for inpatient GAC hospital services are the Northern Philadelphia Area and the Montgomery Area. For inpatient acute rehabilitation services, the relevant geographic market is the Philadelphia Area.

40. As with determining the appropriate service markets to analyze the Transaction, the appropriate geographic markets in which to analyze the Transaction are the areas where a hypothetical monopolist of the hospitals located in these areas could profitably impose a SSNIP on the relevant services. Because commercial insurers would accept a SSNIP rather than market insurance plans that exclude all hospitals providing inpatient GAC hospital services in the Northern Philadelphia Area, all hospitals providing inpatient GAC hospital services in the Montgomery Area, or all IRFs providing inpatient acute rehabilitation services in the Philadelphia Area, these are relevant geographic markets in which to analyze the Transaction.

A.

Inpatient GAC Hospital Services Geographic Markets

41. The Northern Philadelphia Area is approximately the area that includes the following GAC hospitals in Philadelphia—EMCP, Jefferson Frankford Hospital, Temple University Hospital, Temple's Jeanes Hospital, Prime Healthcare's Roxborough Memorial Hospital, and Tower Health's Chestnut Hill Hospital—and in eastern Montgomery County—EMCEP (housed inside Moss at Elkins Park) and Jefferson's Abington. The Northern Philadelphia Area also includes the following specialty hospitals in Philadelphia that provide select inpatient GAC hospital services—St. Christopher's Hospital for Children, Temple's Fox Chase Cancer Center, and Cancer Treatment Centers of America's Philadelphia Comprehensive Care and Research Center. The Northern Philadelphia Area is the main area of competition between Einstein's EMCP and EMCEP and the Jefferson hospitals with which they most directly compete—Abington and Jefferson Frankford.

42. The Montgomery Area is approximately the area that includes the following GAC hospitals in Montgomery County—EMCM, Jefferson's Abington, Jefferson's Lansdale, Main Line Health's Bryn Mawr Hospital, and Prime Healthcare's Suburban Community Hospital—and just outside Montgomery County—Main Line Health's Paoli Hospital, Tower Health's Chestnut Hill Hospital, Tower Health's Phoenixville Hospital, and Prime Healthcare's Roxborough Memorial Hospital. The Montgomery Area also includes a hospital in Montgomery County that provides specialty surgical services—Physicians Care Surgical Hospital. The Montgomery Area is the main area of competition between Einstein's EMCM and the two Jefferson hospitals with which EMCM most directly competes—Abington and Lansdale. A hospital can be in more than one relevant geographic market if it competes, as Abington does, in more than one geographic area within which a hypothetical monopolist could profitably impose a SSNIP.

43. Patients who receive inpatient GAC hospital services in the Northern Philadelphia Area strongly prefer to obtain inpatient GAC hospital services close to where they live. It would be very difficult for a commercial insurer to market successfully a health plan provider network that excluded all hospitals located within the Northern Philadelphia Area. Hence, because a significant number of patients within this geographic market would not view hospitals outside of the market as practical alternatives, a hypothetical monopolist of all of the GAC hospitals within the Northern Philadelphia Area could profitably impose a SSNIP.

44. Likewise, patients who receive inpatient GAC hospital services in the Montgomery Area strongly prefer to obtain inpatient GAC hospital services close to where they live. It would be very difficult for a commercial insurer to market successfully a health plan provider network that excluded all hospitals located within the Montgomery Area. Hence, because a significant number of patients within this geographic market would not view hospitals outside of the market as practical alternatives, a hypothetical monopolist of all of the GAC hospitals within the Montgomery Area could profitably impose a SSNIP.

B.

Inpatient Acute Rehabilitation Services Geographic Market

45. The Philadelphia Area is approximately the area that includes the following IRFs in Philadelphia—Einstein's Moss at EMCP, Einstein's Moss at Jefferson Frankford Hospital, Jefferson's Magee, Jefferson Acute Rehabilitation Unit at TJUH, the Penn Institute for Rehabilitation Medicine, and Trinity Health's Nazareth Hospital Acute Rehabilitation Unit—and in eastern Montgomery County—Einstein's Moss at Elkins Park and Jefferson's Abington Acute Rehabilitation Unit. The Philadelphia Area is the main area of competition between Einstein's Moss at Elkins Park, Moss at EMCP, and Moss at Frankford Hospital, and Jefferson's Magee, Jefferson Acute Rehabilitation Unit at TJUH, and Abington Acute Rehabilitation Unit.

46. As with inpatient GAC hospital services, patients who receive inpatient acute rehabilitation services in the Philadelphia Area strongly prefer to obtain these services close to where they live. It would be very difficult for a commercial insurer to market successfully a health plan provider network that excluded all IRFs located within the Philadelphia Area. Hence, because a significant number of patients within the Philadelphia Area would not view IRFs outside of the area as practical alternatives, a hypothetical monopolist of all of the IRFs within the Philadelphia Area could profitably impose a SSNIP.

VI.

MARKET STRUCTURE AND THE TRANSACTION'S PRESUMPTIVE ILLEGALITY

47. Jefferson and Einstein are two of the largest providers, by commercially insured patient admissions, of inpatient GAC hospital services in the Northern Philadelphia Area and the Montgomery Area. Likewise, Jefferson and Einstein are the two largest providers, by commercially insured patient admissions, of inpatient acute rehabilitation services in the Philadelphia Area. The Transaction will significantly increase concentration in already highly concentrated markets for inpatient GAC hospital services and inpatient acute rehabilitation services in the relevant geographies. These levels of concentration render the Transaction presumptively unlawful under the Merger Guidelines.

48. Under the Merger Guidelines, a merger or acquisition is presumed likely to create or enhance market power—and is presumptively unlawful—when it increases the HHI by more than 200 points and results in a post-acquisition HHI above 2,500 points. Here, in each of the three relevant markets, the Transaction exceeds this concentration threshold.

49. Based on commercial inpatient GAC admissions of patients seeking care in the Northern Philadelphia Area, Respondents would control at least 60% of this market post-Transaction. The Transaction would increase the HHI by at least 1,200 points in the Northern Philadelphia Area, resulting in a post-Transaction HHI of at least 4,500, exceeding the threshold over which the Transaction is presumed likely to create or enhance market power—and is presumptively unlawful.

50. Based on commercial inpatient GAC admissions of patients seeking care in the Montgomery Area, Respondents would control at least 45% of this market post-Transaction. The Transaction would increase the HHI in the Montgomery Area by at least 700 points, resulting in a post-Transaction HHI of at least 3,500. These concentration measures make the Transaction presumptively unlawful.

51. Post-Transaction, Respondents also would control at least 70% of the market for inpatient acute rehabilitation services in the Philadelphia Area. The Transaction would increase the HHI in the Philadelphia Area by at least 2,500 points, resulting in a post-Transaction HHI of at least 5,900. These market concentration measures make the Transaction presumptively unlawful.

VII.

ANTICOMPETITIVE EFFECTS

A.

Competition Between Hospitals Benefits Consumers

52. Competition between hospitals (including IRFs) occurs in two distinct but related stages. First, hospitals compete for inclusion in commercial insurers' health plan provider networks. Second, in-network hospitals compete to attract patients, including commercial insurers' health plan members.

53. In the first stage of hospital competition, hospitals compete to be included in commercial insurers' health plan provider networks. To become an in-network provider, a hospital negotiates with a commercial insurer and, if mutually agreeable terms can be reached, enters into a contract. The financial terms under which a hospital is reimbursed for services rendered to a health plan's members are a central component of those negotiations, regardless of whether reimbursements are based on fee-for-service contracts, risk-based contracts, or other types of contracts.

54. In-network status benefits a hospital by giving it preferential access to the health plan's members. Health plan members typically pay far less to access in-network hospitals than those that are out-of-network. All else being equal, an in-network hospital will attract more patients from a particular health plan than an out-of-network one. This dynamic motivates hospitals to offer lower rates and other more favorable terms to commercial insurers to win inclusion in their networks.

55. From the insurers' perspective, having hospitals in-network is beneficial because it enables the insurer to create a health plan provider network in a particular geographic area that is attractive to current and prospective members, typically local employers and their employees.

56. A critical determinant of the relative bargaining positions of a hospital and a commercial insurer during contract negotiations is whether other, nearby comparable hospitals are available to the commercial insurer and its health plan members as alternatives in the event of a negotiating impasse. Alternative hospitals limit a hospital's bargaining leverage and constrain its ability to obtain more favorable reimbursement terms from commercial insurers. The more attractive alternative hospitals are to a commercial insurer's health plan members in a local area, the greater the constraint on a hospital's bargaining leverage. Where there are fewer meaningful alternatives, a hospital will have greater bargaining leverage to demand and obtain higher reimbursement rates and other more favorable reimbursement terms.

57. A merger between hospitals that are close substitutes in the eyes of commercial insurers and their health plan members tends to increase the merged entity's bargaining leverage. Such mergers lead to higher reimbursement rates by eliminating an available alternative for commercial insurers. This increase in leverage is greater when the merging hospitals are closer substitutes for (and competitors to) each other. This is true even where other factors, such as an insurer's leverage, may impact the pre-merger bargaining dynamic. Preexisting leverage for the insurer does not eliminate the concern about an increase in the post-merger bargaining leverage of the merged entity.

58. Changes in the reimbursement terms negotiated between a hospital and a commercial insurer, including increases in reimbursement rates, significantly impact the commercial insurer's health plan members. "Self-insured" employers rely on a commercial insurer for access to its health plan provider network and negotiated rates, but these employers pay the cost of their employees' healthcare claims directly and bear the full and immediate burden of any rate increase in the healthcare services used by their employees. Employees may bear some portion of the increased cost through increased premiums, co-pays, and deductibles. "Fully-insured" employers pay premiums to commercial insurers—and employees pay premiums, co-pays, and deductibles—in exchange for the commercial insurer assuming financial responsibility for paying hospital costs generated by the employees' use of hospital services. When hospital rates increase, commercial insurers generally pass on a significant portion of these increases to their fully insured customers in the form of higher premiums, co-pays, and deductibles.

59. In the second stage of hospital competition, hospitals compete to attract patients to their facilities. Because health plan members often face similar out-of-pocket costs for in-network hospitals, hospitals in the same network compete to attract patients on non-price features such as location, quality of care, access to services and technology, reputation, physicians and faculty members, amenities, convenience, and patient satisfaction. Hospitals compete on these non-price dimensions to attract all patients, regardless of whether they are covered by commercial insurance (including Medicare Advantage and Medicaid Managed Care), traditional Medicare and Medicaid, or are patients without commercial insurance. A merger of competing

hospitals eliminates this non-price competition and reduces the merged entity's incentive to improve and maintain service and quality. Providers also compete on price terms in this second stage of competition in circumstances when patients pay the full cost of the procedure out of pocket, regardless of whether they are commercially insured.

B.

The Transaction Would Eliminate Beneficial Head-to-Head Competition and Increase Bargaining Leverage

60. Jefferson and Einstein are close competitors for inpatient GAC hospital services. Einstein's internal documents focus on Jefferson as a "major," "primary," and "top" competitor for inpatient GAC hospital services and the "market leader" in its service area. Einstein's strategic planning team observed that "[c]ompetitors continue to pull volume from [EMCP's and EMCEP's] service area." In particular, Jefferson's Abington Health and Aria Health System experienced volume increases and held the second- and third-highest market shares in EMCP's and EMCEP's service area. Conversely, Einstein's growth at EMCM has "come at the expense of the competition," including Jefferson's Abington and Lansdale GAC hospitals. When asked what health systems Einstein aspires to compete with, Einstein's marketing team identified only one: "Jefferson Health is one of the top networks we aspire to compete with. They are better resourced and chosen over our services by potential patients." Similarly, Jefferson recognizes that Einstein is a significant competitor to Jefferson in the Northern Philadelphia and Montgomery Areas—internal Jefferson documents note that Einstein "competes closely" with Jefferson in EMCP's primary service area and that EMCM "competes with Abington Lansdale and Abington Hospital." Because Einstein and Jefferson offer close substitutes for inpatient GAC hospital services, the Transaction would eliminate significant head-to-head competition between Respondents post-merger.

61. Diversion analysis, a standard economic tool that uses data on where patients receive hospital services to determine the extent to which hospitals are substitutes, confirms that Einstein and Jefferson are close competitors for inpatient GAC hospital services. Diversion analysis shows that if Einstein hospitals were to become unavailable to patients for inpatient GAC hospital services, at least 30% of EMCP's patients, 35% of EMCEP's patients, and 17% of EMCM's patients, respectively, would seek care at a Jefferson hospital. Diversion analysis similarly shows that if Jefferson hospitals were unavailable to patients for inpatient GAC hospital services, at least 11% of Abington patients, 7% of Lansdale patients, and 7% of Jefferson Frankford patients, respectively, would seek care at an Einstein hospital. These diversion analyses lead to predictions of significant post-Transaction price increases.

62. Similarly, Jefferson and Einstein are close competitors for inpatient acute rehabilitation services. [redacted] As described by a Magee marketing executive, Magee "compete[s] head to head with [Moss] for everything." In its strategic and financial plan, Magee identified Moss as its "Primary Competitor(s)" for post-acute "Services" and "Reputation/brand," citing Moss's "Rankings, marketing to consumers and physicians," as well as its "Centers of

Excellence." Moss likewise views Magee as a competitive constraint. In an internal document, Einstein's Chief Marketing Officer stated succinctly, "Magee is a threat."

63. Diversion analysis indicates that if Einstein's Moss at Elkins Park were to become unavailable to patients for inpatient acute rehabilitation services, at least 30% of Moss at Elkins Park's patients would seek care at a Jefferson IRF. Likewise, if Jefferson's Magee were to become unavailable to patients for inpatient acute rehabilitation services, at least 18% of Magee's patients would seek care at an Einstein IRF. These diversion analyses also lead to predictions of significant post-Transaction price increases.

64. Offering hospital coverage in the Northern Philadelphia Area and the Montgomery Area and IRF coverage in the Philadelphia Area is important for a commercial insurer to market a health plan provider network successfully to employers with employees in these areas. Other hospitals and IRFs outside of these geographic markets are not adequate substitutes for Jefferson and Einstein. Today, Jefferson and Einstein serve as key providers of inpatient GAC hospital services and inpatient acute rehabilitation services for healthcare consumers in these areas.

65. The Transaction would increase Respondents' bargaining leverage in contract negotiations with commercial insurers. This increase in bargaining leverage would cause the Respondents to negotiate higher reimbursement rates and more favorable reimbursement terms.

[redacted]

66. The growth of "narrow network" and "tiered" health insurance products—which, in contrast to "broad networks," include less than all of the hospitals in a geographic market—can be informative about alternative options within an insurer network. Such networks offer a tradeoff to consumers by including fewer participating hospitals (or fewer participating hospitals in a preferred benefit tier), but at often significantly discounted prices relative to other available provider networks. Hospitals are willing to accept the lower reimbursement terms required to participate in narrow and tiered networks with the expectation that they will gain increased volumes of patients and procedures. Today, commercial insurers treat Respondents as substitutes when constructing narrow network or tiered network products for patients in the Northern Philadelphia, Montgomery, and Philadelphia Areas.

67. By eliminating competition between Einstein and Jefferson, the Transaction will give Respondents leverage to negotiate more favorable terms to participate in narrow and tiered networks, including securing higher reimbursement rates.

C.

The Transaction Would Eliminate Vital Quality and Service Competition

68. Competition drives hospitals to invest in quality initiatives, new technologies, amenities, equipment, and service offerings to differentiate themselves from competitors. Jefferson and Einstein compete with one another across other various non-price dimensions. The Transaction would eliminate this competition, which has provided GAC patients in the Northern Philadelphia and Montgomery Areas, and IRF patients in the Philadelphia Area, with higher quality care and more extensive healthcare service offerings. Jefferson and Einstein closely track each other's quality and brand recognition, and Respondents have substantially invested in improving and expanding their services and facilities to compete against one another.

69. Patients benefit from this direct competition in the quality of care and services that Respondents offer them. The Transaction will dampen the merged firm's incentive to compete on quality of care and service offerings to the detriment of all patients who use these hospitals, including commercially insured, Medicare, Medicaid, and self-pay patients.

VIII.

ENTRY BARRIERS

70. Neither entry by new market participants nor expansion by current market participants would deter or counteract the Transaction's likely harm to competition for inpatient GAC hospital services in the Northern Philadelphia or Montgomery Areas, or to inpatient acute rehabilitation services in the Philadelphia Area.

71. New entry or expansion into the relevant markets would not be likely or timely enough to offset the Transaction's likely harmful competitive effects. Construction of a new hospital (including an IRF) involves high costs and significant financial risk, including the time and resources it would take to conduct studies, develop plans, acquire land or repurpose a facility, garner community support, obtain regulatory approvals, and build and open the facility. Expansion of existing hospitals and repositioning by non-hospital providers to become hospitals would encounter similar barriers, including substantial expense and time associated with planning, receiving regulatory approvals, and construction.

72. Potential entry or expansion also would be insufficient to counteract the anticompetitive effects of the Transaction. Entrants would face significant challenges in replicating the competitiveness and reputation of either Einstein or Jefferson. Both Einstein and Jefferson have established reputations for and substantial expertise in providing quality care, have multiple hospitals in the relevant markets, generate a billion dollars or more in annual revenue, provide healthcare services to tens of thousands of inpatients per year, and offer broad clusters of both inpatient GAC hospital services and inpatient acute rehabilitation services.

IX.

EFFICIENCIES

73. Respondents have not substantiated verifiable, merger-specific efficiencies that would be sufficient to rebut the strong presumption and evidence of the Transaction's likely significant anticompetitive effects in the relevant markets.

X.

VIOLATION

COUNT I – ILLEGAL AGREEMENT

74. The allegations of Paragraphs 1 through 73 above are incorporated by reference as though fully set forth herein.

75. The Integration Agreement constitutes an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

COUNT II – ILLEGAL ACQUISITION

76. The allegations of Paragraphs 1 through 73 above are incorporated by reference as though fully set forth herein.

77. The Transaction, if consummated, may substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and is an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the first day of September, 2020, at 10:00 a.m., is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, NW, Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of

each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference no later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, NW, Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Transaction challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and/or Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Transaction is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant service and geographic markets, with the ability to offer such products and services as Jefferson and Einstein were offering and planning to offer prior to the Transaction.

2. A prohibition against any transaction between Jefferson and Einstein that combines their businesses in the relevant markets, except as may be approved by the Commission.

3. A requirement that, for a period of time, Jefferson and Einstein provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant markets with any other entity operating in the relevant markets.

4. A requirement to file periodic compliance reports with the Commission.

5. Any other relief appropriate to correct or remedy the anticompetitive effects of the Transaction or to restore Einstein as a viable, independent competitor in the relevant service and geographic markets.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this 27 day of February, 2020.

By the Commission, Chairman Simons recused.

ORDER RETURNING MATTER TO ADJUDICATION AND DISMISSING COMPLAINT

On January 6, 2021, this matter was withdrawn from adjudication pursuant to Rule 3.26(c) of the Commission's Rules of Practice, 16 C.F.R. § 3.26(c). The Commission has now determined to return this matter to adjudication for the sole purpose of dismissing the Complaint. Accordingly,

IT IS ORDERED that this matter be, and it hereby is, returned to adjudication; and

IT IS FURTHER ORDERED that the Complaint in this matter be, and it hereby is, **DISMISSED.**

By the Commission.

Complaint

IN THE MATTER OF

E. & J. GALLO WINERY, DRY CREEK CORPORATION, AND CONSTELLATION BRANDS, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

Docket No. C-4730; File No. 191 0110
Complaint, December 23, 2020 – Decision, April 2, 2021

This consent order addresses the $1.7 billion acquisition by E. & J. Gallo Winery of certain assets of Constellation Brands, Inc. The complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition in the United States in the product markets for: (1) entry-level on-premise sparkling wine, (2) low-priced sparkling wine, (3) low-priced brandy, (4) low-priced port, (5) low-priced sherry, and (6) high color concentrates ("HCCs"). The consent order requires that (1) Constellation divest its Paul Masson brandy to the Sazerac Company, Inc.; (2) Gallo divest its Sheffield Cellars and Fairbanks low-priced port and sherry brands to Precept Brands LLC; and (3) Constellation divest its HCCs business to the Vie-Del Company.

Participants

For the *Commission*: *Elizabeth Arens, Lindsey Bohl, Henry Hauser, Marsha Richard, Cathleen Williams,* and *Jonathan Wright.*

For the *Respondents*: *Thomas Pak* and *Kenneth B. Schwartz, Skadden, Arps, Slate, Meagher & Flom LLP; Jon B. Dubrow* and *Raymond A. Jacobsen, Jr., McDermott, Will & Emery.*

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by said Acts, the Federal Trade Commission ("Commission"), having reason to believe that Respondent E. & J. Gallo Winery ("Gallo"), a wholly owned subsidiary of Respondent Dry Creek Corporation ("Dry Creek"), corporations subject to the jurisdiction of the Commission, agreed to acquire certain assets from Constellation Brands, Inc. ("Constellation"), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent Gallo is a corporation organized, existing, and doing business under and by virtue of the laws of the State of California with its executive offices and principal place of business located at 600 Yosemite Blvd., Modesto, California 95354.

2. Respondent Dry Creek is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 600 Yosemite Blvd., Modesto, California 95354.

3. Respondent Constellation is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 207 High Point Drive, Building 100, Victor, New York 14564.

II. JURISDICTION

4. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and engages in business that is in or affects commerce, as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

III. THE ACQUISITION

5. Pursuant to an Asset Purchase Agreement dated April 3, 2019, Gallo proposes to acquire certain assets from Constellation in a transaction originally valued at approximately $1.7 billion ("the Acquisition").

IV. THE RELEVANT MARKETS

6. The relevant lines of commerce in which to analyze the effects of the Acquisition are:

a. Entry-level sparkling wine sold primarily to on-premise retailers, such as restaurants, hotels, and casinos ("entry-level on-premise sparkling wine");

b. Low-priced sparkling wine sold primarily to off-premise retailers, such as grocery stores, liquor stores, and convenience stores ("low-priced sparkling wine");

c. Low-priced brandy;

d. Low-priced port and sherry fortified wines; and

e. High color concentrates, a grape-based additive used to enhance color and flavor.

7. The United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in each of the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

A.
Entry-Level On-Premise Sparkling Wine

8. On-premise retailers such as restaurants, hotels, and casinos often have a need for a low-priced sparkling wine option to use for brunch mimosas, complimentary (or "floor") pours, banquets, and catering purposes. Gallo and Constellation are the two largest suppliers, by volume, of entry-level on-premise sparkling wine in the United States. By combining Gallo's Wycliff brand and Constellation's J. Roget brand, the Acquisition will give Gallo a significant majority of the entry-level on-premise sparkling wine sales in the United States and result in a highly concentrated market.

B.
Low-Priced Sparkling Wine

9. Gallo and Constellation are the two largest suppliers, by volume, of low-priced sparkling wines (industry participants use the term "popular" sparkling wines) sold primarily to customers through off-premise retailers such as grocery stores and mass merchants in the United States. By combining Gallo's André brand and Constellation's brand Cook's, the Acquisition will give Gallo a significant majority of low-priced sparkling wine sales in the United States and result in a highly concentrated market.

C.
Low-Priced Brandy

10. Gallo and Constellation are the two largest suppliers, by volume, of low-priced brandy in the United States. By combining Gallo's E&J Brandy brand and Constellation's Paul Masson brand, the Acquisition will reduce the number of major providers of low-priced brandy from three to two, give Gallo a significant majority of low-priced brandy sales in the United States, and result in a highly concentrated market.

D.
Low-Priced Port and Sherry

11. Gallo and Constellation are the two largest suppliers, by volume, of low-priced port and sherry fortified wines in the United States. By combining Gallo's Fairbanks and Sheffield Cellars brands and Constellation's Taylor brand, the Acquisition will result in Gallo owning three of the top four port and sherry brands, give Gallo a significant majority of low-priced port and sherry sales in the United States, and result in a highly concentrated market.

E.
High Color Concentrates

12. High color concentrates ("HCCs") are a grape-based concentrate product used in the wine and food/non-alcoholic beverage industries to achieve effects such as enhancing color, sweetness, or texture. Gallo and Constellation are the two largest producers, by volume, of HCCs in the United States. The Acquisition will reduce the number of suppliers of HCCs from three to two, give Gallo a significant majority of HCC sales in the United States, and result in a highly concentrated market.

VI. ENTRY CONDITIONS

A.
Entry-Level On-Premise Sparkling Wine

13. Entry or expansion into the entry-level on-premise sparkling wine market is unlikely to occur in a timely and sufficient manner to deter or counteract the anticompetitive effects of the Acquisition. Suppliers must have the specialized equipment necessary to produce sparkling wine, and production costs low enough to offer a product at a competitive price point. Securing an extensive distribution network is a further hurdle.

B.
Popular Sparkling Wine

14. Entry or expansion into the popular sparkling wine market is unlikely to occur in a timely and sufficient manner to deter or counteract the anticompetitive effects of the Acquisition. Producing sparkling wine requires specialized equipment that is costly to install. In addition, an entrant would require a U.S. distribution network, sales force, and retail relationships sufficient to compete with established brands for retail shelf space.

C.
Low-Priced Brandy

15. Entry or expansion into the low-priced brandy market is unlikely to occur in a timely and sufficient manner to deter or counteract the anticompetitive effects of the Acquisition. Large-scale brandy production requires significant capital investment and a large distribution network. Further, the need for certain state and local environmental permits makes entry or expansion difficult.

D.
Low-Priced Port and Sherry

16. Entry or expansion into the low-priced port and sherry markets is unlikely to occur in a timely and sufficient manner to deter or counteract the anticompetitive effects of the Acquisition. The markets for low-priced port and sherry generate little interest from retailers,

distributors, or third-party producers. Overseas port and sherry producers are unlikely to be able to match Gallo's and Constellation's cost structures.

E.
High Color Concentrates

17. Entry or expansion in HCCs is unlikely to occur in a timely and sufficient manner to deter or counteract the anticompetitive effects of the Acquisition. In addition to significant capital investments in production equipment, the production of HCCs requires technical expertise and potential regulatory permits. Attempts at HCC production can only be made annually during a narrow harvest window, so the development process is lengthy.

VII. EFFECTS OF THE ACQUISITION

18. The Acquisition, if consummated, is likely to substantially lessen competition in the relevant lines of commerce in the following ways, among others:

a. by eliminating direct and substantial competition between brands owned by Respondents Gallo and Constellation; and

b. by increasing the likelihood that Respondent Gallo will unilaterally exercise market power.

19. The Acquisition would increase the likelihood that prices of entry-level on-premise sparkling wine, popular sparkling wines, low-priced brandy, low-priced port and sherry, and high color concentrates will increase, and that the quality of these products will decrease, in the relevant geographic market.

VIII. VIOLATIONS CHARGED

20. The agreement described in Paragraph 5 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and the acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on the twenty-third day of December, 2020, issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission") initiated an investigation of the proposed acquisition by Respondent E. & J. Gallo Winery, a wholly-owned subsidiary of Respondent Dry Creek Corporation of certain assets of Respondent Constellation Brands, Inc. ("Constellation"), collectively "Respondents." The Commission's Bureau of Competition prepared and furnished to Respondents the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an Agreement Containing Consent Orders ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint, (2) a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission's Rules, and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission, having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of 30 days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

1. Respondent E. & J. Gallo Winery is a corporation organized, existing, and doing business under, and by virtue of the laws of the state of California with its executive offices and principal place of business located at 600 Yosemite Boulevard, Modesto, California 95354.

2. Respondent Dry Creek Corporation is a corporation organized, existing, and doing business under, and by virtue of the laws of, the State of Delaware with its executive offices and principal place of business located at 600 Yosemite Boulevard, Modesto, California 95354.

3. Respondent Constellation Brands, Inc. is a corporation organized, existing, and doing business under, and by virtue of the laws of, the State of Delaware with its executive offices and principal place of business located at 207 High Point Drive, Building 100, Victor, New York 14564.

4. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Respondents, and this proceeding is in the public interest.

I. Definitions

IT IS HEREBY ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the Decision and Order, which are incorporated therein by reference and made a part hereof, shall apply:

A. "Gallo" means Dry Creek Corporation and its wholly-owned subsidiary E. & J. Gallo Winery, their directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Dry Creek Corporation and E. & J. Gallo Winery, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

B. "Constellation" means Constellation Brands, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Constellation Brands, Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

C. "Precept" means Precept Brands LLC, a limited liability company organized, existing, and doing business under, and by virtue of the laws of, the State of Washington, with its executive offices and principal place of business located at 1910 Fairview Avenue East, Suite 400, Seattle, Washington, 98102.

D. "Sazerac" means Sazerac Company Inc., a corporation organized, existing, and doing business under, and by virtue of the laws of, the State of Louisiana, with its executive offices and principal place of business located at 101 Magazine Street, Fifth Floor, New Orleans, Louisiana 70130, and Sazerac Investments, LLC, a corporation organized, existing and doing business under, and by virtue of the laws of, the State of Delaware, with its offices and principle place of business located at 101 Magazine Street, Fifth Floor, New Orleans, Louisiana 70130.

E. "Vie-Del" means Vie-Del Company, a corporation organized, existing, and doing business under, and by virtue of the laws of, the State of Nevada, with its executive offices and principal place of business located at 11903 S. Chestnut Ave, Fresno, California 93725.

F. "Decision and Order" means the proposed Decision and Order contained in the Consent Agreement or the Decision and Order issued in this matter.

G. "Orders" means this Order to Maintain Assets and the Decision and Order.

H. "Monitor" means any person appointed by the Commission to serve as a Monitor pursuant to the Decision and Order and this Order to Maintain Assets.

II. Asset Maintenance

IT IS FURTHER ORDERED that until Respondents fully transfer a Divestiture Business and related Divestiture Assets to an Acquirer, Respondents shall, subject to their obligations under the Order to Maintain Assets, ensure that the Divestiture Business and related Divestiture Assets are operated and maintained in the ordinary course of business consistent with past practices, and shall:

A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of the Divestiture Business, to minimize the risk of loss of competitive potential of the Divestiture Business, to operate the Divestiture Business in a manner consistent with applicable laws and regulations, and to prevent the destruction, removal, wasting, or deterioration of the Divestiture Assets, except for ordinary wear and tear.

B. Not sell, transfer, encumber, or otherwise impair the Divestiture Assets, or terminate any of the operations of the Divestiture Business, other than in the ordinary course of business consistent with past practice or as prescribed in the Orders.

C. Make all payments required to be paid under any contract or lease when due, and pay all liabilities and satisfy all obligations associated with the Divestiture Business.

D. Provide the Divestiture Business with sufficient working capital to operate at least at current rates of operation, to meet all capital calls, to perform routine or necessary maintenance, to repair or replace facilities and equipment, and to carry on, at least at their scheduled pace, all capital projects, business plans, promotional plans, capital expenditure plans, research and development plans, and commercial activities for the Divestiture Business.

E. Use best efforts to preserve the existing relationships and goodwill with suppliers, customers, employees, vendors, distributors, landlords, licensors, licensees, government entities, brokers, contractors, and others having business relations with the Divestiture Business.

F. Maintain the working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with the Divestiture Business, including by:

1. Filling vacancies that occur in the regular and ordinary course of business consistent with past practice; and

2. Not transferring any employees from the Divestiture Business to another of Respondents' businesses.

G. Maintain and preserve Business Information related to the Divestiture Business.

H. Provide the resources necessary for the Divestiture Business to respond to competition, prevent diminution in sales, and maintain its competitive strength.

I. Continue providing customary levels of support services to the Divestiture Business.

J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of the Divestiture Business, and operate the Divestiture Business in accordance and compliance with all regulatory obligations and requirements.

K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with the Divestiture Business,

Provided, however, Respondents may take actions that an Acquirer has requested or agreed to in writing to facilitate the Acquirer's acquisition of the Divestiture Assets if the relevant actions are consistent with the purposes of the Orders and the Monitor (in consultation with Commission staff) approves the action in advance.

III. Transition Assistance

IT IS FURTHER ORDERED that:

A. Until Respondents have transferred Business Information included in the Divestiture Assets to the Acquirers, Respondents shall ensure that this Business Information is maintained and updated in the ordinary course of business and shall provide the relevant Acquirer with access to this Business Information (wherever located and however stored) and to employees who possess this Business Information.

B. At the option of the Acquirer, Respondents shall provide Transitional Services sufficient to efficiently transfer the Divestiture Business and Divestiture Assets to the Acquirer and allow the Acquirer to operate the Divestiture Business and Divestiture Assets in a manner that is in all material respects equivalent to the manner in which Respondents operated them prior to the Acquisition:

1. As set forth in a Divestiture Agreement, or otherwise reasonably requested by the Acquirer (whether requested before or after the Divestiture Date);

2. At the price set forth in the Divestiture Agreement, or if no price is set forth, at Direct Cost; and

3. For a period sufficient to meet the requirements of this Paragraph.

C. At the option of the Acquirer of the Dessert Wine Assets, Respondent Gallo shall, on terms and conditions and at the price set forth in the relevant Divestiture

Agreement, produce and supply Dessert Wine Products, or components thereof, for sale by the Acquirer. Respondent Gallo shall produce and supply Dessert Wine Products, or components thereof, in quantities sufficient to meet the needs of the Acquirer and in a manner that enables the Acquirer to provide customers with Dessert Wine Products of the same quality and on the same schedule as did Respondent Gallo. Unless the Acquirer requests an earlier termination in writing, Respondent Gallo shall not cease supplying products under this Paragraph until the Acquirer begins Commercial Production of the Dessert Wine Products.

D. At the option of the Acquirer of the Concentrate Assets, Respondent CBI shall, on terms and conditions and at the price set forth in the relevant Divestiture Agreement, produce and supply Concentrate Products, or components thereof, for sale by the Acquirer. Respondent CBI shall produce and supply Concentrate Products, or components thereof, in quantities sufficient to meet the needs of the Acquirer and in a manner that enables the Acquirer to provide customers with Concentrate Products of the same quality and on the same schedule as did Respondent CBI. Unless the Acquirer requests an earlier termination in writing, Respondent CBI shall not cease supplying products under this Paragraph until:

1. The Acquirer begins Commercial Production of the Concentrate Products, and

2. For a 6-month period after the Acquirer begins Commercial Production, the Acquirer independently produces 100% of the products it sells to customers.

E. Until 90 days after Respondent CBI ceases to supply products under Paragraph III.D. above:

1. Respondent CBI shall take no action to, directly or indirectly, induce any person to discontinue or reduce grape concentrate purchases from the Acquirer of the Concentrate Business and shall, at the request of the Acquirer, provide reasonable assistance to the Acquirer to obtain or retain customers for Concentrate Products, and

2. Respondent Gallo shall not, directly or indirectly, induce any person to discontinue or reduce its grape concentrate purchases from the Acquirer of the Concentrate Business,

Provided, however, Respondent Gallo may (i) advertise in newspapers, trade publications, trade shows, or other media in a manner not targeted specifically at customers of the Acquirer; (ii) sell products to a customer that initiates communications with Respondent Gallo to purchase grape concentrate, so long as such customer was not solicited by Respondent Gallo in violation of this Paragraph; and (iii) sell products, including through brokers, as Respondent Gallo has done in its ordinary course.

F. Respondents shall allow each Acquirer to terminate, in whole or part, any agreement to provide Transitional Services at any time upon commercially reasonable notice and without cost or penalty.

G. Respondents shall not cease providing Transitional Services or supplying products to an Acquirer as required by this Order due to breach by an Acquirer of a Divestiture Agreement. Further, Respondents shall not limit any damages (including indirect, special, and consequential damages) that an Acquirer would be entitled to receive in the event of a Respondent's breach of any agreement relating to Transitional Services or product supply required by this Order.

IV. Employees

IT IS FURTHER ORDERED that:

A. Until termination of the Employee Hiring Period for an Acquirer, Respondents shall:

1. Cooperate with and assist the Acquirer to evaluate independently and offer employment to any Divestiture Business Employee who worked in the relevant Divestiture Business;

2. No later than 10 days after a request from the Acquirer, provide to the Acquirer a list of all relevant Divestiture Business Employees, and provide Employee Information for each;

3. No later than 10 days after a request from the Acquirer, provide the Acquirer an opportunity to meet, outside the presence or hearing of any employee or agent of any Respondent, with any relevant Divestiture Business Employee, and to make an offer of employment to any relevant Divestiture Business Employee;

4. Remove any impediments within the control of Respondents that may deter relevant Divestiture Business Employees from accepting employment with the Acquirer, including removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by the Acquirer, and shall not make any counteroffer to a relevant Divestiture Business Employee who receives an offer of employment from the Acquirer; provided, however, that nothing in this Order shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee;

5. Continue to provide the relevant Divestiture Business Employees compensation and benefits, including regularly scheduled raises and bonuses and the vesting of benefits;

6. Provide reasonable financial incentives for the relevant Divestiture Business Employees to continue in their positions, and as may be necessary, to facilitate the employment of relevant Divestiture Business Employees by the Acquirer; and

7. Not interfere, directly or indirectly, with the hiring or employing by the Acquirer of any relevant Divestiture Business Employee, not offer any incentive to such employees to decline employment with the Acquirer, and not otherwise interfere with the recruitment of any relevant Divestiture Business Employee by an Acquirer.

8. Not directly or indirectly, solicit or otherwise attempt to induce a Divestiture Business Employee to reject a written offer of employment from an Acquirer, or terminate existing employment with an Acquirer,

Provided, however, Respondents may:

1. Hire an employee whose employment has been terminated by the Acquirer;

2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more Divestiture Business Employees; or

3. Hire an employee who has applied for employment with a Respondent, as long as such application was not solicited or induced in violation of this Paragraph.

B. Within 6 months after the Divestiture Date, if the Commission determines that any additional employee of a Respondent who worked for or supported the Divestiture Business should be included as a Divestiture Business Employee, the Commission shall so notify the Respondent and as of the date of such notification, the identified employee shall be considered a Divestiture Business Employee under this Order.

V. Confidential Information

IT IS FURTHER ORDERED that:

A. Respondents shall not (i) disclose (including to Respondents' employees) or (ii) use, for any reason or purpose, any Confidential Information solely related to one or more Divestiture Businesses that is received or maintained by Respondents;

Provided, however, that a Respondent may disclose or use such Confidential Information in the course of*:*

1. Performing its obligations or as permitted under the Decision and Order, this Order to Maintain Assets or any Divestiture Agreement; or

2. Complying with financial reporting requirements, historical record-keeping for audit purposes, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the Divestiture Assets or any Divestiture Business, or as required by law, rule or regulation.

B. Respondent shall only disclose Confidential Information solely related to one or more Divestiture Businesses to an employee or other person if disclosure is permitted in Paragraph V.A and the employee or other person has signed an agreement to maintain the confidentiality of such information and not violate the disclosure requirements of this Order.

C. Respondents shall enforce the terms of this Paragraph V and take necessary actions to ensure that their employees and other persons comply with its terms, including implementing access and data controls, training employees, and taking other actions that Respondents would take to protect their own trade secrets and proprietary information.

VI. Additional Obligations

IT IS FURTHER ORDERED that:

A. Until 4 years after the entry of this Order, Respondent CBI shall not terminate the operations of the Sparkling Wine Business and shall take all actions necessary to maintain the full economic viability, marketability and competitiveness of the Sparkling Wine Business.

B. Respondents shall not, except as required to comply with the Order or the Divestiture Agreement with the Acquirer of the Concentrate Business:

1. Use any Divestiture Assets or Excluded Assets related to the Concentrate Business for the production of grape concentrate, or

2. Produce grape concentrate at the Mission Bell Facility.

C. Respondent CBI shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, without the prior approval of the Commission, sell, transfer, convey or lease to Respondent Gallo the Mission Bell Facility, or any Mission Bell Assets used, or used within 6 months of the Acquisition Date, at the Mission Bell Facility,

Provided, however, this Paragraph VI.C shall not apply to the assets identified in the Non-Public Appendix VII attached to the Decision and Order.

D. Respondent Gallo shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, without the prior approval of the Commission, acquire or lease the Mission Bell Facility, or any Mission Bell Assets used, or used within 6 months of the Acquisition Date, at the Mission Bell Facility,

Provided, however, this Paragraph VI.D shall not apply to the assets identified in the Non-Public Appendix VII attached to the Decision and Order.

E. No later than 2 days after the Divestiture Date for the Concentrate Business, Respondent Gallo shall create and maintain a website with the URL MegaNatural.com. Except as otherwise agreed to in writing by Respondent Gallo and Vie-Del, the website shall contain only one webpage that contains the following:

1. No logos, trade dress or other imagery used by Respondent Gallo or by Vie-Del;

2. The title MegaNatural; and;

3. Two buttons of identical size, format and prominence and related statements of identical font, font size and placement that comply with the following:

   a. A button captioned "Color Concentrates" that links to www.vie-del.com and is located directly above the statement, "click here if you are interested in MegaNatural color concentrates products, including Mega Red or Mega Purple," and

   b. A button captioned "Polyphenolics" that links to www.polyphenolics.com and is located directly above the statement, "click here if you are interested in MegaNatural Polyphenolics products."

F. Gallo shall not use or retain information regarding any third party who selects the Color Concentrates button on the MegaNatural.com website.

G. Starting on the Divestiture Date for the Concentrate Business until the earlier of 5 years after issuance of the Decision and Order or 2 years after Respondent CBI ceases to supply products under Paragraph VI.D above, Respondent Gallo shall:

1. Not directly link any webpage on the website polyphenolics.com, or any other website Respondent Gallo creates or maintains for the primary purpose of selling polyphenolics, to a website or webpage used or maintained by Gallo that markets products that compete with Concentrate Products;

2. Not use the MEGANATURALBP.com or MEGANATURAL-BP.com domain names; and

3. Not market products that compete with Concentrate Products on any website that includes MegaNatural in its URL.

H. Respondent Gallo shall not interfere with Vie-Del's ability to use "MegaNatural," or any other derivation or variant thereof, in connection with the marketing or sale of Concentrate Products or other grape concentrates by entering into exclusive arrangements regarding the term MegaNatural in connection to advertising words, sponsored links, hyperlinks, search priorities, or any other domain name.

VII. Monitor

IT IS FURTHER ORDERED that:

A. The Commission appoints William Berlin as the Monitor to observe and report on Respondents' compliance with the terms of the Orders. The Monitor shall serve pursuant to the agreement between the Monitor and Respondents contained in the Monitor Agreement Appendix to the Orders, provided, however, such agreement shall not limit, or be construed to limit, the terms of the Monitor Paragraph of the Orders.

B. No later than one day after the Commission issues the Order to Maintain Assets, Respondents shall:

1. Confer on the Monitor all rights, power, and authorities necessary to permit the Monitor to monitor Respondents' compliance with the terms of the Orders as set forth in Monitor Paragraph of the Orders; and

2. Consent to the terms and conditions regarding such rights, powers, and authorities of the Monitor set forth in the Monitor Paragraph of the Orders.

C. The Monitor:

1. Shall have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;

2. Shall act in consultation with the Commission or its staff;

3. Shall serve as an independent third party and not as an employee, agent, or fiduciary of Respondents or of the Commission;

4. Shall serve at the expense of Respondents, without bond or other security;

5. May employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;

6. Shall enter into a confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into such a confidentiality agreement;

7. Shall notify Respondents and staff of the Commission, in writing, of any potential financial, professional, personal, or other conflicts of interest within 5 days should they arise;

8. Within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission, the Monitor shall report in writing to the Commission regarding Respondents' compliance with its obligations under the Orders and, where relevant, each Acquirer's or its Manufacturing Designee's progress toward obtaining the Product Approvals necessary to manufacture each Divestiture Product acquired by that Acquirer, independently of Respondents; and

9. Shall serve until 30 days after all Divestiture Agreements to provide Transition Manufacturing or transition services have expired or been terminated or until such other time as may be determined by the Commission or its staff.

D. Respondents shall (i) provide the Monitor full and complete access to all information and facilities, and, as necessary, make such arrangements with third parties, to allow the monitor to monitor Respondents' compliance with its obligations under the Orders; and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform his/her duties pursuant to the Orders.

E. Respondents shall indemnify and hold the Monitor harmless against losses, claims, damages, liabilities, or expenses (including attorney's fees and out of pocket costs) that arise out of, or in connection with, any claim concerning the Monitor's performance of the Monitor's duties under the Orders, whether or not such claim results in liability, except, to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitor's gross negligence or willful misconduct. For purposes of this Paragraph, the term "Monitor" shall include all persons retained by the Monitor in the performance of his or her duties under the Orders.

F. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement; provided, however, that such agreement does not restrict the Monitor from providing any information to the Commission.

G. Respondents shall not require nor compel the Monitor to disclose to Respondents the substance of communications with the Commission, including the Monitor's written reports submitted to the Commission, or with any person with whom the Monitor communicates in the performance of the Monitor's duties.

H. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor and such substitute Monitor shall be afforded all rights, powers, and authorities and subject to all obligations of the Monitor Paragraph of the Orders:

1. The Commission shall select the substitute Monitor, subject to the consent of Respondents which consent shall not be unreasonably withheld. Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor if, upon notice by staff of the Commission of the identity of the substitute Monitor to Respondents, Respondents has not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within 10 days after such notice; and

2. Not later than 5 days after the Commission appoints a substitute Monitor, Respondents shall enter into an agreement with the substitute Monitor that (i) contains substantially the same terms as the agreement attached as Monitor Agreement Appendix to the Orders or (ii) is approved by the Commission and confers on the substitute Monitor the rights, powers, and authority of a Monitor under the Monitor Paragraph of the Orders.

I. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

VIII. Divestiture Trustee

IT IS FURTHER ORDERED that:

A. If Respondents have not fully complied with the divestiture and other obligations as required by Paragraph II of the Decision and Order with respect to some or all of the Divestiture Assets, the Commission may appoint a Divestiture Trustee to divest the relevant Divestiture Assets and perform Respondents' other obligations in a manner that satisfies the requirements of the Decision and Order. The Divestiture Trustee appointed pursuant to this Paragraph may be the same person appointed as Monitor.

B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to divest the relevant assets in accordance with the terms of the Decision and Order. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondents to comply with the Orders.

C. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

D. Within 10 days after appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestiture or other action required by the Decision and Order.

E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order to Maintain Assets, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest relevant Divestiture

Assets and takes such other action as may be required to perform Respondents' other obligations in a manner that satisfies the requirements of the Decision and Order;

2. The Divestiture Trustee shall have 12 months from the date the Commission approves the trustee agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestitures can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or in the case of a court-appointed Divestiture Trustee, by the court; The Divestiture Trustee shall have 12 months from the date the Commission approves the trustee agreement described herein to accomplish the divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of the one year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestitures can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or in the case of a court-appointed Divestiture Trustee, by the court;

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by the Decision and Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestitures. Any delays in divestitures caused by Respondents shall extend the time for divestitures under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court;

4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestitures shall be made in the manner and to Acquirers as required by the Decision and Order, provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity for Divestiture Assets related to a particular Divestiture Business, and if the Commission determines to approve more than one such acquiring entity for the divestiture, the Divestiture Trustee shall divest to the acquiring

entity selected by Respondents from among those approved by the Commission, provided further, however, that Respondents shall select such entity within 5 days of receiving notification of the Commission's approval;

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by the Decision and Order;

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph VIII.E.6, the term "Divestiture Trustee" shall include all persons retained by the Divestiture Trustee pursuant to this Order to Maintain Assets;

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the Divestiture Assets required to be divested by the Decision and Order;

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 60 days concerning the Divestiture Trustee's efforts to accomplish each divestiture; and

9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other

representatives and assistants to sign a customary confidentiality agreement; provided, however, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

F. The Commission may require, among other things, the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

G. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph VIII, and who will have the same authority and responsibilities as the original Divestiture Trustee.

H. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures and other obligations or action required by the Decision and Order.

IX. Compliance Reports

IT IS FURTHER ORDERED that Respondents shall submit verified written reports ("compliance reports") in accordance with the following:

A. Respondents shall submit interim compliance reports 30 days after this Order to Maintain Assets is issued, and every 30 days thereafter until the Commission issues a Decision and Order in this matter.

B. Each compliance report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondents are complying with their obligations under this Order to Maintain Assets. Conclusory statements are insufficient. Respondents shall include in their compliance reports, among other information or documentation that may be necessary to demonstrate compliance, a full description of the measures Respondents have implemented or plan to implement to ensure that Respondents have complied or will comply with each paragraph of this Order to Maintain Assets.

C. Respondents shall retain all material written communications with each party identified in the compliance report and all non-privileged memoranda, reports, and recommendations concerning fulfilling Respondents' obligations under this Order to Maintain Assets and provide copies of these documents to Commission staff upon request; and

D. Respondents shall verify each compliance report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondents shall submit an original and 2 copies of each compliance report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov; provided, however, that Respondents need only file electronic copies of the 30-day reports required by Paragraph IX.A of this Order to Maintain Assets. In addition, Respondents shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

X. Change in Respondent

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least 30 days prior to:

A. Its proposed dissolution (i.e., the dissolution of E. & J. Gallo Winery, Dry Creek Corporation, or Constellation Brands, Inc.);

B. Its proposed acquisition, merger or consolidation (i.e., the acquisition, merger or consolidation of E. & J. Gallo Winery, Dry Creek Corporation, or Constellation Brands, Inc.); or

C. Any other changes in the Respondent, including assignment and the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order to Maintain Assets.

XI. Access

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request and upon 5 days' notice to the relevant Respondent, made to its principal place of business as identified in this Order to Maintain Assets, registered office of its United States subsidiary, or its headquarters office, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative of the Commission and at the expense of the Respondent; and

B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XII. Purpose

IT IS FURTHER ORDERED that the purpose this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Brandy Business, the Concentrate Business and the Dessert Wine Business through their full transfer and delivery to Acquirers; to minimize any risk of loss of competitive potential for the Brandy Business, the Concentrate Business, and the Dessert Wine Business; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the divestiture Assets except for ordinary wear and tear.

XIII. Term

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate three days after the Decision and Order in this matter becomes final or the Commission withdraws acceptance of the Decision and Order pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34.

By the Commission.

DECISION

The Federal Trade Commission initiated an investigation of the proposed acquisition by Respondent E. & J. Gallo Winery, a wholly owned subsidiary of Respondent Dry Creek Corporation, of certain assets of Respondent Constellation Brands, Inc. The Commission's Bureau of Competition prepared and furnished to Respondents the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an Agreement Containing Consent Order ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint, (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission's Rules, and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the said Acts, and that a complaint should issue stating its charges in that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings:

1. Respondent E. & J. Gallo Winery is a corporation organized, existing, and doing business under, and by virtue of the laws of, the State of California with its executive offices and principal place of business located at 600 Yosemite Boulevard, Modesto, California 95354.

2. Respondent Dry Creek Corporation is a corporation organized, existing, and doing business under, and by virtue of the laws of, the State of Delaware with its executive offices and principal place of business located at 600 Yosemite Boulevard, Modesto, California 95354.

3. Respondent Constellation Brands, Inc. is a corporation organized, existing, and doing business under, and by virtue of the laws of, the State of Delaware with its executive offices and principal place of business located at 207 High Point Drive, Building 100, Victor, New York 14564.

4. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

I. Definitions

IT IS HEREBY ORDERED that**,** as used in this Order, the following definitions apply**:**

A. "Respondent Gallo" means Dry Creek Corporation, its wholly-owned subsidiary E. & J. Gallo Winery, their directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Dry Creek Corporation and E. & J. Gallo Winery, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

B. "Respondent CBI" means Constellation Brands, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Constellation Brands, Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

C. "Vie-Del" means Vie-Del Company, a corporation organized, existing, and doing business under, and by virtue of the laws of, the State of Nevada, with its executive offices and principal place of business located at 11903 S. Chestnut Ave, Fresno, California 93725.

D. "Precept" means Precept Brands LLC, a limited liability company organized, existing, and doing business under, and by virtue of the laws of, the State of Washington, with its executive offices and principal place of business located at 1910 Fairview Avenue East, Suite 400, Seattle, Washington, 98102.

E. "Sazerac" means Sazerac Company Inc., a corporation organized, existing, and doing business under, and by virtue of the laws of, the State of Louisiana, with its executive offices and principal place of business located at 101 Magazine Street, Fifth Floor, New Orleans, Louisiana 70130, and Sazerac Investments, LLC, a corporation organized, existing and doing business under, and by virtue of the laws of, the State of Delaware, with its offices and principle place of business located at 101 Magazine Street, Fifth Floor, New Orleans, Louisiana 70130.

F. "Commission" means the Federal Trade Commission.

G. "Acquisition" means the proposed acquisition described in the Second Amended and Restated Asset Purchase Agreement between Constellation Brands, Inc. and E. & J. Gallo Winery made and entered into as of May 22, 2020, as amended by the First Amendment to the Second Amended and Restated Asset Purchase Agreement, dated September 28, 2020.

H. "Acquisition Date" means the date the Acquisition is consummated.

I. "Acquirer" means the following:

1. Sazerac or any other person that acquires the Divestiture Assets for the Brandy Business pursuant to this Order;

2. Precept or any other person that acquires the Divestiture Assets for the Dessert Wine Business pursuant to this Order; or

3. Vie-Del or any other person that acquires the Divestiture Assets for the Concentrate Business pursuant to this Order.

J. "Brandy Business" means the development, sourcing for, production, marketing, sale, and distribution of spirits under the "Grande Amber" (Paul Masson) brand.

K. "Business Information" means books, records, data, and information, wherever located and however stored, including documents, written information, graphic materials, and data and information in electronic format. Business Information includes books, records, information, and data relating to sales, marketing,

logistics, products and SKUs, pricing, promotions, advertising, personnel, accounting, business strategy, information technology systems, customers, suppliers, vendors, and all other information. For clarity, Business Information includes Respondents' rights and control over information and material provided to any other person.

L. "Commercial Production" means the ability to produce, market, sell and deliver a Divestiture Product in quantities that meet current customer demand and at a level of quality that meets the requirements for sales during the two years prior to the Divestiture Date.

M. "Concentrate Business" means the development, sourcing for, production, marketing, sale, and distribution of grape concentrates and permeates by Respondent CBI.

Provided that the Concentrate Business shall not include grape concentrates and associated inputs used in the production of products that are being sold to Respondent Gallo in the Acquisition.

N. "Concentrate Products" mean the grape concentrates and permeates that CBI used or sold, as of the Acquisition Date, through the Concentrate Business,

O. "Confidential Information" means Business Information and Intellectual Property that is not in the public domain.

P. "Consent" means an approval, consent, ratification, waiver, or other authorization from any person.

Q. "Contracts" means all agreements, contracts, leases, license agreements, consensual obligations, promises or undertakings (whether written or oral and whether express or implied), whether or not legally binding.

R. "Dessert Wine Business" means the development, sourcing for, production, marketing, sale and distribution of wine under the Fairbanks and Sheffield dessert wine brands, including the Sheffield Silver Lane brand.

S. "Dessert Wine Products" means the products that Gallo sold, as of the Acquisition Date through the Dessert Wine Business.

T. "Direct Cost" means the cost of labor, materials, travel, and other expenditures directly incurred to provide Transitional Services. The cost of any labor included in Direct Cost shall not exceed the hours of labor provided times the then-current average hourly wage rate, including benefits, for the employee providing such labor.

U. "Divestiture Agreement" means

1. Asset Purchase Agreement among Constellation Brands, Inc., Sazerac Investments LLC and Sazerac Company Inc., dated June 24, 2020 and the Trademark License Agreement by and between Sazerac Company Inc. (Licensor) and E. & J. Gallo Winery (Licensee), and all amendments, exhibits, attachments, agreements, and schedules thereto, attached to this Decision and Order as Non- Public Appendix I;

2. Amended and Restated Asset Purchase Agreement by and between Constellation Brands U.S. Operations, Inc. and Vie-Del Company dated October 15, 2020, and all amendments, exhibits, attachments, agreements, and schedules thereto, attached to this Decision and Order as Non-Public Appendix III;

3. Asset Purchase Agreement dated September 11, 2020, by and between E. & J. Gallo Winery and Precept Brands LLC, and all amendments, exhibits, attachments, agreements, and schedules thereto, attached to this Decision and Order as Non-Public Appendix V; or

4. Any other agreement between Respondents or the Divestiture Trustee and an Acquirer to purchase Divestiture Assets, and all amendments, exhibits, attachments, agreements, and schedules thereto.

V. "Divestiture Assets" means a Respondent's rights, title, and interest in and to all property and assets, real, personal, or mixed, tangible and intangible, of every kind and description, wherever located, used in, or relating to a Divestiture Business, other than Excluded Assets, including:

1. All tangible personal property, including any tangible personal property removed from the location of the business being divested after the date of the announcement of the Acquisition and not replaced,

Provided, however, the Divestiture Assets shall only include manufacturing equipment used by Respondent CBI in the Concentrate Business that is requested by Acquirer of the Concentrate Assets within 90 days after Respondent CBI ceases supplying Concentrate Products under Paragraph IV.D of this Order, and the price for such requested equipment shall be as specified in the relevant Divestiture Agreement or, if no price is specified, at no cost.

2. All inventories;

3. All Contracts and all outstanding offers or solicitations to enter into any Contract, and all rights thereunder and related thereto,

4. All Governmental Authorizations and all pending applications therefor or renewals thereof, to the extent transferable;

5. All Business Information,

Provided however, (i) if a Respondent has a legal obligation to retain original Business Information related to a Divestiture Business, Respondent may provide Acquirer with a full, complete copy and provide the Acquirer with access to the original when the Acquirer needs the original for regulatory or evidentiary purposes, and (ii) if a document or record contains Business Information related to a Divestiture Business that cannot be separated from Business Information not related to the Divestiture Business without impairing the meaning or usefulness of the Business Information, Respondents may retain the document or record and provide the Acquirer with a full, complete copy of the document or record; and

6. All intangible rights and property, including Intellectual Property owned or licensed (as licensor or licensee) by Respondents that is not Licensed Intellectual Property, going concern value, goodwill, and telephone and telecopy listings.

W. "Divestiture Business" means the Brandy Business, the Dessert Wine Business or the Concentrate Business.

X. "Divestiture Business Employee" means any full-time or part-time employee or independent contractor of a Respondent who, on or after April 3, 2019, worked, in whole or in part, in the Brandy Business, the Concentrate Business, or the Dessert Wine Business.

Y. "Divestiture Date" means the date on which a Respondent or a Divestiture Trustee consummates the divestiture of the Brandy Business, the Dessert Wine Business or the Concentrate Business as required by Paragraph II of this Order.

Z. "Divestiture Trustee" means the person appointed by the Commission pursuant to Paragraph X of this Order.

AA. "Employee Hiring Period" means:

1. For Sazerac or another Acquirer of the Brandy Business, until one year after the Divestiture Date for the Brandy Business for the Acquirer of the Brandy Business,

2. For Vie-Del or another Acquirer of the Concentrate Business, until one year after Respondent CBI fulfills its obligation to supply product under Paragraph IV.D of this Order, and

3. For Precept or another Acquirer of the Dessert Wine Business, until one year after Respondent Gallo fulfills its obligation to supply product under Paragraph IV.C of this Order.

BB. "Employee Information" means for each Divestiture Business Employee, to the extent permitted by law, the following information summarizing the employment history of each employee that includes:

1. Name, job title or position, date of hire, and effective service date;

2. Specific description of the employee's responsibilities;

3. The base salary or current wages;

4. Most recent bonus paid, aggregate annual compensation for Respondent's last fiscal year, and current target or guaranteed bonus, if any;

5. Written performance reviews for the past three years, if any;

6. Employment status (i.e., active or on leave or disability; full-time or part-time);

7. Any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

8. At the Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the employee.

CC. "Excluded Assets" are the assets on the attached Non-Public Appendices II (Excluded Brandy Assets), IV (Excluded Concentrate Assets) and VI (Excluded Dessert Wine Assets).

DD. "Governmental Authorization" means a consent, license, registration, or permit issued, granted, given or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement.

EE. "Intellectual Property" means intellectual property of any kind including patents, patent applications, mask works, trademarks, service marks, copyrights, trade dress, commercial names, internet web sites, internet domain names, inventions, discoveries, written and unwritten know-how, trade secrets, and proprietary information.

FF. "Licensed Intellectual Property" means Intellectual Property that it is predominately or primarily used in or related to businesses not being divested, is used in or related to a Divestiture Business, and is not an Excluded Asset.

GG. "Mission Bell Assets" mean tangible property, plant and equipment assets used at the Mission Bell Facility such as production equipment, vehicles, furniture, computers and software and does not include current assets such as inventory and supplies.

HH. "Mission Bell Facility" means collectively, Respondent CBI's Mission Bell Winery facilities located at (a) 12667 Road 24, Madera, California 93637, (b) 23715 Avenue 12, Madera, California 93637, (c) 23774 Avenue 12 1/2, Madera, California 93637, and (d) 24246 Avenue 13, Madera, California 93637.

II. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.

JJ. "Orders" means this Order and the Order to Maintain Assets.

KK. "Sparkling Wine Business" means the development, sourcing for, production, marketing, sale, and distribution of sparkling wine under the "Cook's" and "J Roget" brands.

LL. "Transitional Services" means services to transfer the Divestiture Assets and Business to an Acquirer and enable the Acquirer to use the assets and operate the business in a manner at least equivalent to their use and operation by Respondent, including technical assistance, operational assistance, training and providing information about all aspects of the Divestiture Business and the Divestiture Assets, including research and development, quality control, operation, maintenance and repair of facilities and equipment, regulatory compliance, customers, sales, marketing, customer service, purchasing, logistics, supply chain management, finance and accounting, employee benefits, payroll, information technology and systems, logistics.

II. Divestiture

IT IS FURTHER ORDERED that:

A. No later than 10 days after the Acquisition Date, Respondent CBI shall:

1. Divest, absolutely and in good faith, the Divestiture Assets related to the Brandy Business to Sazerac, and the Divestiture Assets related to the Concentrate Business to Vie-Del, and

2. Grant a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to Sazerac for Licensed Intellectual Property related to the Brandy Business, and to Vie-Del for Licensed Intellectual Property related to the Concentrate Business.

B. No later than 10 days after the Acquisition Date, Respondent Gallo shall:

1. Divest, absolutely and in good faith, the Divestiture Assets related to the Dessert Wine Business to Precept, and

2. Grant a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to Precept for Licensed Intellectual Property related to the Dessert Wine Business.

C. If a Respondent has divested all or part of the Divestiture Assets related to a Divestiture Business prior to the date this Order becomes final and at the time the Commission determines to make this Order final, the Commission notifies the Respondent that:

1. The Acquirer is not an acceptable purchaser of relevant Divestiture Assets, then the Respondent shall immediately rescind the divestiture to that Acquirer, and shall divest the relevant Divestiture Assets no later than 180 days from the date this Order is issued, absolutely and in good faith, at no minimum price, to one or more persons that receive the prior approval of the Commission; or

2. The manner in which a Respondent has divested the relevant Divestiture Assets is not acceptable, the Commission may direct the Respondent, or appoint a Divestiture Trustee and direct the Divestiture Trustee, to modify the manner of divestiture as the Commission determines is necessary to satisfy the requirements of this Order. The Respondent, or the Divestiture Trustee, shall promptly modify the divestiture in the manner the Commission directs.

D. If within one year after issuing this Order or, for the Concentrate Business before the termination of supply under Paragraph IV.D, the Commission determines, in consultation with the Acquirer of a Divestiture Business and the Monitor, that the Acquirer of that Business needs one or more Excluded Assets to operate the Divestiture Business in a manner that achieves the purposes of this Order, Respondents shall divest, absolutely and in good faith, such Excluded Assets to the Acquirer.

E. Respondents shall obtain, no later than the Divestiture Date and at their sole expense, each Consent that is necessary to effect the complete transfer and divestiture of the Divestiture Assets to the relevant Acquirer and enable the Acquirer to operate all aspects of the relevant Divestiture Business,

Provided, however, Respondents may satisfy the requirement to obtain a Consent by certifying that an Acquirer has entered into an equivalent agreement or arrangement directly with the relevant party that is acceptable to the Commission, or has otherwise obtained all necessary Consents and waivers.

III. Divestiture Agreement

IT IS FURTHER ORDERED that**:**

A. Each Divestiture Agreement shall be incorporated by reference into this Order and made a part hereof, and any failure by Respondents to comply with the terms of a Divestiture Agreement shall constitute a violation of this Order*; provided, however,* that no Divestiture Agreement shall limit, or be construed to limit, the terms of this Order. To the extent any provision in a Divestiture Agreement varies from or conflicts with any provision in this Order such that Respondents cannot fully comply with both, Respondents shall comply with this Order.

B. Respondents shall not modify or amend the terms of a Divestiture Agreement after the Commission issues this Order without the prior approval of the Commission, except as otherwise provided in Commission Rule 2.41(f)(5), 16 C.F.R. § 2.41(f)(5).

IV. Transition Assistance

IT IS FURTHER ORDERED that:

A. Until Respondents have transferred Business Information included in the Divestiture Assets to the Acquirers, Respondents shall ensure that this Business Information is maintained and updated in the ordinary course of business and shall provide the relevant Acquirer with access to this Business Information (wherever located and however stored) and to employees who possess this Business Information.

B. At the option of the Acquirer, Respondents shall provide Transitional Services sufficient to efficiently transfer the Divestiture Business and Divestiture Assets to the Acquirer and allow the Acquirer to operate the Divestiture Business and Divestiture Assets in a manner that is in all material respects equivalent to the manner in which Respondents operated them prior to the Acquisition:

1. As set forth in a Divestiture Agreement, or otherwise reasonably requested by the Acquirer (whether requested before or after the Divestiture Date);

2. At the price set forth in the Divestiture Agreement, or if no price is set forth, at Direct Cost; and

3. For a period sufficient to meet the requirements of this Paragraph.

C. At the option of the Acquirer of the Dessert Wine Assets, Respondent Gallo shall, on terms and conditions and at the price set forth in the relevant Divestiture Agreement, produce and supply Dessert Wine Products, or components thereof, for sale by the Acquirer. Respondent Gallo shall produce and supply Dessert

Wine Products, or components thereof, in quantities sufficient to meet the needs of the Acquirer and in a manner that enables the Acquirer to provide customers with Dessert Wine Products of the same quality and on the same schedule as did Respondent Gallo. Unless the Acquirer requests an earlier termination in writing, Respondent Gallo shall not cease supplying products under this Paragraph until the Acquirer begins Commercial Production of the Dessert Wine Products.

D. At the option of the Acquirer of the Concentrate Assets, Respondent CBI shall, on terms and conditions and at the price set forth in the relevant Divestiture Agreement, produce and supply Concentrate Products, or components thereof, for sale by the Acquirer. Respondent CBI shall produce and supply Concentrate Products, or components thereof, in quantities sufficient to meet the needs of the Acquirer and in a manner that enables the Acquirer to provide customers with Concentrate Products of the same quality and on the same schedule as did Respondent CBI. Unless the Acquirer requests an earlier termination in writing, Respondent CBI shall not cease supplying products under this Paragraph until:

1. The Acquirer begins Commercial Production of the Concentrate Products, and

2. For a six-month period after the Acquirer begins Commercial Production, the Acquirer independently produces 100% of the products it sells to customers.

E. Until 90 days after Respondent CBI ceases to supply products under Paragraph IV.D. above:

1. Respondent CBI shall take no action to, directly or indirectly, induce any person to discontinue or reduce grape concentrate purchases from the Acquirer of the Concentrate Business and shall, at the request of the Acquirer, provide reasonable assistance to the Acquirer to obtain or retain customers for Concentrate Products, and

2. Respondent Gallo shall not, directly or indirectly, induce any person to discontinue or reduce its grape concentrate purchases from the Acquirer of the Concentrate Business,

Provided, *however*, Respondent Gallo may (i) advertise in newspapers, trade publications, trade shows, or other media in a manner not targeted specifically at customers of the Acquirer; (ii) sell products to a customer that initiates communications with Respondent Gallo to purchase grape concentrate, so long as such customer was not solicited by Respondent Gallo in violation of this Paragraph; and (iii) sell products, including through brokers, as Respondent Gallo has done in its ordinary course.

F. Respondents shall allow each Acquirer to terminate, in whole or part, any agreement to provide Transitional Services at any time upon commercially reasonable notice and without cost or penalty.

G. Respondents shall not cease providing Transitional Services or supplying products to an Acquirer as required by this Order due to breach by an Acquirer of a Divestiture Agreement. Further, Respondents shall not limit any damages (including indirect, special, and consequential damages) that an Acquirer would be entitled to receive in the event of a Respondent's breach of any agreement relating to Transitional Services or product supply required by this Order.

V. Asset Maintenance

IT IS FURTHER ORDERED that until Respondents fully transfer a Divestiture Business and related Divestiture Assets to an Acquirer, Respondents shall, subject to their obligations under the Order to Maintain Assets, ensure that the Divestiture Business and related Divestiture Assets are operated and maintained in the ordinary course of business consistent with past practices, and shall**:**

A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of the Divestiture Business, to minimize the risk of loss of competitive potential of the Divestiture Business, to operate the Divestiture Business in a manner consistent with applicable laws and regulations, and to prevent the destruction, removal, wasting, or deterioration of the Divestiture Assets, except for ordinary wear and tear.

B. Not sell, transfer, encumber, or otherwise impair the Divestiture Assets, or terminate any of the operations of the Divestiture Business, other than in the ordinary course of business consistent with past practice or as prescribed in the Orders.

C. Make all payments required to be paid under any contract or lease when due, and pay all liabilities and satisfy all obligations associated with the Divestiture Business.

D. Provide the Divestiture Business with sufficient working capital to operate at least at current rates of operation, to meet all capital calls, to perform routine or necessary maintenance, to repair or replace facilities and equipment, and to carry on, at least at their scheduled pace, all capital projects, business plans, promotional plans, capital expenditure plans, research and development plans, and commercial activities for the Divestiture Business.

E. Use best efforts to preserve the existing relationships and goodwill with suppliers, customers, employees, vendors, distributors, landlords, licensors, licensees, government entities, brokers, contractors, and others having business relations with the Divestiture Business.

F. Maintain the working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with the Divestiture Business, including by:

1. Filling vacancies that occur in the regular and ordinary course of business consistent with past practice; and

2. Not transferring any employees from the Divestiture Business to another of Respondents' businesses.

G. Maintain and preserve Business Information related to the Divestiture Business.

H. Provide the resources necessary for the Divestiture Business to respond to competition, prevent diminution in sales, and maintain its competitive strength.

I. Continue providing customary levels of support services to the Divestiture Business.

J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of the Divestiture Business, and operate the Divestiture Business in accordance and compliance with all regulatory obligations and requirements.

K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with the Divestiture Business,

Provided, however, Respondents may take actions that an Acquirer has requested or agreed to in writing to facilitate the Acquirer's acquisition of the Divestiture Assets if the relevant actions are consistent with the purposes of the Orders and the Monitor (in consultation with Commission staff) approves the action in advance.

VI. Employees

IT IS FURTHER ORDERED that:

A. Until termination of the Employee Hiring Period for an Acquirer, Respondents shall:

1. Cooperate with and assist the Acquirer to evaluate independently and offer employment to any Divestiture Business Employee who worked in the relevant Divestiture Business;

2. No later than 10 days after a request from the Acquirer, provide to the Acquirer a list of all relevant Divestiture Business Employees, and provide Employee Information for each;

3. No later than 10 days after a request from the Acquirer, provide the Acquirer an opportunity to meet, outside the presence or hearing of any employee or agent of any Respondent, with any relevant Divestiture Business Employee, and to make an offer of employment to any relevant Divestiture Business Employee;

4. Remove any impediments within the control of Respondents that may deter relevant Divestiture Business Employees from accepting employment with the Acquirer, including removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by the Acquirer, and shall not make any counteroffer to a relevant Divestiture Business Employee who receives an offer of employment from the Acquirer; *provided, however,* that nothing in this Order shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee;

5. Continue to provide the relevant Divestiture Business Employees compensation and benefits, including regularly scheduled raises and bonuses and the vesting of benefits;

6. Provide reasonable financial incentives for the relevant Divestiture Business Employees to continue in their positions, and as may be necessary, to facilitate the employment of relevant Divestiture Business Employees by the Acquirer; and

7. Not interfere, directly or indirectly, with the hiring or employing by the Acquirer of any relevant Divestiture Business Employee, not offer any incentive to such employees to decline employment with the Acquirer, and not otherwise interfere with the recruitment of any relevant Divestiture Business Employee by an Acquirer.

8. Not directly or indirectly, solicit or otherwise attempt to induce a Divestiture Business Employee to reject a written offer of employment from an Acquirer, or terminate existing employment with an Acquirer,

Provided, however, Respondents may:

1. Hire an employee whose employment has been terminated by the Acquirer;

2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more Divestiture Business Employees; or

3. Hire an employee who has applied for employment with a Respondent, as long as such application was not solicited or induced in violation of this Paragraph.

B. Within 6 months after the Divestiture Date, if the Commission determines that any additional employee of a Respondent who worked for or supported the Divestiture Business should be included as a Divestiture Business Employee, the Commission shall so notify the Respondent and as of the date of such notification, the identified employee shall be considered a Divestiture Business Employee under this Order.

VII. Confidential Information

IT IS FURTHER ORDERED that:

A. Respondents shall not (i) disclose (including to Respondents' employees) or (ii) use for any reason or purpose, any Confidential Information solely related to one or more Divestiture Businesses that is received or maintained by Respondents;

Provided, *however*, that a Respondent may disclose or use such Confidential Information in the course of:

1. Performing its obligations or as permitted under this Order, the Order to Maintain Assets, or any Divestiture Agreement; or

2. Complying with financial reporting requirements, historical record-keeping for audit purposes, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the Divestiture Assets or any Divestiture Business, or as required by law, rule or regulation.

B. Respondent shall only disclose Confidential Information solely related to one or more Divestiture Businesses to an employee or other person if disclosure is permitted in Paragraph VII.A. and the employee or other person has signed an agreement to maintain the confidentiality of such information and not violate the disclosure requirements of this Order.

C. Respondents shall enforce the terms of this Paragraph VII and take necessary actions to ensure that their employees and other persons comply with its terms, including implementing access and data controls, training employees, and taking other actions that Respondents would take to protect their own trade secrets and proprietary information.

VIII. Additional Obligations

IT IS FURTHER ORDERED that:

A. Until 4 years after the entry of this Order, Respondent CBI shall not terminate the operations of the Sparkling Wine Business and shall take all actions necessary to maintain the full economic viability, marketability and competitiveness of the Sparkling Wine Business.

B. Respondents shall not, except as required to comply with this Order or the Divestiture Agreement with the Acquirer of the Concentrate Business:

1. Use any Divestiture Assets or Excluded Assets related to the Concentrate Business for the production of grape concentrate, or

2. Produce grape concentrate at the Mission Bell Facility.

C. Respondent CBI shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, without the prior approval of the Commission, sell, transfer, convey or lease to Respondent Gallo the Mission Bell Facility, or any Mission Bell Assets used, or used within 6 months of the Acquisition Date, at the Mission Bell Facility,

Provided, however, this Paragraph VIII.C. shall not apply to the assets identified in the attached Non-Public Appendix VII.

D. Respondent Gallo shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, without the prior approval of the Commission, acquire or lease the Mission Bell Facility, or any Mission Bell Assets used, or used within 6 months of the Acquisition Date, at the Mission Bell Facility,

Provided, however, this Paragraph VIII.D. shall not apply to the assets identified in the attached Non-Public Appendix VII.

E. No later than 2 days after the Divestiture Date for the Concentrate Business, Respondent Gallo shall create and maintain a website with the URL MegaNatural.com. Except as otherwise agreed to in writing by Respondent Gallo and Vie-Del, the website shall contain only one webpage that contains the following:

1. No logos, trade dress or other imagery used by Respondent Gallo or by Vie-Del;

2. The title MegaNatural; and

3. Two buttons of identical size, format and prominence and related statements of identical font, font size and placement that comply with the following:

   a. A button captioned "Color Concentrates" that links to www.vie-del.com and is located directly above the statement, "click here if you are interested in MegaNatural color concentrates products, including Mega Red or Mega Purple," and

   b. A button captioned "Polyphenolics" that links to www.polyphenolics.com and is located directly above the statement, "click here if you are interested in MegaNatural Polyphenolics products."

F. Gallo shall not use or retain information regarding any third party who selects the Color Concentrates button on the MegaNatural.com website.

G. Starting on the Divestiture Date for the Concentrate Business until the earlier of 5 years after issuance of this Order or 2 years after Respondent CBI ceases to supply products under Paragraph IV.D above, Respondent Gallo shall:

1. Not directly link any webpage on the website polyphenolics.com, or any other website Respondent Gallo creates or maintains for the primary purpose of selling polyphenolics, to a website or webpage used or maintained by Gallo that markets products that compete with Concentrate Products;

2. Not use the MEGANATURALBP.com or MEGANATURAL-BP.com domain names; and

3. Not market products that compete with Concentrate Products on any website that includes MegaNatural in its URL.

H. Respondent Gallo shall not interfere with Vie-Del's ability to use "MegaNatural," or any other derivation or variant thereof, in connection with the marketing or sale of Concentrate Products or other grape concentrates by entering into exclusive arrangements regarding the term MegaNatural in connection to advertising words, sponsored links, hyperlinks, search priorities, or any other domain name.

IX. Monitor

IT IS FURTHER ORDERED that**:**

A. The Commission appoints William Berlin as the Monitor to observe and report on Respondents' compliance with the terms of the Orders. The Monitor shall serve pursuant to the agreement between the Monitor and Respondents contained in the

Monitor Agreement Appendix to the Orders, *provided, however,* such agreement shall not limit, or be construed to limit, the terms of the Monitor Paragraph of the Orders.

B. No later than one day after the Commission issues the Order to Maintain Assets, Respondents shall:

1. Confer on the Monitor all rights, power, and authorities necessary to permit the Monitor to monitor Respondents' compliance with the terms of the Orders as set forth in Monitor Paragraph of the Orders; and

2. Consent to the terms and conditions regarding such rights, powers, and authorities of the Monitor set forth in the Monitor Paragraph of the Orders.

C. The Monitor:

1. Shall have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;

2. Shall act in consultation with the Commission or its staff;

3. Shall serve as an independent third party and not as an employee, agent, or fiduciary of Respondents or of the Commission;

4. Shall serve at the expense of Respondents, without bond or other security;

5. May employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;

6. Shall enter into a confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into such a confidentiality agreement;

7. Shall notify Respondents and staff of the Commission, in writing, of any potential financial, professional, personal, or other conflicts of interest within 5 days should they arise;

8. Within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission, the Monitor shall report in writing to the Commission regarding Respondents' compliance with its obligations under the Orders and, where relevant, each Acquirer's or its Manufacturing Designee's progress toward obtaining the Product Approvals necessary to

manufacture each Divestiture Product acquired by that Acquirer, independently of Respondents; and

9. Shall serve until 30 days after all Divestiture Agreements to provide Transition Manufacturing or transition services have expired or been terminated or until such other time as may be determined by the Commission or its staff.

D. Respondents shall (i) provide the Monitor full and complete access to all information and facilities, and, as necessary, make such arrangements with third parties, to allow the monitor to monitor Respondents' compliance with its obligations under the Orders; and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform his/her duties pursuant to the Orders.

E. Respondents shall indemnify and hold the Monitor harmless against losses, claims, damages, liabilities, or expenses (including attorney's fees and out of pocket costs) that arise out of, or in connection with, any claim concerning the Monitor's performance of the Monitor's duties under the Orders, whether or not such claim results in liability, except, to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitor's gross negligence or willful misconduct. For purposes of this Paragraph, the term "Monitor" shall include all persons retained by the Monitor in the performance of his or her duties under the Orders.

F. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement; provided, however, that such agreement does not restrict the Monitor from providing any information to the Commission.

G. Respondents shall not require nor compel the Monitor to disclose to Respondents the substance of communications with the Commission, including the Monitor's written reports submitted to the Commission, or with any person with whom the Monitor communicates in the performance of the Monitor's duties.

H. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor and such substitute Monitor shall be afforded all rights, powers, and authorities and subject to all obligations of the Monitor Paragraph of the Orders:

1. The Commission shall select the substitute Monitor, subject to the consent of Respondents which consent shall not be unreasonably withheld. Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor if, upon notice by staff of the Commission of the identity of the substitute Monitor to Respondents, Respondents has not

opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within 10 days after such notice; and

2. Not later than 5 days after the Commission appoints a substitute Monitor, Respondents shall enter into an agreement with the substitute Monitor that (i) contains substantially the same terms as the agreement attached as Monitor Agreement Appendix to the Orders or (ii) is approved by the Commission and confers on the substitute Monitor the rights, powers, and authority of a Monitor under the Monitor Paragraph of the Orders.

I. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

X. Divestiture Trustee

IT IS FURTHER ORDERED that:

A. If Respondents have not fully complied with the divestiture and other obligations required by Paragraph II of this Order with respect to some or all of the Divestiture Assets, the Commission may appoint a trustee to divest the relevant Divestiture Assets in a manner that satisfies the requirements of this Order. The Divestiture Trustee appointed pursuant to this Paragraph may be the same person appointed as Monitor.

B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondents to comply with this Order.

C. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

D. Within 10 days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestitures or other action required by this Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.

E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest relevant Divestiture Assets and takes such other action as may be required to perform Respondents' other obligations in a manner that satisfies the requirements of this Order;

2. The Divestiture Trustee shall have 12 months from the date the Commission approves the trustee agreement described herein to accomplish the divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of the one year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestitures can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or in the case of a court-appointed Divestiture Trustee, by the court; The Divestiture Trustee shall have 12 months from the date the Commission approves the trustee agreement described herein to accomplish the divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of the one year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestitures can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or in the case of a court-appointed Divestiture Trustee, by the court;

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestitures. Any delays in divestitures caused by Respondents shall extend the time for divestitures under this Paragraph in an amount equal to

the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court;

4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestitures shall be made in the manner and to Acquirers as required by this Order, provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity for Divestiture Assets related to a particular Divestiture Business, and if the Commission determines to approve more than one such acquiring entity for the divestiture, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission, *provided further*, *however*, that Respondents shall select such entity within 5 days of receiving notification of the Commission's approval;

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order;

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph X.6, the term "Divestiture Trustee" shall include all persons retained by the Divestiture Trustee pursuant to this Order;

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the Divestiture Assets the Divestiture Trustee is required to divest by Paragraph X of this Order;

8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 60 days concerning the Divestiture Trustee's efforts to accomplish each divestiture; and

9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement, provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

F. The Commission may require, among other things, the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

G. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph X, and who will have the same authority and responsibilities as the original Divestiture Trustee.

H. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures and other obligations or action required by this Order.

XI. Compliance Reports

IT IS FURTHER ORDERED that**:**

A. Respondents shall:

1. Notify Commission staff via email at bccompliance@ftc.gov of the Acquisition Date and each Divestiture Date no later than 5 days after the occurrence of each; and

2. Submit each Divestiture Agreement to the Commission at ElectronicFilings@ftc.gov and bccompliance@ftc.gov no later than 30 days after the relevant Divestiture Date.

B. Respondent CBI and Respondent Gallo shall submit verified written reports ("compliance reports") in accordance with the following:

1. Each Respondent shall submit:

   a. Interim compliance reports 30 days after this Order is issued, every 30 days thereafter until Respondents have fully complied with the provisions of Paragraphs II, IV, V and VI of this Order, and every 90 days thereafter until Respondents have fully complied with the provisions of Paragraphs VIII.A. of this Order;

   b. Annual compliance reports one year after the date this Order is issued and annually thereafter for the next 9 years on the anniversary of that date; and

   c. Additional compliance reports as the Commission or its staff may request.

2. Each compliance report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondents are complying with this Order. Conclusory statements that a Respondent has complied with its obligations under this Order are insufficient. Respondents shall include in their reports, among other information or documentation that may be necessary to demonstrate compliance, a full description of the measures Respondents have implemented and plan to implement to comply with each paragraph of this Order, including notice of any change or modification to the Processing and Winemaking Services Agreement.

3. Respondents shall retain all material written communications with each party identified in its compliance report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondents' obligations under this Order and shall provide copies of these documents to Commission staff upon request.

4. Respondents shall verify each compliance report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondents shall submit an original and 2 copies of each compliance report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov; provided, however, the Respondents need only file electronic copies of the 30-day reports required by XI.B.1.a. In addition, Respondents shall provide a copy of each compliance report to the Monitor.

XII. Change in Respondent

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least 30 days prior to**:**

A. Its proposed dissolution (i.e. the dissolution of E. & J. Gallo Winery, Dry Creek Corporation, or Constellation Brands, Inc.);

B. Its proposed acquisition, merger or consolidation (i.e. the acquisition, merger or consolidation of E. & J. Gallo Winery, Dry Creek Corporation or Constellation Brands, Inc.); or

C. Any other change in the Respondent, including assignment and the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

XIII. Access

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and 5 days' notice to the relevant Respondent, made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters office, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative of the Commission and at the expense of the Respondent; and

B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XIV. Purpose

IT IS FURTHER ORDERED that the purpose of this Order is to remedy the harm to competition the Commission alleged in its Complaint and ensure the Acquirers can operate the Divestiture Businesses in a manner at least equivalent in all material respects to the manner in which Respondents operated the Divestiture Businesses prior to the Acquisition.

XV. Term

IT IS FURTHER ORDERED that this Order shall terminate the second day of April, 2031.

By the Commission.

Non-Public Appendix I Brandy Divestiture Agreement

Non-Public Appendix II Excluded Brandy Assets

Non-Public Appendix III Concentrate Divestiture Agreement

Non-Public Appendix IV Excluded Concentrate Assets

Non-Public Appendix V Dessert Wine Divestiture Agreement

Analysis to Aid Public Comment

Non-Public Appendix VI Excluded Dessert Wine Assets

Non-Public Appendix VII Excluded Mission Bell Facility Assets

ANALYSIS OF CONSENT ORDERS TO AID PUBLIC COMMENT

I. INTRODUCTION AND BACKGROUND

The Federal Trade Commission ("Commission") has accepted for public comment, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Respondent E. & J. Gallo Winery ("Gallo"), a wholly owned subsidiary of Respondent Dry Creek Corporation ("Dry Creek"), and Respondent Constellation Brands, Inc. ("Constellation") (collectively, "Respondents"). The purpose of the Consent Agreement is to remedy the anticompetitive effects that would likely result from Gallo's acquisition of certain Constellation assets ("the Acquisition").

To resolve the Commission's concerns, Gallo and Constellation elected to remove J Roget, Cook's, Paul Masson brandy, high color concentrates ("HCCs"), and the Mission Bell winery from the asset purchase agreement. Under the terms of the proposed Decision and Order ("Order") contained in the Consent Agreement, Constellation is required to maintain the viability of the J Roget and Cook's assets. The Order also requires that (1) Constellation divest its Paul Masson brandy to the Sazerac Company, Inc. ("Sazerac"); (2) Gallo divest its Sheffield Cellars and Fairbanks low-priced port and sherry brands to Precept Brands LLC ("Precept"); and (3) Constellation divest its HCCs business to the Vie-Del Company ("Vie-Del").

The Commission and the Respondents have also agreed to an Order to Maintain Assets. This order requires Gallo and Constellation to retain and maintain the assets that the Consent Agreement requires them to divest, pending their divestiture. The Commission's Complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the United States in the product markets for: (1) entry-level on-premise sparkling wine, (2) low-priced sparkling wine, (3) low-priced brandy, (4) low-priced port, (5) low-priced sherry, and (6) HCCs.

The proposed Consent Agreement has been placed on the public record for 30 days for receipt of comments from interested persons. Comments received during this period will

become part of the public record. After 30 days, the Commission will review the comments received and decide whether it should withdraw, modify, or finalize the Consent Agreement.

II. THE PARTIES

Gallo is a privately owned company headquartered in Modesto, California. Founded in 1933, Gallo is the largest family-owned winery in the world, with over 100 wine and spirit brands, and a portfolio that includes white wines, red wines, sparkling wines, dessert or fortified wines, brandy, and vodka. Gallo owns 15 wineries situated throughout California and Washington, over 23,000 acres of vineyards across California, glass and bottling facilities, storage facilities, and distribution channels in states where legally permitted.

Headquartered in Victor, New York, Constellation is a publically traded alcoholic beverage company. Founded in 1945, Constellation is the third-largest producer of beer and one of the world's leading premium wine companies. Constellation is one of the three largest wine suppliers in the United States; in fiscal year 2018, it generated approximately $8.3 billion in gross revenue.

On April 3, 2019, Gallo entered into an Asset Purchase Agreement with Constellation. Pursuant to the agreement, Gallo would acquire more than 30 mostly low-priced wine, brandy, concentrate and additive brands along with several wine-making facilities from Constellation in a transaction originally valued at approximately $1.7 billion.

III. THE RELEVANT MARKETS

Gallo's proposed acquisition of certain Constellation assets would likely result in substantial competitive harm in the following product markets: entry-level on-premise sparkling wine, low-priced sparkling wine, low-priced brandy, low-priced port and low-priced sherry fortified wines, and HCCs. The United States is the relevant geographic market in which to assess the competitive effects of the proposed Acquisition.

A. Entry-Level On-Premise Sparkling Wine

Entry-level sparkling wine is often sold to on-premise retailers, such as restaurants, casinos, and hotels, for specific uses (*e.g.*, brunch mimosas, complimentary or "floor" pours, banquets, and catering). Sparkling wine outside of the entry-level tier is generally priced significantly higher than entry-level on-premise sparkling wine.

Gallo and Constellation are the two largest suppliers, by volume, of entry-level on-premise sparkling wine in the United States. Absent relief, Gallo would have acquired Constellation's J Roget brand, resulting in significant increases in concentration in a highly concentrated market, and giving rise to a presumption of increased market power under the Horizontal Merger Guidelines. Further, Gallo's Wycliff brand and Constellation's J Roget brand are close and vigorous competitors in the United States. Absent relief, the Acquisition would have substantially lessened the significant head-to-head competition between Gallo and Constellation, and would likely have increased Gallo's ability and incentive to raise prices post-

Acquisition. Entry into this market is difficult due to the specialized equipment and massive scale needed to produce sparkling wine at a low cost. In addition, the need for a nationwide distribution network and sales team to work with retailers present further obstacles to entry and expansion.

B. Low-Priced Sparkling Wine

Low-priced sparkling wine (generally described in the industry as "popular" sparkling wine) is predominately sold to off-premise retailers such as grocery stores, liquor stores, and convenience stores. Low-priced sparkling wine does not significantly compete with more expensive "premium" brands.

Gallo's André and Constellation's Cook's brands are the two largest low-priced sparkling wine brands in the United States, with other competitors being significantly smaller. Absent relief, Gallo would have acquired Constellation's Cook's brand, resulting in significant increases in concentration and a highly concentrated market, and giving rise to a presumption of increased market power under the Horizontal Merger Guidelines. André and Cook's directly compete for shelf space and sales in the off-premise retail channel. Absent relief, the Acquisition would have substantially lessened the significant head-to-head competition between André and Cook's and would likely have increased Gallo's ability and incentive to raise prices post-Acquisition. Entry into this market is difficult due to the specialized equipment and massive scale needed to produce low-priced sparkling wine. The need for a national distribution network and sales force, and retail relationships sufficient to compete with established brands for retail shelf space, present additional hurdles to entry and expansion.

C. Low-Priced Brandy

Brandy is a distilled spirit made from fruit, typically wine grapes. After distillation, it must be aged for at least two years in order to be labeled and sold as "brandy" in the United States. There is a large price and quality difference between low-priced brandies, which are typically produced domestically, and high-end imported brandies (primarily cognacs). Further, low-priced brandies do not compete closely with other types of spirits such as whiskeys, rums, vodkas, tequilas, and gins, since brandy has a unique taste profile and is often consumed straight rather than as a mixer.

Gallo's E & J Brandy and Constellation's Paul Masson brandy are the two largest low-priced brandies. Absent relief, Gallo would have acquired Constellation's Paul Masson brand, resulting in significant increases in concentration and a highly concentrated market, and giving rise to a presumption of increased market power under the Horizontal Merger Guidelines. Gallo and Constellation consider each other's pricing when determining the price of their own low-priced brandy brands and compete to develop new products for these brands. Absent relief, the Acquisition would have substantially lessened the significant head-to-head competition between E & J Brandy and Paul Masson, would likely result in lower quality, and would likely increase Gallo's ability and incentive to raise prices post-Acquisition. Entry is unlikely to deter or counteract the anticompetitive effects of the Acquisition due to the significant capital investment

and distribution network required for large-scale brandy production. Further, the need for certain state and local environmental permits makes entry or expansion difficult.

D. Low-Priced Port and Low-Priced Sherry

Port and sherry are types of fortified wines (wines to which a distilled spirit has been added, giving them a higher alcohol by volume) that are used for both cooking and consumption. Due to their flavor profile, alcohol level, and use, port and sherry brands are distinct from table wines and generic cooking wines. Further, there is a significant price gap between low-priced, domestic brands of port and sherry and high-end imports.

Gallo, which owns both the Sheffield Cellars and Fairbanks brands, and Constellation, which owns the Taylor brand, are the two largest suppliers, by volume, of low-priced port and low-priced sherry fortified wines in the United States. Absent relief, Gallo would have owned three of the top four low-priced port and sherry brands. The Acquisition would have resulted in significant increases in concentration and lead to highly concentrated markets, resulting in a presumption of increased market power under the Horizontal Merger Guidelines. Gallo and Constellation are each other's closest competitors. Absent relief, the Acquisition would have substantially lessened the significant head-to-head competition between Gallo and Constellation, and would likely increase Gallo's ability and incentive to raise prices post-Acquisition. Entry into these markets is unlikely to occur due to the low level of interest in low-priced port and sherry from retailers, distributors, and third-party producers. In addition, producers of high-end imports have cost structures that render them unable to introduce a product at a price similar to domestic brands'.

E. High Color Concentrates

HCCs are grape-based additives that have been concentrated using sophisticated filtration technologies into a thick, shelf-stable syrup. HCCs are made from a specific grape varietal, Rubired, and are used by winemakers to deepen the color and enhance the taste and texture of red wines. HCCs are also used by food and beverage manufacturers in jellies, juices, and other products. HCCs have unique qualities that are not replicable through the use of lower-level concentrates or other winemaking techniques.

Gallo and Constellation are the two largest HCC producers in the United States, and there is only one other domestic producer. Absent relief, the Acquisition would have resulted in significant increases in concentration and lead to a highly concentrated market, resulting in a presumption of increased market power under the Horizontal Merger Guidelines. Gallo and Constellation are each other's closest competitors. Absent relief, the Acquisition would have substantially lessened the significant head-to-head competition between Gallo and Constellation, and would likely increase Gallo's ability and incentive to raise prices post-Acquisition. Entry into this market is difficult due to the need for technical expertise and significant capital investments in production equipment. In addition to potentially needing certain regulatory permits, firms making attempts at HCC production can only do so annually during a narrow harvest window, which results in a lengthy development process.

IV. THE PROPOSED CONSENT AGREEMENT

The proposed Consent Agreement remedies the likely anticompetitive effects in the aforementioned product markets. The proposed Order requires that Constellation retain and maintain the assets of the J Roget and Cook's brands. The Order also requires the following divestitures: Constellation will divest its Paul Masson brandy to Sazerac; Gallo will divest its Sheffield Cellars and Fairbanks low-priced port and sherry brands to Precept; and Constellation will divest its HCCs business to Vie-Del, no later than 10 days after the closing of the Acquisition. The Order further prohibits Constellation from selling or leasing, and Gallo from buying, the Mission Bell production facility without prior Commission approval. Constellation produces Cook's and HCCs at the Mission Bell facility and will provide an interim supply of HCCs to the purchaser of the HCCs business.

The proposed Order and Order to Maintain Assets also appoint William Berlin as Monitor. The Monitor will ensure that the parties comply with their obligations under the proposed Orders and keep the Commission informed about the status of the transfer of the assets and rights to the approved acquirers.

Finally, the proposed Consent Agreement contains standard terms regarding each acquirer's access to employees, protection of material confidential information, and compliance reporting requirements, among other things, to ensure the viability of the divested businesses.

A. Entry-Level On-Premise Sparkling Wine

The proposed Consent Agreement remedies the likely anticompetitive effects of the proposed Acquisition in the entry-level on-premise sparkling wine market by requiring that Constellation take all actions necessary to retain and maintain the full economic viability, marketability, and competitiveness of its J Roget brand until four years after entry of the Consent Agreement. This remedy will preserve the status quo in the entry-level on-premise sparkling wine market, resulting in no change in market concentration.

B. Low-Priced Sparkling Wine

The proposed Consent Agreement remedies the likely anticompetitive effects of the proposed Acquisition in the low-priced sparkling wine market by requiring that Constellation take all actions necessary to retain and maintain the full economic viability, marketability, and competitiveness of its Cook's brand until four years after entry of the Consent Agreement. This remedy will preserve the status quo in the low-priced sparkling wine market, resulting in no change in market concentration.

C. Low-Priced Brandy

The proposed Consent Agreement remedies the likely anticompetitive effects of the proposed Acquisition in the low-priced brandy market by requiring Constellation to divest the Paul Masson brandy to Sazerac. This remedy would preserve the status quo in the low-priced brandy market, resulting in no change in market concentration.

D. Low-Priced Port and Low-Priced Sherry

The proposed Consent Agreement remedies the likely anticompetitive effects of the proposed Acquisition in the low-priced port and low-priced sherry markets by requiring Gallo to divest its Sheffield Cellars and Fairbanks brands to Precept. This remedy would preserve the status quo in the low-priced port and low-priced sherry markets, resulting in no change in market concentration.

E. High Color Concentrates

The proposed Consent Agreement remedies the likely anticompetitive effects of the proposed Acquisition in the HCCs market by requiring Constellation to divest its HCCs business to Vie-Del. The proposed Consent Agreement would preserve three independent HCCs producers and result in no change in market concentration.

* * *

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement to aid the Commission in determining whether it should make the proposed Consent Agreement final. This analysis is not an official interpretation of the proposed Consent Agreement and does not modify its terms in any way.

Complaint

IN THE MATTER OF

GENNEX MEDIA LLC,
AND
AKIL KURJI

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4741; File No. 202 3122
Complaint, April 9, 2021 – Decision, April 9, 2021

This consent order addresses Gennex Media LLC's use of "Made in USA" claims to advertise and sell customizable promotional products to consumers. The complaint alleges that respondents violated of Section 5(a) of the Federal Trade Commission Act by representing that the customizable promotional products they offer are all or virtually all made in the United States. The consent order prohibits Respondents from making U.S.-origin claims for their products unless either: (1) the final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States; (2) a clear and conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients or components, and/or processing; or (3) for a claim that a product is assembled in the United States, the product is last substantially transformed in the United States, the product's principal assembly takes place in the United States, and United States assembly operations are substantial.

Participants

For the *Commission*: *Julia Solomon Ensor*.

For the *Respondents*: *Erica Lai, Melissa H. Maxman,* and *Andrew Pecoraro, Cohen & Gresser LLP*.

COMPLAINT

The Federal Trade Commission, having reason to believe that Gennex Media LLC, a limited liability company also d/b/a Brandnex, BrandStrong, PMGOA, and Promotional Manufacturing Group of America, and Akil Kurji, individually and as an officer of Gennex Media LLC (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Gennex Media LLC ("Gennex"), also doing business as Brandnex, BrandStrong, PMGOA, and Promotional Manufacturing Group of America, is a Texas limited liability company with its principal office or place of business at 4771 Sweetwater Blvd. #241, Sugar Land, TX 77479.

2. Respondent Akil Kurji ("Kurji") is Gennex's sole officer and shareholder. Individually or in concert with others, he controlled or had the authority to control, or

participated in the acts and practices of Gennex, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Gennex.

3. At all times material to this Complaint, Kurji has been responsible for Gennex's ongoing operations. Kurji's responsibilities include, but are not limited to: creating content for the Brandnex.com website; approving changes to the Brandnex.com website; creating content for social media posts; approving all social media content; and creating and approving content for YouTube.

4. At all times material to this Complaint, Kurji was responsible for the contracts between Gennex and its suppliers, including overseas suppliers.

5. The acts and practices of Respondents alleged in this Complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

6. Since at least 2012, Respondents have advertised, offered for sale, sold, and distributed customizable promotional products to consumers, including, but not limited to, wristbands, lanyards, temporary tattoos, and buttons.

7. Respondents have sold their promotional products on their websites including, but not limited to, brandnex.com and pmgoa.com, as well as on third-party sales platforms such as amazon.com.

8. Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for customizable promotional products, including but not necessarily limited to the attached Exhibits A through D. These materials contain the following statements and depictions:

a. "Made in USA"

(Exhibit A, Brandnex website)

b. "MADE IN USA"

(Exhibit B, Brandnex Price List)

c. "Made in USA" and "USA MADE."

(Exhibit C, Brandnex Facebook Header)

d. ". . . MANUFACTURED RIGHT HERE IN AMERICA!"

(Exhibit D, Brandnex YouTube Video).

9. In numerous instances, including, but not limited to, the promotional materials referenced in Paragraph 8, Respondents have represented, expressly or by implication, that their customizable promotional products are all or virtually all made in the United States.

10. In fact, in numerous of these instances, Respondents' customizable promotional products are wholly imported from China.

11. In some cases, Respondents' products ship directly from Chinese manufacturers to consumers, without even passing through a U.S. facility controlled by Respondents.

12. Therefore, Respondents' express or implied representations that their customizable promotional products are all or virtually all made in the United States deceive consumers.

13. Despite knowing that, in numerous instances, Respondents' customizable promotional products are wholly imported from China, Kurji formulated or approved the promotional materials referenced in Paragraph 8.

Count I
False or Unsubstantiated Representation – Made in USA

14. In connection with the advertising, promotion, offering for sale, or sale of customizable promotional products, Respondents have represented, directly or indirectly, expressly or by implication, that such products, including the materials and subcomponents used to make such products, are all or virtually all made in the United States.

15. In fact, in numerous instances, Respondents' customizable promotional products are wholly imported or incorporate significant imported materials or subcomponents. Therefore, the representation set forth in paragraph 14 is false or misleading, or was not substantiated at the time the representation was made.

Violations of Section 5

16. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this 9th day of April, 2021, has issued this Complaint against Respondents.

By the Commission.

Complaint

Exhibit A

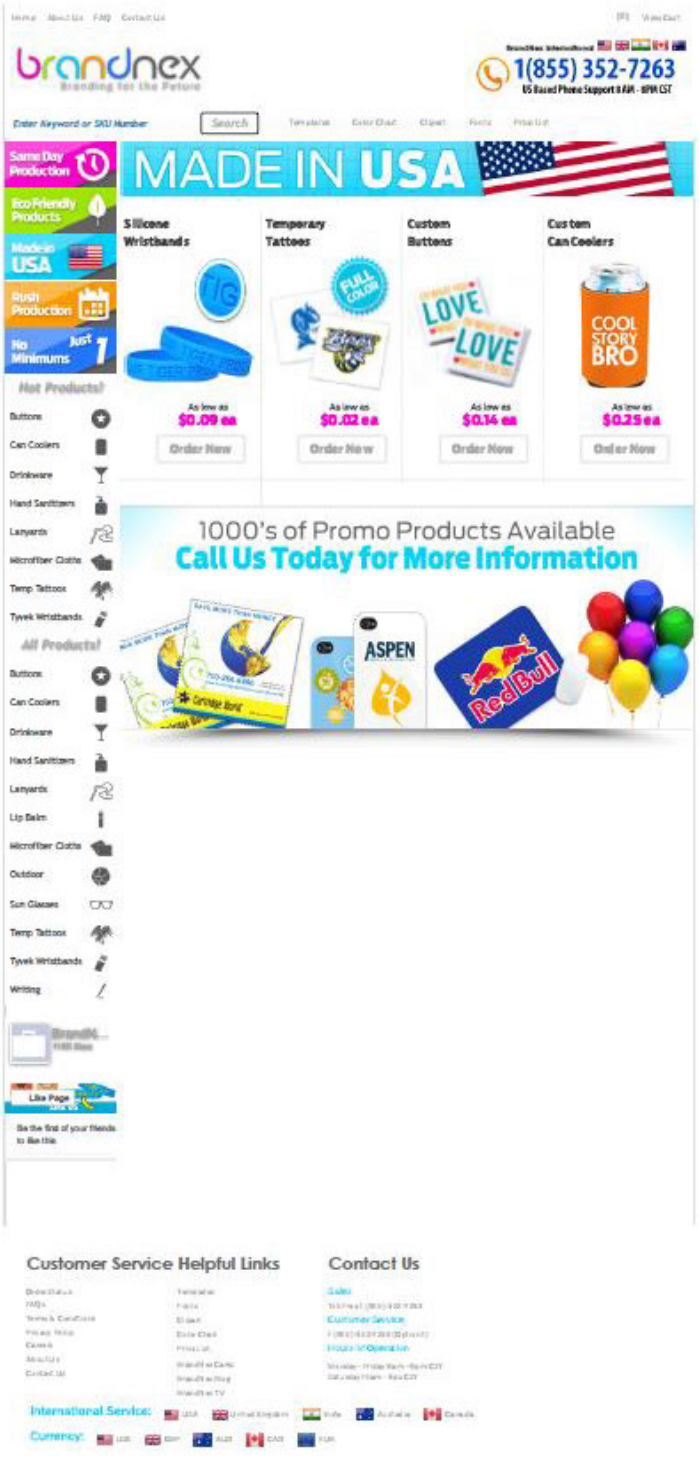
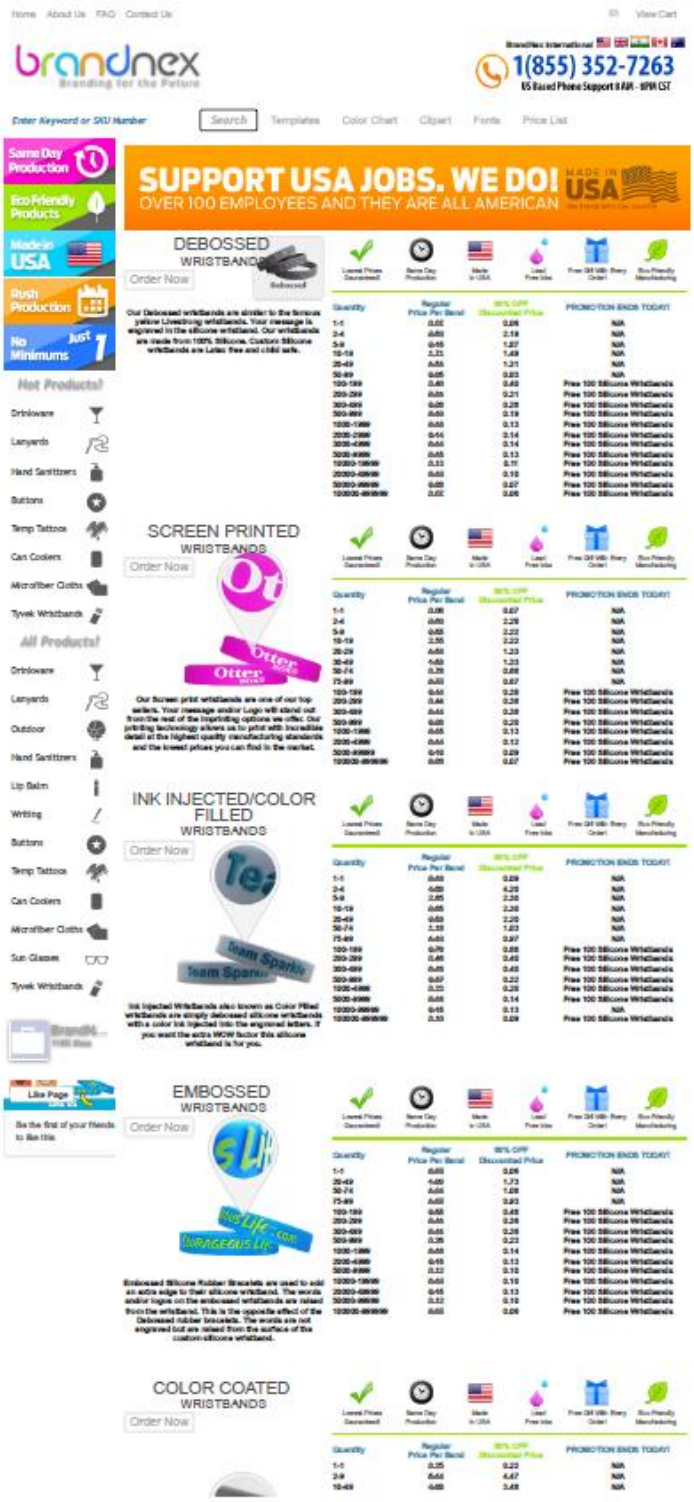


Exhibit A

Exhibit B


brandnex
1(855) 352-7263
SUPPORT USA JOBS. WE DO!
OVER 100 EMPLOYEES AND THEY ARE ALL AMERICAN
DEBOSSED WRISTBANDS
SCREEN PRINTED WRISTBANDS
INK INJECTED/COLOR FILLED WRISTBANDS
EMBOSSED WRISTBANDS
COLOR COATED WRISTBANDS

Complaint

Exhibit B
p. 2 of 3

Exhibit B
p. 3 of 3

Complaint

Exhibit C

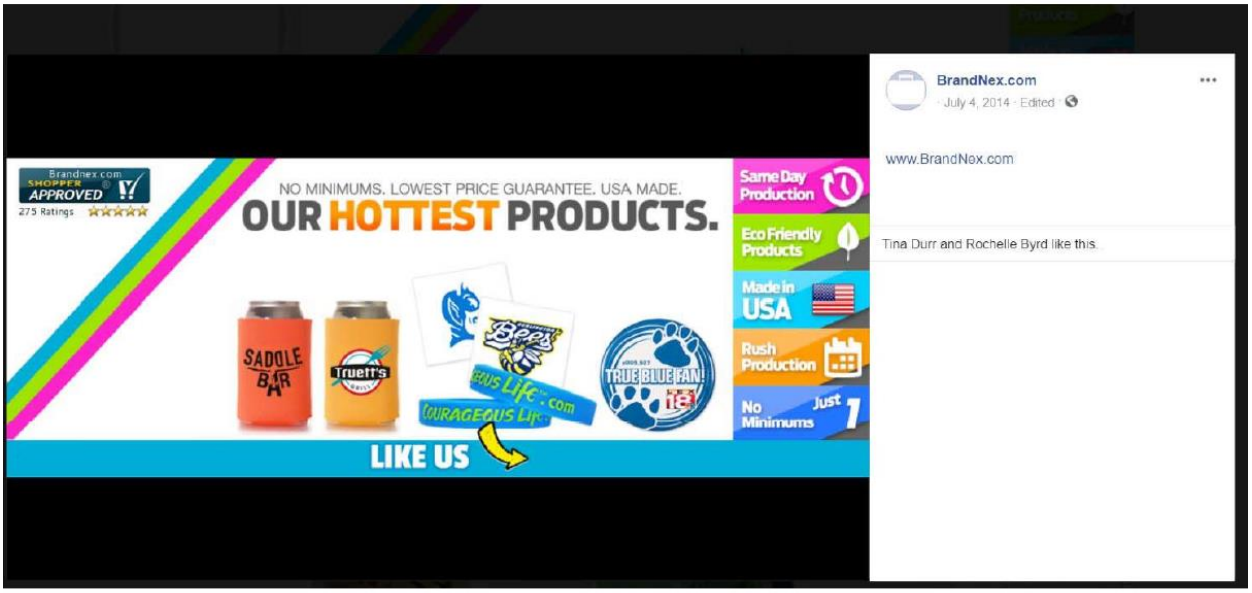
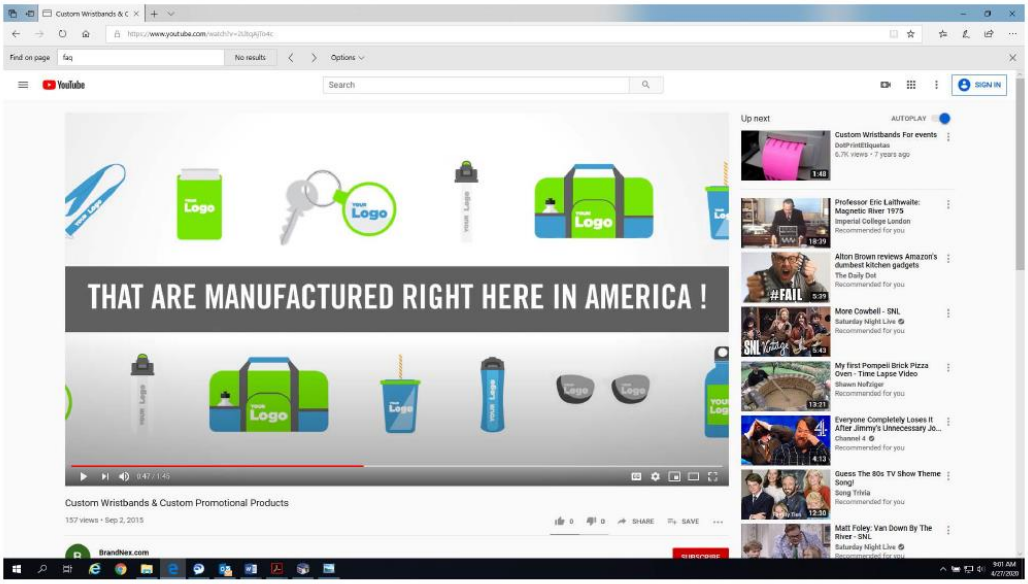


Exhibit C

Exhibit D



DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated

in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further

conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

    a. Respondent Gennex Media LLC ("Gennex"), also doing business as Brandnex, BrandStrong, PMGOA, and Promotional Manufacturing Group of America, a Texas limited liability company with its principal office or place of business at 4771 Sweetwater Blvd. #241, Sugar Land, TX 77479.

    b. Respondent Akil Kurji, Corporate Respondent Gennex's sole officer and shareholder. Individually or in concert with others, he formulates, directs, or controls Gennex's policies, acts, or practices. His principal office or place of business is the same as that of Gennex.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "**Clear(ly) and conspicuous(ly)**" means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

    1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the

communication even if the representation requiring the disclosure ("triggering representation") is made through only one means.

2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.

5. On a product label, the disclosure must be presented on the principal display panel.

6. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the triggering representation appears.

7. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.

8. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.

9. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

B. "**Made in the United States**" means any representation, express or implied, that a product or service, or a specified component thereof, is of U.S.-origin, including, but not limited to, a representation that such product or service is "made," "manufactured," "built," "produced," or "crafted" in the United States or in America, or any other U.S.- origin claim.

C. "**Respondents**" means the Corporate Respondent and the Individual Respondent, individually, collectively, or in any combination.

1. "**Corporate Respondent**" means Gennex Media LLC, a limited liability company also doing business as Brandnex, BrandStrong, PMGOA, and Promotional Manufacturing Group of America, and its successors and assigns.

2. "**Individual Respondent**" means Akil Kurji.

Provisions

I.
Prohibited Misrepresentations Regarding U.S.-Origin Claims

IT IS ORDERED that Respondents, and Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any customizable promotional product, or any other product or service, must not make any representation, expressly or by implication, that a product or service is Made in the United States unless:

A. The final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States; or

B. A Clear and Conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients or components, and/or processing; or

C. For a claim that a product is assembled in the United States, the product is last substantially transformed in the United States, the product's principal assembly takes place in the United States, and United States assembly operations are substantial.

II.
Prohibited Misleading and Unsubstantiated Country-of-Origin Representations

IT IS FURTHER ORDERED that Respondents, and Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any customizable promotional product, or any other product or service, must not make any representation, expressly or by implication, regarding the country of origin of any product or service unless the representation is non-misleading, including that, at the time such representation is made, Respondents possess and rely upon a reasonable basis for the representation.

III.
Monetary Relief IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $146,249.24, which Respondents stipulate their undersigned counsel holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

IV.
Additional Monetary Provisions

IT IS FURTHER ORDERED that:

A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondents have no right to challenge any activities pursuant to this Provision.

E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that payment is due, the entire amount will immediately become due and payable.

F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.

G. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers) may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

V.
Customer Information

IT IS FURTHER ORDERED that Respondents must directly or indirectly provide sufficient customer information to enable the Commission to efficiently administer consumer redress. If a representative of the Commission requests in writing any information related to redress, Respondents must provide it, in the form prescribed by the Commission representative, within 14 days.

VI.
Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order, sworn under penalty of perjury.

B. Individual Respondent, for any business that such Respondent, individually or collectively with the Corporate Respondent, is the majority owner or controls directly or indirectly, and Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

VII.
Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondent must describe if he knows or should know due to his own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which he performs services, whether as an employee or otherwise, and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. Each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of the Corporate Respondent or any entity that Respondent has any ownership interest in or controls, directly or indirectly, that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, the Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b)

title or role in any business activity, including (i) any business for which such Respondent performs services, whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondent has direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Gennex Media LLC.

VIII.
Recordkeeping

IT IS FURTHER ORDERED that Respondents must create certain records and retain each such record for 5 years, unless otherwise specified below. Specifically, Corporate Respondent and Individual Respondent for any business that such Respondent, individually or collectively with the other Respondent, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. Personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. Records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. A copy of each unique advertisement or other marketing material making a representation subject to this Order; and

F. For 5 years from the date of the last dissemination of any representation covered by this Order, all materials that were relied upon in making the representation.

IX.
Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Respondent, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

X.
Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court

alleging any violation of this Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Gennex Media LLC and Akil Kurji ("Respondents").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves Respondents' use of "Made in USA" claims to advertise and sell customizable promotional products to consumers. According to the FTC's complaint, Respondents represented that the customizable promotional products they offer are all or virtually all made in the United States. In fact, in numerous instances, Respondents' customizable promotional products are wholly imported from China. Indeed, in some instances the products ship directly to consumers from China without passing through Respondents' U.S. facility. According to the complaint, Kurji, Gennex's sole officer and shareholder, formulated or approved marketing materials with U.S.-origin claims despite knowing numerous products

advertised are imported. Based on the foregoing, the complaint alleges that Respondents engaged in deceptive acts or practices in violation of Section 5(a) of the FTC Act.

The proposed consent order contains provisions designed to prevent Respondents from engaging in similar acts and practices in the future. Consistent with the FTC's Enforcement Policy Statement on U.S. Origin Claims, Part I prohibits Respondents from making U.S.-origin claims for their products unless either: (1) the final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States; (2) a clear and conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients or components, and/or processing; or (3) for a claim that a product is assembled in the United States, the product is last substantially transformed in the United States, the product's principal assembly takes place in the United States, and United States assembly operations are substantial.

Part II prohibits Respondents from making any country-of-origin claim about a product or service unless the claim is true, not misleading, and Respondents have a reasonable basis substantiating the representation.

Parts III through V are monetary provisions. Part III imposes a judgment of $146,249.24. Part IV includes additional monetary provisions relating to collections. Part V requires Respondents to provide sufficient customer information to enable the Commission to administer consumer redress, if appropriate.

Parts VI through IX are reporting and compliance provisions. Part VI requires Respondents to acknowledge receipt of the order, to provide a copy of the order to certain current and future principals, officers, directors, and employees, and to obtain an acknowledgement from each such person that they have received a copy of the order. Part VII requires Respondents to file a compliance report within one year after the order becomes final and to notify the Commission within 14 days of certain changes that would affect compliance with the order. Part VIII requires Respondents to maintain certain records, including records necessary to demonstrate compliance with the order. Part IX requires Respondents to submit additional compliance reports when requested by the Commission and to permit the Commission or its representatives to interview Respondents' personnel.

Finally, Part X is a "sunset" provision terminating the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

Complaint

IN THE MATTER OF

EVERALBUM, INC.
D/B/A
EVER AND PARAVISION

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4743; File No. 192 3172
Complaint, May 6, 2021 – Decision, May 6, 2021

This consent order addresses Everalbum, Inc.'s use of the Ever mobile app, called "Friends" to develop facial recognition technology. The complaint alleges that Everalbum violated Section 5(a) of the Federal Trade Commission Act by misrepresenting the company's practices with respect to Ever users' content and that, in four instances, Everalbum used images it extracted from Ever users' photos in the development of face recognition technology. The consent order requires Respondent to delete (A) photos and videos of Ever app Users who requested deactivation of their accounts, (B) face recognition data that it created without obtaining Users' affirmative express consent, and (C) models and algorithms it developed in whole or in part using images from Users' photos. The consent order also prohibits Respondent from making misrepresentations related to the collection, use, disclosure, maintenance, or deletion of Covered Information (as defined in the order); consumers' ability to control any of these actions; the extent to which Everalbum accesses or permits access to Covered Information; the extent, purpose, and duration of Everalbum's retention of Covered Information after consumers deactivate their accounts; or the extent to which Everalbum otherwise protects the privacy, security, availability, confidentiality, or integrity of any Covered Information.

Participants

For the *Commission*: *James Trilling* and *Robin Wetherill.*

For the *Respondents*: *Michelle Kisloff, Lance Murashige,* and *Harriet Pearson, of Hogan Lovells US LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Everalbum, Inc., a corporation ("Respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Everalbum, Inc. ("Everalbum"), also doing business as Ever and Paravision, is a Delaware corporation with its principal office or place of business at 1160 Gorgas Ave., San Francisco, California 94129.

2. The acts and practices of Respondent alleged in this Complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

EVERALBUM'S BUSINESS PRACTICES

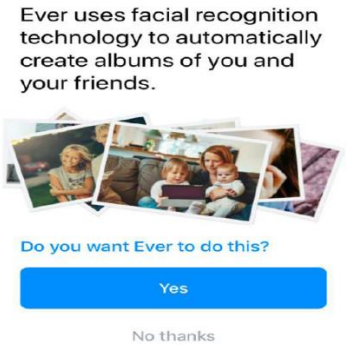
3. Since 2015, Everalbum has provided Ever, a photo storage and organization application, to consumers. Ever is available as both an iOS and Android mobile application ("app"), as well as in a web and desktop format. Globally, approximately 12 million consumers have installed Ever.

4. Ever allows consumers to upload photos and videos to Ever's cloud servers from sources such as the user's mobile device, computer, or accounts with social media services, such as Facebook or Instagram, or cloud-based storage services, such as Dropbox or One Drive. By storing photos and videos on Ever's servers, consumers can free up storage space on their devices. Ever uses automated features to organize users' photos and videos into albums by location and date.

The Ever App's Face Recognition Feature

5. In February 2017, Everalbum launched its "Friends" feature, which operates on both the iOS and Android versions of the Ever app. The Friends feature uses face recognition to group users' photos by faces of the people who appear in the photos. The user can choose to apply "tags" to identify by name (e.g., "Jane") or alias (e.g., "Mom") the individuals who appear in their photos. These tags are not available to other Ever users. When Everalbum launched the Friends feature, it enabled face recognition by default for all users of the Ever mobile app. At that time, Everalbum did not provide users of the Ever mobile app an option to turn off or disable the feature.

6. Starting in May 2018, Everalbum rolled out a process through which Ever presented Ever mobile app users located in Texas, Illinois, Washington, or the European Union with a pop-up message that, as shown below, requests that those users choose whether they would like the Ever application to use face recognition. In so doing, Everalbum disabled the Friends feature and face recognition for those users unless and until they clicked "Yes" to turn on the Friends feature and face recognition. At the same time, Everalbum also introduced into the Ever mobile app a setting that allowed users located in Texas, Illinois, Washington, or the European Union to turn on or off the face recognition feature.



7. In April 2019, Everalbum rolled out to Ever mobile app users located outside of Texas, Illinois, Washington, and the European Union the pop-up message requesting that users choose whether they would like the Ever application to use face recognition. This functioned identically to the pop-up message previously provided to users located in Texas, Illinois, Washington, and the European Union. That is, Everalbum disabled the Friends feature and face recognition unless and until the users clicked "Yes" to turn on the Friends feature and face recognition. At this time, Everalbum also rolled out to all Ever mobile app users the setting that allows users to turn on or off face recognition.

8. Since Everalbum has presented Ever mobile app users with the pop-up message requesting that users choose whether they would like the Ever application to use face recognition, approximately 25% of the approximately 300,000 users who made a selection when presented with the pop-up message chose to turn face recognition off.

9. Since July 2018, Everalbum has posted in the "Help" section of its website, everalbum.com, an article entitled *What is Face Recognition*? That article includes the following statements:

> *When face recognition is enabled*, the technology analyzes the photos and videos that you upload to create a string of numbers that we call a "face embedding" (emphasis added).
>
> ***
>
> *When face recognition is turned on, you are letting us know* that it's ok for us to use the face embeddings of the people in your photos and videos, including you, and that you have the approval of everyone featured in your photos and videos (emphasis added).

10. However, prior to April 2019, Ever mobile app users who were located anywhere other than Texas, Illinois, Washington, and the European Union did not need to, and indeed could not, take any affirmative action to "let[Everalbum] know" that it should apply face recognition to the users' photos. In fact, for those users, face recognition was enabled by default and the users lacked the ability to disable it. Thus, the article was misleading for Ever mobile app users located outside of Texas, Illinois, Washington, and the European Union.

Everalbum's Use of Ever Users' Photos to Train Its Face Recognition Technology

11. Everalbum's application of face recognition to photos uploaded by Ever mobile app users, in some cases without affirmative express consent, was not limited to providing the Friends feature. When Everalbum initially launched the Ever app's Friends feature in February 2017, the company used publicly available face recognition technology to power the feature. However, the company quickly began developing its own face recognition technology, including, in four instances, by using images it extracted from Ever users' photos to attempt to improve the technology.

12. Between September 2017 and August 2019, Everalbum combined millions of facial images that it extracted from Ever users' photos with facial images that Everalbum obtained from publicly available datasets in order to create four new datasets to be used in the development of its face recognition technology. In each instance, Everalbum used computer scripts to identify and compile from Ever users' photos images of faces that met certain criteria (i.e., not associated with a deactivated Ever account, not blurry, not too small, not a duplicate of another image, associated with a specified minimum number of images of the same tagged identity, and, in three of the four instances, not identified by Everalbum's machines as being an image of someone under the age of thirteen).

13. When compiling the second dataset in April 2018, in addition to applying the criteria described in paragraph 12, Everalbum did not include any facial images extracted from the photos of Ever users Everalbum believed to be residents of either the United States or European Union based on the users' IP addresses.

14. After testing it, Everalbum discarded the face recognition technology that it developed in the Fall of 2017 and April 2018 using the first two datasets it had compiled by combining facial images it had extracted from Ever user' photos with facial images obtained from publicly available datasets.

15. When compiling the third dataset in June 2018, in addition to applying the criteria described in paragraph 12, Everalbum excluded facial images extracted from the photos of Ever users Everalbum believed to be residents of Illinois, Texas, Washington, or the European Union based on the users' IP addresses. In this instance, Everalbum submitted the resulting face recognition technology to the National Institute of Science and Technology for accuracy testing and comparison to competing face recognition technologies.

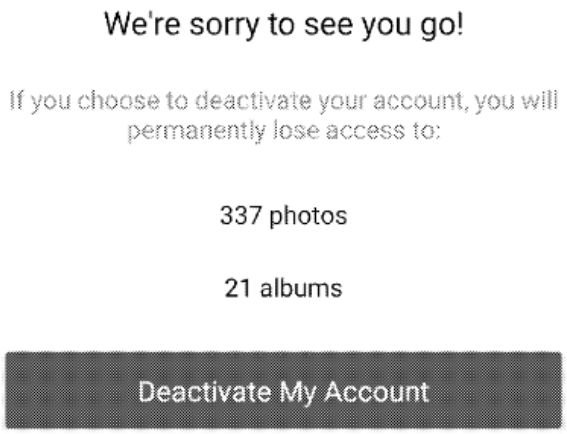
16. When compiling the fourth dataset in August 2019, in addition to applying the criteria described in paragraph 12, Everalbum excluded facial images extracted from the photos of Ever users who had not either turned on the setting, or clicked "Yes" on the pop-up message, described in paragraphs 6-7 above. Everalbum used the resulting face recognition technology both in the Ever app and to build the face recognition services offered by its enterprise brand, Paravision (formerly Ever AI). Paravision offers its face recognition technology to enterprise customers for purposes such as security, access control, and facilitating payments. Everalbum has not shared images from Ever users' photos or Ever users' photos, videos, or personal information with Paravision's customers.

Everalbum's Account Deactivation Process

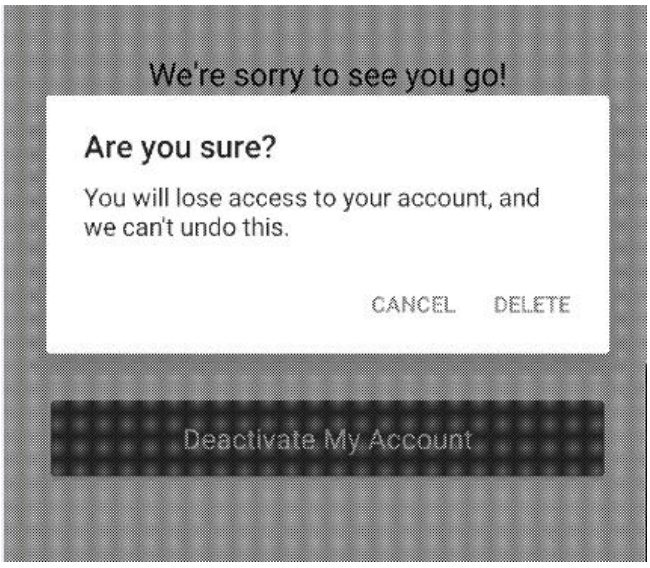
17. Everalbum offers users who no longer wish to use Ever the ability to deactivate their Ever accounts. Since January 2017, approximately 36,000 Ever users have deactivated their accounts.

18. As shown below, when a user chooses to deactivate their Ever account, Everalbum displays a message that tells the user: "We're sorry to see you go! If you choose to deactivate your account, you will permanently lose access to [##] photos and [##] albums." (The

message specifies the numbers of photos and albums stored in the user's Ever account.) The message includes a button for the user to click to deactivate their account.



19. If the user clicks the "Deactivate My Account" button, as shown below, Everalbum then displays a second message stating: "Are you sure? You will lose access to your account and we can't undo this." That message includes buttons that present the user with the choice to "CANCEL" or "DELETE."



20. In response to customer inquiries about deleting an Ever account, in multiple instances, Everalbum has stated: "[Y]ou can deactivate your account at any time by signing into our app, going to 'Settings' > 'General Settings' > 'Deactivate'. *Please note that this will permanently delete all photos and videos stored on your account as well*" (emphasis added).

21. Everalbum's Privacy Policy also states:

> If you wish to deactivate your account or request that we no longer use your information to provide you any services or certain services, such as our Friends feature or our face recognition services, you can do that via your account settings, or you can email us at privacy@everalbum.com. Please understand that we may need to retain and use your information for a certain period of time to comply with our legal obligations, resolve disputes, and enforce our agreements. Consistent with these requirements, *we will try to delete your information as soon as possible upon request*. Please note, however, that there might be latency in deleting information from our servers and backed-up versions might exist after deletion (emphasis added).

22. Contrary to the statements Everalbum has made that account deactivation will result in Everalbum deleting the user's photos and videos, until at least October 2019, Everalbum did not, in fact, delete the photos or videos of any users who had deactivated their accounts and instead retained them indefinitely. Everalbum began implementing in October 2019 a practice of deleting all the photos and videos associated with Ever accounts that have been deactivated for more than three months.

Count I

Misrepresentation Regarding Ever Users' Ability to Control the Ever App's Face Recognition Feature

23. As described in Paragraph 9, Respondent represented, directly or indirectly, expressly or by implication, that Everalbum was not using face recognition unless the user enabled it or turned it on.

24. In fact, as set forth in Paragraphs 5-8 and 10, until April 2019, Everalbum was using face recognition by default for all Ever mobile app users who were located anywhere other than Texas, Illinois, Washington, and the European Union and did not provide those users with a setting to use the app and turn off face recognition. Therefore, the representation set forth in Paragraph 9 is false or misleading.

Count II

Misrepresentation Regarding Deletion of Ever Users' Photos Upon Account Deactivation

25. As described in Paragraphs 18-21, Respondent has represented, directly or indirectly, expressly or by implication, that Everalbum would delete Ever users' photos and videos upon users' deactivation of their accounts.

26. In fact, as set forth in Paragraph 22, until October 2019, Everalbum did not delete any Ever users' photos and videos upon account deactivation and instead stored them indefinitely. Therefore, the representation set forth in Paragraphs 18-21 is false or misleading.

Violations of Section 5

27. The acts and practices of Respondent as alleged in this Complaint constitute unfair or deceptive acts or practices, in or affecting commerce, in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this 6th day of May, 2021, has issued this Complaint against Respondent.

By the Commission.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondent named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violations of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondent that it neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of thirty (30) days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondent is Everalbum, Inc., also d/b/a Ever and Paravision, a Delaware corporation with its principal office or place of business at 1160 Gorgas Ave., San Francisco, California 94129.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "Affected Work Product" means any models or algorithms developed in whole or in part using Biometric Information Respondent collected from Users of the "Ever" mobile application.

B. "Biometric Information" means data that depicts or describes the physical or biological traits of an identified or identifiable person, including depictions (including images), descriptions, recordings, or copies of an individual's facial or other physical features (e.g., iris/retina scans), finger or handprints, voice, genetics, or characteristic movements or gestures (e.g., gait or typing pattern).

C. "Clearly and Conspicuously" means that a required disclosure is difficult to miss (i.e., easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

   1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure ("triggering representation") is made through only one means.

   2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

   3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.

5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the triggering representation appears.

6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.

7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.

8. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

D. "Covered Information" means information from or about an individual consumer, including: (1) a first and last name; (2) a physical address; (3) an email address or other online contact information, such as an instant messaging user identifier or a screen name; (4) a telephone number; (5) a Social Security number; (6) a driver's license or other government-issued identification number; (7) a financial account number; (8) credit or debit card information; (9) photos and videos; (10) Biometric Information; (11) descriptive information derived from Biometric Information, including a Face Embedding; (12) a persistent identifier, such as a customer number held in a "cookie," a static Internet Protocol ("IP") address, a mobile device ID, processor serial number, user ID, or any other persistent identifier that can be used to recognize a user over time and/or across different devices, websites or online services; or (13) any information combined with any of (1) through (12) above.

E. "Face Embedding" means data, such as a numeric vector, derived in whole or in part from an image of an individual's face.

F. "Respondent" means Everalbum, Inc., also doing business as Ever and Paravision, and its successors and assigns.

G. "User" means a person who has downloaded, accessed, and/or used software, such as a mobile application, developed, operated, or offered by Respondent and marketed to consumers for personal use, including the "Ever" mobile application.

Provisions

I. Prohibition against Misrepresentations

IT IS ORDERED that Respondent; and Respondent's officers, agents, and employees; and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with any product or service must not misrepresent in any manner, expressly or by implication:

A. The extent to which Respondent collects, uses, discloses, maintains, or deletes any Covered Information;

B. The extent to which consumers can control the collection, use, disclosure, maintenance, or deletion of Covered Information;

C. The extent to which Respondent accesses or permits access to Covered Information;

D. The extent to which, purposes for which, or duration of time during which Respondent retains any Covered Information following a consumer's deletion or deactivation of a user account with Respondent; or

E. The extent to which Respondent otherwise protects the privacy, security, availability, confidentiality, or integrity of any Covered Information.

II. Notice and Affirmative Express Consent Provision

IT IS FURTHER ORDERED that Respondent; and Respondent's officers, agents, and employees; and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with any product or service, prior to using Biometric Information collected from a User to (1) create a Face Embedding or (2) train, develop, or alter any face recognition model or algorithm, must:

A. Clearly and Conspicuously disclose to the User from whom Respondent has collected the Biometric Information, separate and apart from any "privacy policy," "terms of use" page, or other similar document, all purposes for which Respondent will use, and to the extent applicable, share, the Biometric Information; and

B. Obtain the affirmative express consent of the User from whom Respondent collected the Biometric Information.

Provided, however, Respondent need not comply with this provision in connection with any product or service that is only offered to Users outside the United States.

III. Deletion

IT IS FURTHER ORDERED that Respondent; and Respondent's officers, agents, and employees; and all other persons in active concert or participation with any of them, who receive actual notice of this Order, must, unless prohibited by law:

A. Within thirty (30) days after the issuance date of this Order, delete or destroy all photos and videos that Respondent collected from Users who requested deactivation of their Ever accounts on or before the issuance date of this Order, and provide a written statement to the Commission, sworn under penalty of perjury, confirming that all such information has been deleted or destroyed;

B. Within ninety (90) days after the issuance of this Order, delete or destroy all Face Embeddings derived from Biometric Information Respondent collected from Users who have not, by that date, provided express affirmative consent for the creation of the Face Embeddings, and provide a written statement to the Commission, sworn under penalty of perjury, confirming that all such information has been deleted or destroyed; and

C. Within ninety (90) days after the issuance of this Order, delete or destroy any Affected Work Product, and provide a written statement to the Commission, sworn under penalty of perjury, confirming such deletion or destruction.

Provided, however, that any photos, videos, Face Embeddings, Affected Work Product, or other matter that Respondent is otherwise required to delete or destroy pursuant to this provision may be retained, and may be disclosed, as requested by a government agency or otherwise required by law, regulation, court order, or other legal obligation, including as required by rules applicable to the safeguarding of evidence in pending litigation. In each written statement to the Commission required by this provision, Respondent shall describe in detail any relevant information that Respondent retains on any of these bases and the specific government agency, law, regulation, court order, or other legal obligation that prohibits Respondent from deleting or destroying such information. Within thirty (30) days after the obligation to retain the information has ended, Respondent shall provide an additional written statement to the Commission, sworn under penalty of perjury, confirming that Respondent has deleted or destroyed such information.

IV. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondent obtain acknowledgments of receipt of this Order:

A. Respondent, within ten (10) days after the issuance date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For ten (10) years after the issuance date of this Order Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives having managerial responsibilities for conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within ten (10) days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within thirty (30) days, a signed and dated acknowledgment of receipt of this Order.

V. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondent make timely submissions to the Commission:

A. One year after the issuance date of this Order, Respondent must submit a compliance report, sworn under penalty of perjury, in which Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Respondent; (b) identify all of the Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, what Covered Information is collected, and the means of advertising, marketing, and sales; (d) describe in detail whether and how Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

B. Respondent must submit a compliance notice, sworn under penalty of perjury, within fourteen (14) days of any change in the following: (a) any designated point of contact or (b) the structure of Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

C. Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Respondent within fourteen (14) days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "In re Everalbum, Inc., FTC File No. 1923172."

VI. Recordkeeping

IT IS FURTHER ORDERED that Respondent must create certain records for ten (10) years after the issuance date of the Order, and retain each such record for five (5) years, unless otherwise specified below. Specifically, Respondent must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. Personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. Copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. A copy of each widely disseminated representation by Respondent that describes the extent to which Respondent maintains or protects the privacy, security, availability, confidentiality, or integrity of any Covered Information, including any representation concerning a change in any website, mobile app, or other service controlled by Respondent that relates to privacy, security, availability, confidentiality, or integrity of Covered Information; and

E. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission.

VII. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondent's compliance with this Order:

A. Within ten (10) days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit representatives of the Commission to interview anyone affiliated with Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

VIII. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate twenty (20) years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than twenty (20) years;

B. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Dissenting Statement

STATEMENT OF COMMISSIONER ROHIT CHOPRA

Today's facial recognition technology is fundamentally flawed and reinforces harmful biases. I support efforts to enact moratoria or otherwise severely restrict its use. Until such time, it is critical that the FTC meaningfully enforce existing law to deprive wrongdoers of technologies they build through unlawful collection of Americans' facial images and likenesses.

The case of Everalbum is a troubling illustration of just some of the problems with facial recognition. Everalbum operates a business line called Paravision, which developed and marketed facial recognition technology, including to clients in the security and air travel industries.[1] The company enhanced their facial recognition technology by allegedly baiting consumers into using Ever, a "free" app that allowed users to store and modify photos.[2]

As outlined in the complaint, Everalbum made promises that users could choose not to have facial recognition technology applied to their images, and that users could delete the images and their account. In addition to those promises, Everalbum had clear evidence that many of the photo app's users did not want to be roped into facial recognition. The company broke its promises, which constitutes illegal deception according to the FTC's complaint. This matter and the FTC's proposed resolution are noteworthy for several reasons.

First, the FTC's proposed order requires Everalbum to forfeit the fruits of its deception. Specifically, the company must delete the facial recognition technologies enhanced by any improperly obtained photos. Commissioners have previously voted to allow data protection law violators to retain algorithms and technologies that derive much of their value from ill-gotten data.[3] This is an important course correction.

Second, the settlement does not require the defendant to pay any penalty. This is unfortunate. To avoid this in the future, the FTC needs to take further steps to trigger penalties, damages, and other relief for facial recognition and data protection abuses. Commissioners have

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1 PARAVISION, https://www.paravision.ai/ (last visited on Jan. 4, 2020).

2 Compl., In the Matter of Everalbum, Inc. et al., Docket No. 1923172. This is not the only photo-sharing application that has drawn scrutiny for its ties to facial recognition and surveillance technology. Kashmir Hill & Aaron Krolik, *How Photos of Your Kids Are Powering Surveillance Technology*, N.Y. TIMES (Oct. 11, 2019), https://www.nytimes.com/interactive/2019/10/11/technology/flickr-facial-recognition html.

3 The Commission voted 3-2 on a settlement with Google and YouTube allowed the companies to retain algorithms and other technologies enhanced by illegally obtained data on children. Based on my analysis, the Commission also allowed Google and YouTube to profit from its conduct, even after paying a civil penalty. *See* Dissenting Statement of Commissioner Rohit Chopra In the Matter of Google LLC and Youtube, LLC, Comm'n File No. 1723083 (Sep. 4, 2019), https://www ftc.gov/public-statements/2019/09/statement-commissioner-rohit-chopra-regarding-youtube. The Commission voted 3-2 on a settlement with Facebook to address unlawful facial recognition practices that violated a 2012 Commission order. Like the Google/YouTube settlement, Facebook was not required to forfeit any facial recognition or other related technologies. The settlement also provided an unusual immunity clause for senior executives, including Mark Zuckerberg and Sheryl Sandberg. *See also* Dissenting Statement of Commissioner Rohit Chopra In re Facebook, Inc., Comm'n File No. 1823109 (Jul. 24, 2019), https://www.ftc.gov/public-statements/2019/07/dissenting-statement-commissioner-rohit-chopra-regarding-matter-facebook.

voted to enter into scores of settlements that address deceptive practices regarding the collection, use, and sharing of personal data. There does not appear to be any meaningful dispute that these practices are illegal. However, since Commissioners have not restated this precedent into a rule under Section 18 of the FTC Act, we are unable to seek penalties and other relief for even the most egregious offenses when we first discover them.[4]

Finally, the Everalbum matter makes it clear why it is important to maintain states' authority to protect personal data. Because the people of Illinois, Washington, and Texas passed laws related to facial recognition and biometric identifiers, Everalbum took greater care when it came to these individuals in these states.[5] The company's deception targeted Americans who live in states with no specific state law protections.

With the tsunami of data being collected on individuals, we need all hands on deck to keep these companies in check. State and local governments have rightfully taken steps to enact bans, moratoria, and other restrictions on the use of these technologies. While special interests are actively lobbying for federal legislation to delete state data protection laws, it will be important for Congress to resist these efforts. Broad federal preemption would severely undercut this multi- front approach and leave more consumers less protected.

It will be critical for the Commission, the states, and regulators around the globe to pursue additional enforcement actions to hold accountable providers of facial recognition technology who make false accuracy claims and engage in unfair, discriminatory conduct.[6]

4 Statement of Commissioner Rohit Chopra Regarding the Report to Congress on Protecting Older Adults, Comm'n File No. P144400 (Oct. 19, 2020), https://www ftc.gov/public-statements/2020/10/statement-commissioner-rohit-chopra-regarding-report-congress-protecting; Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256

5 Compl., *supra* note 2.

6 Prepared Remarks of Commissioner Rohit Chopra at Asia Pacific Privacy Authorities 54th APPA Forum (Dec. 7, 2020), https://www.ftc.gov/public-statements/2020/12/prepared-remarks-commissioner-rohit-chopra-asia-pacific-privacy.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission" or "FTC") has accepted, subject to final approval, an agreement containing a consent order from Everalbum, Inc., also doing business as Ever and Paravision ("Everalbum" or "Respondent").

The proposed consent order ("proposed order") has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission again will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

Since 2015, Everalbum has operated "Ever," a photo storage and organization application available as an iOS or Android mobile application ("app") and in web and desktop formats. Ever allows consumers to upload photos and videos (collectively, "content") from mobile devices, computers, or social media or cloud-based storage service accounts to Ever's cloud servers.

In February 2017, Everalbum launched a new feature of the Ever mobile app, called "Friends." The Friends feature uses face recognition to organize users' photos by faces of the people who appear in them. When Everalbum launched the Friends feature, it enabled face recognition by default for all users of the Ever mobile app.

Everalbum's application of face recognition to Ever app users' content has not been limited to providing the Friends feature. The Commission's proposed complaint alleges that, in four instances, Everalbum used images it extracted from Ever users' photos in the development of face recognition technology. In one such instance, Everalbum used the resulting face recognition technology both in the Ever app and to build the face recognition services offered by its enterprise brand, Paravision (formerly Ever AI).

The proposed two-count complaint alleges that Everalbum violated Section 5(a) of the FTC Act by misrepresenting the company's practices with respect to Ever users' content.

Proposed complaint Count I alleges that Everalbum misrepresented the circumstances under which the company would apply face recognition to Ever users' content. According to the proposed complaint, Everalbum published a help article entitled "What is Face Recognition?" on its website in July 2018. The proposed complaint alleges that the help article represented that the Ever app's "Friends" feature was not active—and, therefore, that Everalbum would not apply face recognition technology to users' content—unless users affirmatively enabled the feature. The proposed complaint further alleges that the help article was false or misleading, because, until April 2019, for users in most geographic locations, Everalbum applied face recognition to users' content by default and users could not use an app setting to turn off face recognition.

Proposed complaint Count II alleges that Everalbum misrepresented that the company would delete the content of Ever users who chose to deactivate their Ever accounts. According to the proposed complaint, when Ever users sought to deactivate their accounts, Everalbum presented them with pop-up messages that represented that account deactivation would result in

Everalbum deleting their content. The proposed complaint alleges that Everalbum also made a similar representation in response to consumer inquiries and in its privacy policy. Despite its representations, Everalbum allegedly did not delete any users' content upon account deactivation and instead stored the content indefinitely.

The proposed order contains provisions to address Respondent's conduct and prevent it from engaging in the same or similar acts or practices in the future.

Provision I of the proposed order prohibits Respondent from making misrepresentations related to the collection, use, disclosure, maintenance, or deletion of Covered Information (as defined in the order); consumers' ability to control any of these actions; the extent to which Everalbum accesses or permits access to Covered Information; the extent, purpose, and duration of Everalbum's retention of Covered Information after consumers deactivate their accounts; or the extent to which Everalbum otherwise protects the privacy, security, availability, confidentiality, or integrity of any Covered Information.

Part II of the proposed order requires Respondent to clearly and conspicuously disclose, and obtain consumers' affirmative express consent for, all purposes for which it will use or share User's Biometric Information before using the information to create data needed for face recognition analysis or to develop face recognition models or algorithms.

Part III of the proposed order requires Respondent to delete (A) photos and videos of Ever app Users who requested deactivation of their accounts, (B) face recognition data that it created without obtaining Users' affirmative express consent, and (C) models and algorithms it developed in whole or in part using images from Users' photos.

Parts IV through VII of the proposed order are reporting and compliance provisions, which include recordkeeping requirements and provisions requiring Respondent to provide information or documents necessary for the Commission to monitor compliance. Part VIII of the proposed order states that the order will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

Complaint

IN THE MATTER OF

BASF SE, BASF CORPORATION, AND DIEM LABS, LLC

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4744; File No. 192 3088
Complaint, May 24, 2021 – Decision, May 24, 2021

This consent order addresses BASF SE and BASF Corporation's advertising for Hepaxa and Hepaxa PD capsules containing omega-3 fatty acids. The complaint alleges that respondents violated Sections 5 and 12 of the FTC Act by representing that Hepaxa reduces liver fat in most adults with Non-alcoholic Fatty Liver Disease ("NAFLD") within six months, that Hepaxa PD reduces liver fat in most children with NAFLD within six months, that tests prove that Hepaxa reduces liver fat in adults with NAFLD and that tests prove that Hepaxa PD reduces liver fat in children with NAFLD. The consent order prohibits any representation that Hepaxa, Hepaxa PD, and any other Dietary Supplement, Food, or Drug that contains one or more omega-3 fatty acids or is promoted by a Respondent or its subsidiary to benefit cardiac, metabolic, or hepatic health or functions, including the prevention, mitigation, treatment, or cure of any disease of such systems, reduces liver fat in adults or children with NAFLD, or cures, mitigates, or treats any disease, including but not limited to liver disease, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

Participants

For the *Commission*: *Janet Evans* and *Keith Fentonmiller.*

For the *Respondents*: *Willard K. Tom, Morgan Lewis and Bockius; Jeffrey H. Daichman, Kane Kessler P.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that BASF SE, a corporation, BASF Corporation, a corporation, DIEM Labs, LLC, a limited liability company, Cai Berg, individually and as President and CEO of DIEM Labs, LLC, and Tim Prince, individually and as an officer of DIEM Labs, LLC (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent BASF SE ("BASF") is a multi-national corporation based in Ludwigshafen, Germany. BASF is the publicly-traded parent company of the BASF Group, which has subsidiaries and joint ventures in more than 90 countries, including the United States. Through its Nutrition & Health division, BASF develops, produces, and markets dietary supplements, medical foods, aroma additives, and animal nutrition ingredients in Europe, North America, South America and in the Asia-Pacific region. BASF AS is BASF's main operating

company in Norway and serves as the head of BASF's omega-3 business. BASF developed the omega-3 fish oil supplements Hepaxa and Hepaxa PD for the North American market to treat Non-Alcoholic Fatty Liver Disease ("NAFLD"). NAFLD, also called hepatic steatosis or fatty liver disease, is an excessive build-up of fat in the liver from causes other than alcohol use, such as obesity, diabetes, or high cholesterol. BASF sponsored human clinical testing of Hepaxa in the United States, prepared articles about the benefits of Hepaxa and Hepaxa PD for persons with NAFLD, posted the articles on Hepaxa-USA.com, and promoted Hepaxa research at the 2018 American Association for the Study of Liver Diseases conference in San Francisco, California. BASF supplies Hepaxa products to DIEM Labs, LLC ("DIEM"), the exclusive distributor for the U.S. market. BASF also reviews and approves all Hepaxa-related marketing and advertising materials prepared by DIEM for the U.S. market, including content on Hepaxa-USA.com.

2. Respondent BASF Corporation ("BASF US") is a Delaware corporation with offices at 100 Park Avenue, Florham Park, New Jersey 07932. BASF US is BASF's largest subsidiary and operates as BASF's North American headquarters. BASF US retained DIEM to serve as the sole U.S. distributor of Hepaxa and Hepaxa PD and issued a press release regarding Hepaxa and Hepaxa PD's benefits.

3. Respondent DIEM is a Michigan limited liability company, with its principal office or place of business at 221 Dino Dr., Ann Arbor, MI 48103-9123. DIEM serves as BASF's sole distributor of Hepaxa and Hepaxa PD in the United States, and engages in marketing activities for the products.

4. Individual Respondent Cai Berg is DIEM's President and CEO. He is also 50% owner of the corporation that owns 99% of DIEM. He is primarily responsible for DIEM's operations, contracting, human resources, finances, and product development. He was copied on all correspondence relating to the clinical trial conducted on Hepaxa, including correspondence relating to the fact that the trial failed to demonstrate that Hepaxa reduced fatty liver, and he engaged in communication with BASF regarding the results of the study. He also reviewed and approved DIEM's advertising for Hepaxa and promoted the product at medical conferences. At all times material to this Complaint, acting alone or in concert with others, he formulated, directed, controlled, had the authority to control, or participated in the acts and practices of DIEM set forth in this Complaint. His principal office or place of business is 221 Dino Dr., Ann Arbor, MI 48103-9123.

5. Individual Respondent Timothy Prince is DIEM's Director of Sales. He was provided with access to the raw data from the Hepaxa clinical study and made suggestions for alternative analyses of the data in an effort to find a successful sales pitch for the product. Thereafter, he participated in preparing deceptive advertising for Hepaxa and trained the Hepaxa sales force. He personally promoted Hepaxa as an effective treatment for NAFLD at various medical conferences. Individually or in concert with others, he controlled or had the authority to control and participated in the acts and practices of DIEM, including the acts and practices alleged in this complaint. His principal office or place of business is 221 Dino Dr., Ann Arbor, MI 48103-9123.

6. Respondents advertise, label, promote, offer for sale, sell, and distribute Hepaxa and Hepaxa PD, products containing omega-3 long-chain polyunsaturated fatty acids (abbreviated as "omega-3 PUFAs" or "n-3 PUFAs") sourced from fish oil. Respondents sell 120-capsule bottles of Hepaxa to treat adults with NAFLD. The product label recommends a daily dose of four capsules. Respondents also offer 120-capsule bottles of Hepaxa PD to treat children ages ten to eighteen with NAFLD. Hepaxa PD's product label recommends a daily dosage of one to two capsules, depending on the child's body weight. Each Hepaxa and Hepaxa PD capsule contains 675 mg of omega-3 fatty acids, consisting of at least 320 mg eicosapentaenoic acid ("EPA") and 260 mg docosahexaenoic acid ("DHA"). Consumers can purchase a bottle of Hepaxa or Hepaxa PD for $48 by calling a 1-800 number, sending a fax, or by ordering online at www.Hepaxa-USA.com. Hepaxa and Hepaxa PD are "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

7. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

8. Respondents have disseminated or caused to be disseminated advertisements and promotional materials for Hepaxa and Hepaxa PD through the Hepaxa-USA.com website, Google AdWords that directed consumers to Hepaxa-USA.com, banner advertisements on Medscape and WebMD, press releases, and posts on Twitter and LinkedIn. These materials contain the following statements and depictions, among others:

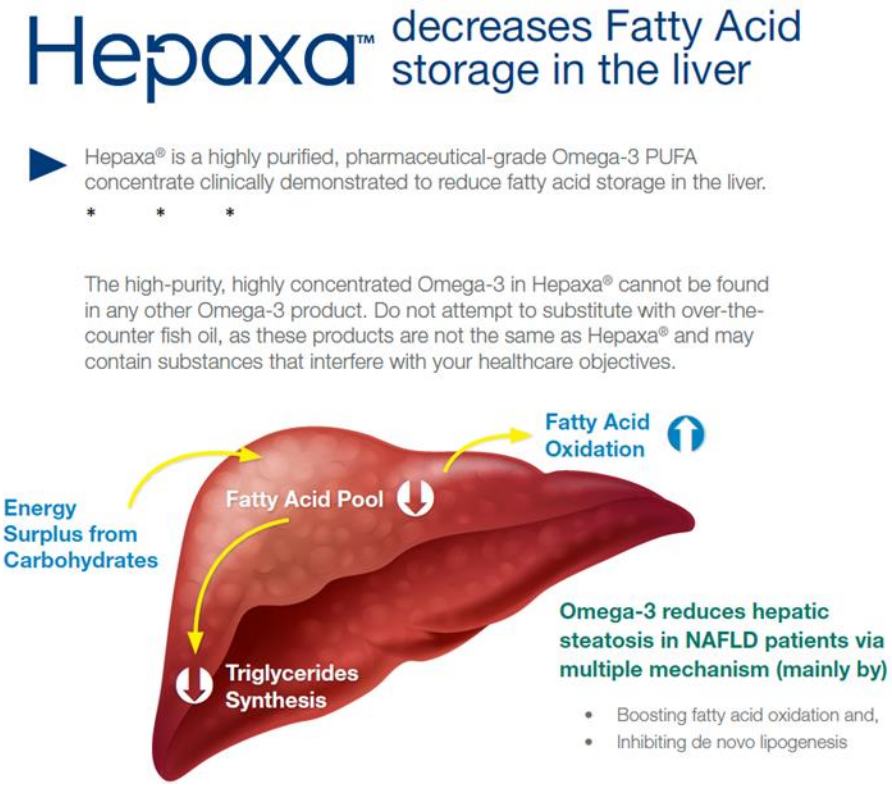
a. Hepaxa-USA.com Landing Page (originally posted October 2018)

* * *

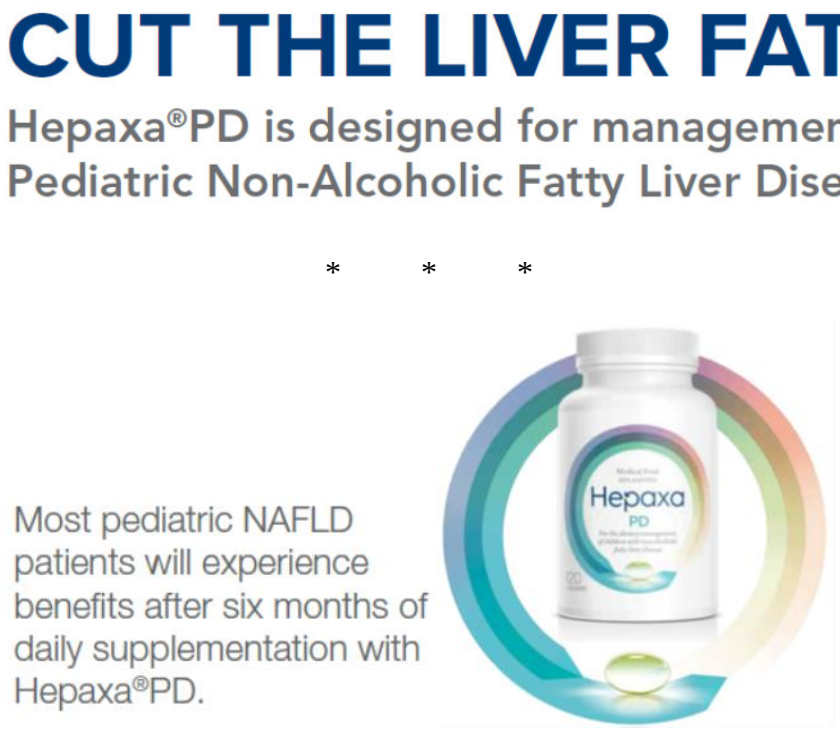
b. Hepaxa-USA.com Pages Specific to Hepaxa (posted Oct. 2018-Dec. 2019)

* * *

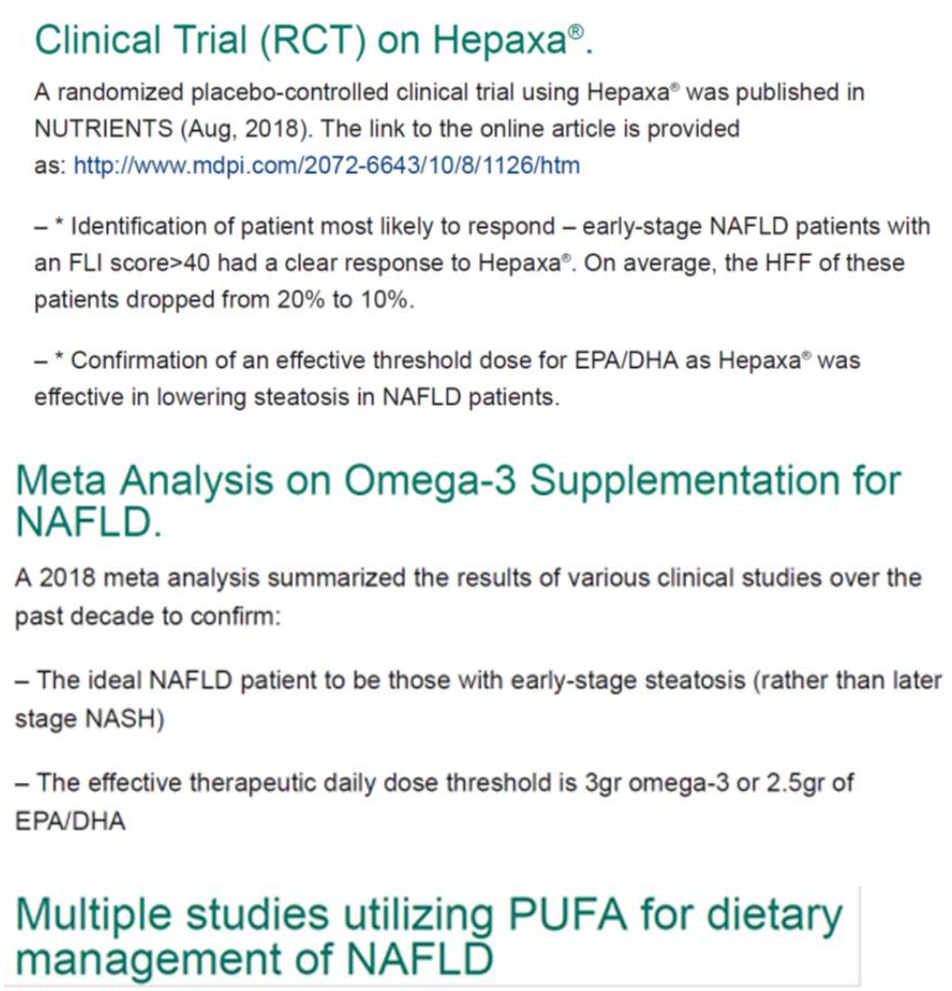
* * *



c. Hepaxa-USA.com Pages Specific to Hepaxa PD (available online Oct. 2018-Dec. 2019)



d. Hepaxa-USA.com Pages Regarding Clinical Evidence (available online Oct. 2018-Dec. 2019)



Clinical Trial (RCT) on Hepaxa®.

A randomized placebo-controlled clinical trial using Hepaxa® was published in NUTRIENTS (Aug, 2018). The link to the online article is provided as: http://www.mdpi.com/2072-6643/10/8/1126/htm

– * Identification of patient most likely to respond – early-stage NAFLD patients with an FLI score>40 had a clear response to Hepaxa®. On average, the HFF of these patients dropped from 20% to 10%.

– * Confirmation of an effective threshold dose for EPA/DHA as Hepaxa® was effective in lowering steatosis in NAFLD patients.

Meta Analysis on Omega-3 Supplementation for NAFLD.

A 2018 meta analysis summarized the results of various clinical studies over the past decade to confirm:

– The ideal NAFLD patient to be those with early-stage steatosis (rather than later stage NASH)

– The effective therapeutic daily dose threshold is 3gr omega-3 or 2.5gr of EPA/DHA

Multiple studies utilizing PUFA for dietary management of NAFLD

Complaint

Hepaxa® | Clinical Evidence

STUDY	SIZE	DURATION	Liver Fat Reduction vs. Placebo	Liver Enzyme Reduction vs. Placebo	Lipid Levels Improvement vs. Placebo
Capanni et al., 2006	N=56	12 months	✓	✓	✓
Chen et al., 2008	N=46	6 months	✓	✓	✓
Cussons et al., 2009	N=25	2 months	✓	NS	✓
Li et al., 2015	N=78	6 months	✓	✓	✓
Sofi et al., 2010	N=11	12 months	✓	✓	✓
Spadaro et al., 2008	N=36	6 months	✓	✓	✓
Zhu et al., 2008	N=144	6 months	✓	✓	✓

Click for white paper on Adult NAFLD Management

In an RCT, DHA supplementation decreases liver fat and visceral fat, and ameliorates metabolic abnormalities in children with NAFLD. [A]

In an RCT, DHA supplementation improves liver steatosis in children with NAFLD. [B]

In an RCT, DHA supplementation in children decreased the rate of steatosis, elevated ALT and elevated AST in the 12-month treatement in the PUFA group. [C]

Multiple studies utilizing PUFA for dietary management of Pediatric NAFLD

STUDY	STUDY SIZE	STUDY DURATION	Improvement of Liver Fat	Reduction in Liver Enzymes	Change in Insulin/Insulin Resistance	Decrease in Triglycerides
Nobili V et al, 2011, 2013	N=60	24 months	✓	✓	✓	✓
Pacifico L et al, 2015	N=58	6 months	✓	✓	✓	✓
Boyraz M et al., 2015	N=108	12 months	✓	✓	✓	✓
Janczyk et al., 2015	N=64	6 months	NS	✓	NS	NS

Click for white paper on Pediatric NAFLD Management

* * *

Complaint

Pediatric NAFLD can be reversed.

If NAFLD is addressed early, with adjustment to diet and exercise, many children can naturally reverse their liver fat composition to less than 5%. Doing so can restore their natural liver function and help to improve their overall and long-term health.

However, many children with NAFLD patients have been unsuccessful in making lifestyle changes to the extent needed for better health. In these cases, doctors want to provide extra help. Clinical studies have shown that daily use of poly unsaturated fatty acids (PUFA) like Hepaxa®PD can reduce liver fat and in time reverse steatosis in NAFLD. Hepaxa®PD is designed to help the dietary management of steatosis in children with early stage NAFLD.

* * *

Clinical Evidence for management of Pediatric NAFLD with (PUFA) Hepaxa®PD

Clinical Support (6-24 months)

In a double-blind, placebo controlled trial, DHA supplementation decreases liver and visceral fat, and ameliorates metabolic abnormalities in children with NAFLD.[3]

DHA SIGNIFICANTLY DECREASES the MRI-determined liver fat content independently of BMI-SDS changes in 6 months.
(Average age 10.8)

* * *

In a randomized controlled trial, DHA supplementation improves liver steatosis in children with NAFLD.[1]

Groups	Cleared of Fatty Liver	Reverting to Degree 1	Probability of Moderate Steatosis	Probabilty of Degree 3
DHA Groups	10-15%	40-50%	25-35%	Reduced from 60% to <10%
Placebo	0%	20%	45%	Reduced from 60% to 40%

e. BASF Press Release (posted February 22, 2018 at www.basf.com/global/en/media/news-releases/2018/02/p-18-130.html)

BASF launches Hepaxa as first dedicated product in the U.S. to help patients manage Non-Alcoholic Fatty Liver Disease

FLORHAM PARK, NJ, and ANN ARBOR, MI, February 22, 2018 – BASF Corporation is introducing Hepaxa™, a product that can help tens of millions of patients manage Non-Alcoholic Fatty Liver Disease (NAFLD), one of the most common forms of chronic liver disease. Providing highly concentrated and pure eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), Hepaxa is the first product in the U.S. specifically designed to address a buildup of fat in the liver, known as steatosis, in NAFLD patients. Hepaxa will be distributed nationally through DIEM Labs, LLC.

Tony Graetzer
+1-201-704-2670
Send email

Studies have shown that NAFLD patients are deficient in EPA and DHA. Hepaxa increases the levels of these important fatty acids in the blood, which improves the liver´s ability to process excessive fat stored there while inhibiting the conversion of dietary carbohydrates into fat.

A 2017 BASF study has shown that Hepaxa is effective and safe in the dietary management of NAFLD patients. BASF plans to publish the clinical results of this product-specific human intervention trial in the second half of 2018.

Hepaxa is manufactured using a patented purification technology removing persistent organic pollutants and other unwanted lipids such as cholesterol, which are naturally found in all fish oil-based products. Research has shown that one specific pollutant, PCB 153, is particularly harmful to NAFLD patients. The liver function of NAFLD patients is compromised and it is important to avoid additional exposure to unwanted components of traditional fish oil.

“BASF’s launch of Hepaxa is the result of our research and development efforts targeting liver health, where we are capitalizing on our unique scientific competencies,” says Christoph Garbotz, Head of Commercial Management Advanced Health Solutions, BASF. “With NAFLD rapidly becoming a major public health concern worldwide, we are proud to now offer this first-to-market, dedicated solution for NAFLD patients in the U.S.”

“Hepaxa is uniquely positioned to support the dietary management of steatosis in NAFLD patients,” says Tim Prince, Director of Sales at DIEM Labs. “Healthcare providers are continuously looking for an adjunctive treatment to exercise and weight loss therapy to recommend to their patients. Hepaxa can now be used to begin turning around NAFLD in as little as six months.”

Hepaxa is available as a medical food product in the U.S. to NAFLD patients 10 years and older for use under physician supervision. Physicians and healthcare professionals may request clinical support literature and product samples, and patients can gather information to share with their physicians, at www.Hepaxa-USA.com.

f. BASF Press Release (posted Oct. 29, 2018 at www.basf.com/global/en/media/news-releases/2018/10/p-18-356.html)

BASF
We create chemistry

News Release

29 October 2018

BASF clinical trial reveals significant reduction in liver fat content in patients with non-alcoholic fatty liver disease

Oslo, Norway – October 29, 2018 – BASF AS completed a randomized, placebo-controlled clinical trial in the U.S., newly published in Nutrients, evaluating the use of high concentrate omega-3 to correct the nutritional deficiency of omega-3 fatty acid in patients with non-alcoholic fatty liver disease (NAFLD). Several studies have shown that NAFLD patients have lower levels of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)[i].

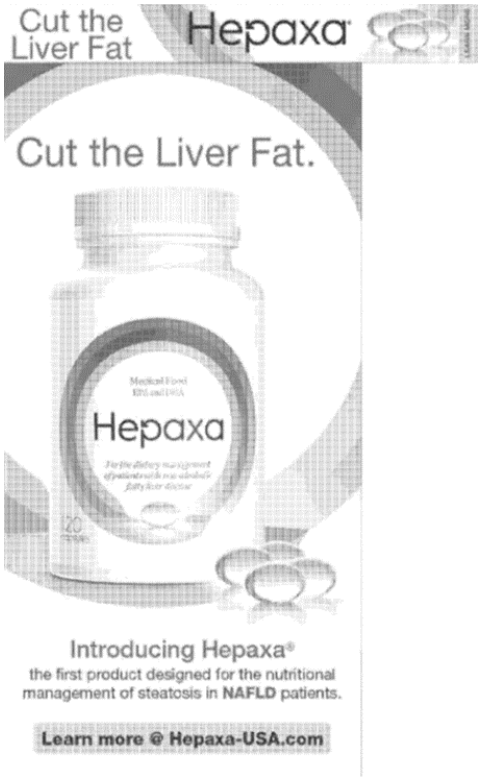
The study, covering 176 patients, demonstrates that intervention with high concentrate omega-3 for 24 weeks significantly raises the omega-3 index in adults with NAFLD compared to placebo, thereby correcting the patients' nutritional deficiency. Patients showed reductions of up to 44% in liver fat after placebo correction, providing evidence that clinical management of NAFLD with high concentrate omega-3 has a beneficial outcome on liver fat. This intervention study supports a recently published meta-analysis that concluded that omega-3 fatty acids are associated with significant improvements in liver fat and liver function tests with approximately 3g of EPA and DHA daily.

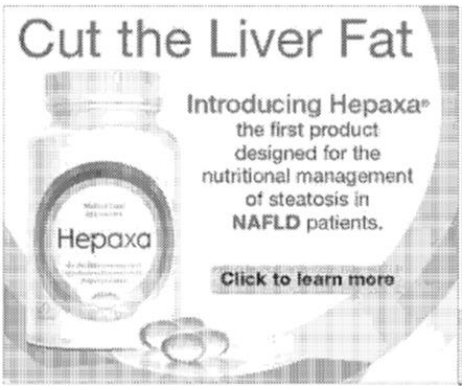
"Science has always been the backbone of all our development work and efforts in the area of liver health, and this study is further evidence that Hepaxa can significantly reduce liver fat content, which is crucial in managing NAFLD." says Derek Tobin, Team Leader for Innovation, Advanced Health Solutions, BASF.

g. LinkedIn Posts

h. Twitter Post

i. Online Banner Ads





9. The clinical trial referred to in Paragraphs 10.E, 10.F, and 10.G. was published as Derek Tobin, et al., Evaluation of a High Concentrate Omega-3 for Correcting the Omega-3 Fatty Acid Nutritional Deficiency in Non-Alcoholic Fatty Liver Disease (CONDIN), 10 Nutrients 1126 (2018). The CONDIN study was a randomized, double-blind human clinical trial designed to evaluate whether Hepaxa raises levels of omega-3 PUFAs in red blood cells and reduces liver fat in adults with NAFLD. For six months, 81 subjects in the treatment arm received Hepaxa and 86 in the control arm took an olive oil placebo. All study participants were advised to reduce calorie intake and to maintain stable physical activity levels. Liver fat was measured using Magnetic Resonance Imaging in 120 subjects, 60 in each arm. At the end of the study, the MRI data showed no statistically significant reduction in liver fat in the Hepaxa patients, as compared to the placebo patients.

10. Due to the CONDIN study's failure to show an effect on liver fat, BASF, DIEM, and the researchers subjected the data to "post hoc" analyses of different subgroups of test subjects, in an attempt to find a positive selling message. A post hoc analysis is a statistical analysis conducted after the data have been collected in hopes of discovering statistical relationships that suggest cause and effect. Unplanned, post hoc subgroup analyses pose a high risk of generating spurious findings and need to be confirmed by further studies. Therefore, post hoc analyses yield results that are exploratory, at best.

11. BASF and DIEM settled on a post hoc analysis that stratified patients by their baseline Fatty Liver Index ("FLI") score. The FLI score derives from an algorithm combining waist circumference and body mass index with blood serum levels of triglycerides and a specific liver enzyme. The post hoc analysis found that a small subgroup of patients with a baseline FLI over 40 experienced a statistically significant reduction in liver fat after using Hepaxa, as compared to placebo; however, this subgroup included only five Hepaxa patients and twelve placebo patients.

12. Other than the CONDIN study, Respondents have not conducted a human clinical trial on Hepaxa's effect on liver fat. Respondents have not tested Hepaxa PD on children at all. Moreover, there are no competent and reliable human clinical trials of products that are the same as Hepaxa. Other liver fat studies on which Respondents rely tested omega-3 PUFAs from a variety of sources, many of which contained significantly different amounts of DHA or EPA, and/or included omega-3 PUFAs not found in Hepaxa or Hepaxa PD.

Count I
False or Unsubstantiated Efficacy Claims

13. In connection with the advertising, promotion, offering for sale, or sale of Hepaxa and Hepaxa PD, Respondents have represented, directly or indirectly, expressly or by implication, that:

a. Hepaxa reduces liver fat in most adults with NAFLD within six months; and

b. Hepaxa PD reduces liver fat in most children with NAFLD within six months.

14. The representations set forth in Paragraph 13 are false or misleading or were not substantiated at the time the representations were made.

Count II
False Establishment Claim

15. In connection with the advertising, marketing, promotion, offering for sale, or sale of Hepaxa and Hepaxa PD, including through the means described in Paragraph 10, Respondents have represented, directly or indirectly, expressly or by implication, that:

a. Tests prove that Hepaxa reduces liver fat in adults with NAFLD; and

b. Tests prove that Hepaxa PD reduces liver fat in children with NAFLD.

16. In fact:

a. Tests do not prove that Hepaxa reduces liver fat in adults with NAFLD; and

b. Tests do not prove that Hepaxa PD reduces liver fat in children with NAFLD.

17. Therefore, the representations set forth in Paragraph 17 are false or misleading.

Violations of Sections 5 and 12

18. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by the Secretary and its official seal to be affixed hereto, at Washington, DC, this twenty-fourth day of May, 2021.

By the Commission.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Proposed Respondents are:

   a. BASF SE, multi-national corporation based in Ludwigshafen, Germany, and

   b. BASF Corporation, a Delaware corporation with offices at 100 Park Avenue, Florham Park, New Jersey 07932.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For the purpose of this Order, the following definitions apply:

A. "**Covered Product**" means Hepaxa, Hepaxa PD, and any other Dietary Supplement, Food, or Drug that contains one or more Omega-3 fatty acids or is promoted by a Respondent or its subsidiary to benefit cardiac, metabolic, or hepatic health or functions, including the prevention, mitigation, treatment, or cure of any disease of such systems.

B. "**Dietary Supplement**" means: (1) any product labeled as a Dietary Supplement or otherwise represented as a Dietary Supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

C. "**Drug**" means: (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans; (3) articles (other than Food) intended to affect the structure or any function of the body of humans; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

D. "**Essentially Equivalent Product**" means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers,

excipients) in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

E. "**Food**" means: (1) any article used for Food or drink for humans; (2) chewing gum; and (3) any article used for components of any such article.

F. "**Respondents**" means BASF SE, and its successors and assigns, and BASF Corporation, and its successors and assigns.

Provisions

I. Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing for Substantiation

IT IS ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that such product reduces liver fat in adults or children with Non-alcoholic Fatty Liver Disease (NAFLD), or cures, mitigates, or treats any disease, including but not limited to liver disease, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Provision, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. Prohibited Claims: Other Health-Related Claims

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection

with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation, other than representations covered under the Provision of this Order entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing for Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. Prohibited Misrepresentations Regarding Tests, Studies, or Other Research

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not misrepresent, in any manner, expressly or by implication, including through the use of any product or program name, endorsement, depiction, or illustration:

A. that any Covered Product is clinically proven to reduce liver fat in adults or children with NAFLD;

B. that any Covered Product is clinically proven to cure, mitigate, or treat any disease;

C. that the health benefits, performance, or safety of any Covered Product is scientifically or clinically proven or otherwise established; or

D. the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research relating to the health benefits, performance, safety, or side effects of any Covered Product.

IV. FDA-Approved Claims

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, Respondents' officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them from:

A. for any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new Drug application approved by the Food and Drug Administration; and

B. for any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

V. Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. all protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. all documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. all documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. all documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part, by: (1) the Respondent; (2) the Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with the Respondent; (4) any person or entity affiliated with or acting on behalf of the Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by the Respondent, the Respondent must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to the Respondent's size and complexity, the nature and scope of the Respondent's activities, and the sensitivity of the personal information collected from or about the participants.

VI. Monetary Relief

IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $259,596, which Respondents stipulate their designated agent, Wilmington Trust, holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

VII <u>Additional Monetary Provisions</u>

IT IS FURTHER ORDERED that:

A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a

proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondent's practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondents have no right to challenge any activities pursuant to this Provision.

E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that payment is due, the entire amount will immediately become due and payable.

F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.

G. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers), which Respondents have previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

VIII. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order.

B. Each Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives having managerial responsibilities for conduct related to the

subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

IX. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondents must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

B. Each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the

United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re BASF SE.

X. Recordkeeping

IT IS FURTHER ORDERED that Respondents must create certain records for 10 years after the issuance date of the Order, and retain each such record for 5 years. Specifically, Corporate Respondent must create and retain the following records:

A. accounting records showing the revenues from such product;

B. personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. records of all consumer complaints concerning the subject matter of the order and all refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. a copy of each unique advertisement or other marketing material making a representation subject to this Order;

F. for 5 years from the date of the last dissemination of any representation covered by this Order:

1. all materials that were relied upon in making the representation; and

2. all tests, studies, analysis, demonstrations, other research or other such evidence in Respondent's possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

G. for 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communication relate to Respondents' compliance with this Order.

H. for 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents, that demonstrate non-compliance or tend to show any lack of compliance by Respondents with this Order.

XI. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 30 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, the Commission is authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview any employee or other person affiliated with Respondent who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission may use all other lawful means, including posing, through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

XII. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order with BASF SE and BASF Corporation ("BASF Respondents"). It also has accepted, subject to final approval, an agreement containing a consent order with DIEM Labs, LLC, and others ("DIEM Respondents"). The proposed consent orders have been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comment received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreements and the comments received, and will decide whether it should withdraw from one or both of the agreements and take appropriate actions or make final the agreements' proposed orders.

This matter involves Respondents' advertising for Hepaxa and Hepaxa PD capsules containing omega-3 fatty acids. The Commission's proposed complaint alleges that advertising for the Hepaxa products represented that Hepaxa reduces liver fat in most adults with Non-alcoholic Fatty Liver Disease ("NAFLD") within six months, and that Hepaxa PD reduces liver fat in most children with NAFLD within six months. The complaint further alleges that Respondents' advertising represented that tests prove that Hepaxa reduces liver fat in adults with NAFLD and that tests prove that Hepaxa PD reduces liver fat in children with NAFLD. According to the proposed complaint, these claims are false or misleading or were not substantiated at the time the representations were made, in violation of Sections 5 and 12 of the FTC Act.

Analysis to Aid Public Comment

The proposed orders include injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The proposed orders against the BASF Respondents and DIEM Respondents are substantially similar. In both orders, "Covered Products" is defined as Hepaxa, Hepaxa PD, and any other Dietary Supplement, Food, or Drug that contains one or more omega-3 fatty acids or is promoted by a Respondent or its subsidiary to benefit cardiac, metabolic, or hepatic health or functions, including the prevention, mitigation, treatment, or cure of any disease of such systems.

Part I of the orders prohibits any representation that a Covered Product reduces liver fat in adults or children with Non-alcoholic Fatty Liver Disease (NAFLD), or cures, mitigates, or treats any disease, including but not limited to liver disease, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety, or side effects of any covered product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III prohibits misrepresentations about tests and studies. Part IV provides Respondents a safe harbor for making claims approved by the Food and Drug Administration ("FDA"). Part V requires that, with regard to any human clinical test or study upon which Respondents rely to substantiate any claim covered by the order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part VI provides for monetary relief, and Part VII describes the procedures and legal rights related those payments. Together, Respondents are paying the full amount of consumer injury, $416,914.00. DIEM Order Part VIII requires the company to provide sufficient customer information to enable the Commission to efficiently administer consumer redress to purchasers of Hepaxa and Hepaxa PD.

DIEM Order Part IX and BASF Order Part VIII require Respondents to submit acknowledgments of receipts of the order. DIEM Order Part X and BASF Order Part IX require the filing of compliance reports with the Commission, including notification to the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. DIEM Order Part XI and BASF Order Part X contain recordkeeping requirements. DIEM Order Part XII and BASF Order XI contain other requirements related to the Commission's monitoring of Respondents' order compliance. Finally, DIEM Order Part XIII and BASF Order Part XII state that the orders will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the orders, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

Complaint

IN THE MATTER OF

BASF SE, BASF CORPORATION, AND DIEM LABS, LLC

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4745; File No. 192 3088
Complaint, May 24, 2021 – Decision, May 24, 2021

This consent order addresses DIEM Labs, LLC's advertising for Hepaxa and Hepaxa PD capsules containing omega-3 fatty acids. The complaint alleges that respondent violated Sections 5 and 12 of the FTC Act by representing that Hepaxa reduces liver fat in most adults with Non-alcoholic Fatty Liver Disease ("NAFLD") within six months, that Hepaxa PD reduces liver fat in most children with NAFLD within six months, that tests prove that Hepaxa reduces liver fat in adults with NAFLD and that tests prove that Hepaxa PD reduces liver fat in children with NAFLD. The consent order prohibits any representation that Hepaxa, Hepaxa PD, and any other Dietary Supplement, Food, or Drug that contains one or more omega-3 fatty acids or is promoted by a Respondent or its subsidiary to benefit cardiac, metabolic, or hepatic health or functions, including the prevention, mitigation, treatment, or cure of any disease of such systems, reduces liver fat in adults or children with NAFLD, or cures, mitigates, or treats any disease, including but not limited to liver disease, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

Participants

For the *Commission*: *Janet Evans* and *Keith Fentonmiller.*

For the *Respondents*: *Willard K. Tom, Morgan Lewis and Bockius; Jeffrey H. Daichman, Kane Kessler P.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that BASF SE, a corporation, BASF Corporation, a corporation, DIEM Labs, LLC, a limited liability company, Cai Berg, individually and as President and CEO of DIEM Labs, LLC, and Tim Prince, individually and as an officer of DIEM Labs, LLC (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent BASF SE ("BASF") is a multi-national corporation based in Ludwigshafen, Germany. BASF is the publicly-traded parent company of the BASF Group, which has subsidiaries and joint ventures in more than 90 countries, including the United States. Through its Nutrition & Health division, BASF develops, produces, and markets dietary supplements, medical foods, aroma additives, and animal nutrition ingredients in Europe, North America, South America and in the Asia-Pacific region. BASF AS is BASF's main operating

company in Norway and serves as the head of BASF's omega-3 business. BASF developed the omega-3 fish oil supplements Hepaxa and Hepaxa PD for the North American market to treat Non-Alcoholic Fatty Liver Disease ("NAFLD"). NAFLD, also called hepatic steatosis or fatty liver disease, is an excessive build-up of fat in the liver from causes other than alcohol use, such as obesity, diabetes, or high cholesterol. BASF sponsored human clinical testing of Hepaxa in the United States, prepared articles about the benefits of Hepaxa and Hepaxa PD for persons with NAFLD, posted the articles on Hepaxa-USA.com, and promoted Hepaxa research at the 2018 American Association for the Study of Liver Diseases conference in San Francisco, California. BASF supplies Hepaxa products to DIEM Labs, LLC ("DIEM"), the exclusive distributor for the U.S. market. BASF also reviews and approves all Hepaxa-related marketing and advertising materials prepared by DIEM for the U.S. market, including content on Hepaxa-USA.com.

2. Respondent BASF Corporation ("BASF US") is a Delaware corporation with offices at 100 Park Avenue, Florham Park, New Jersey 07932. BASF US is BASF's largest subsidiary and operates as BASF's North American headquarters. BASF US retained DIEM to serve as the sole U.S. distributor of Hepaxa and Hepaxa PD and issued a press release regarding Hepaxa and Hepaxa PD's benefits.

3. Respondent DIEM is a Michigan limited liability company, with its principal office or place of business at 221 Dino Dr., Ann Arbor, MI 48103-9123. DIEM serves as BASF's sole distributor of Hepaxa and Hepaxa PD in the United States, and engages in marketing activities for the products.

4. Individual Respondent Cai Berg is DIEM's President and CEO. He is also 50% owner of the corporation that owns 99% of DIEM. He is primarily responsible for DIEM's operations, contracting, human resources, finances, and product development. He was copied on all correspondence relating to the clinical trial conducted on Hepaxa, including correspondence relating to the fact that the trial failed to demonstrate that Hepaxa reduced fatty liver, and he engaged in communication with BASF regarding the results of the study. He also reviewed and approved DIEM's advertising for Hepaxa and promoted the product at medical conferences. At all times material to this Complaint, acting alone or in concert with others, he formulated, directed, controlled, had the authority to control, or participated in the acts and practices of DIEM set forth in this Complaint. His principal office or place of business is 221 Dino Dr., Ann Arbor, MI 48103-9123.

5. Individual Respondent Timothy Prince is DIEM's Director of Sales. He was provided with access to the raw data from the Hepaxa clinical study and made suggestions for alternative analyses of the data in an effort to find a successful sales pitch for the product. Thereafter, he participated in preparing deceptive advertising for Hepaxa and trained the Hepaxa sales force. He personally promoted Hepaxa as an effective treatment for NAFLD at various medical conferences. Individually or in concert with others, he controlled or had the authority to control and participated in the acts and practices of DIEM, including the acts and practices alleged in this complaint. His principal office or place of business is 221 Dino Dr., Ann Arbor, MI 48103-9123.

6. Respondents advertise, label, promote, offer for sale, sell, and distribute Hepaxa and Hepaxa PD, products containing omega-3 long-chain polyunsaturated fatty acids (abbreviated as "omega-3 PUFAs" or "n-3 PUFAs") sourced from fish oil. Respondents sell 120-capsule bottles of Hepaxa to treat adults with NAFLD. The product label recommends a daily dose of four capsules. Respondents also offer 120-capsule bottles of Hepaxa PD to treat children ages ten to eighteen with NAFLD. Hepaxa PD's product label recommends a daily dosage of one to two capsules, depending on the child's body weight. Each Hepaxa and Hepaxa PD capsule contains 675 mg of omega-3 fatty acids, consisting of at least 320 mg eicosapentaenoic acid ("EPA") and 260 mg docosahexaenoic acid ("DHA"). Consumers can purchase a bottle of Hepaxa or Hepaxa PD for $48 by calling a 1-800 number, sending a fax, or by ordering online at www.Hepaxa-USA.com. Hepaxa and Hepaxa PD are "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

7. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

8. Respondents have disseminated or caused to be disseminated advertisements and promotional materials for Hepaxa and Hepaxa PD through the Hepaxa-USA.com website, Google AdWords that directed consumers to Hepaxa-USA.com, banner advertisements on Medscape and WebMD, press releases, and posts on Twitter and LinkedIn. These materials contain the following statements and depictions, among others:

a. Hepaxa-USA.com Landing Page (originally posted October 2018)

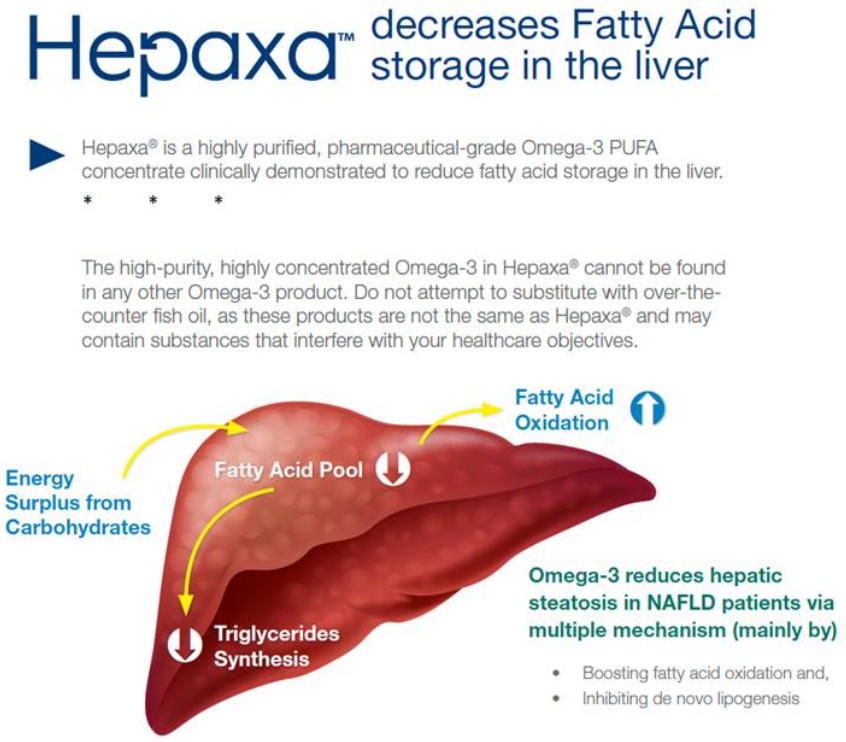
* * *

b. Hepaxa-USA.com Pages Specific to Hepaxa (posted Oct. 2018-Dec. 2019)

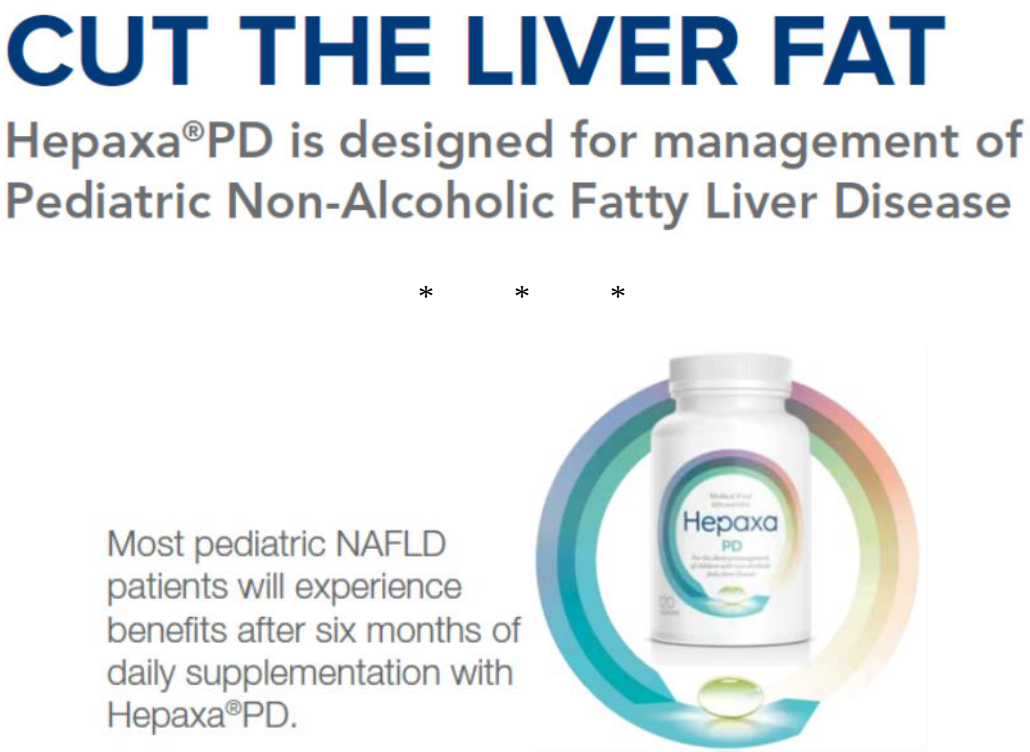
* * *

* * *

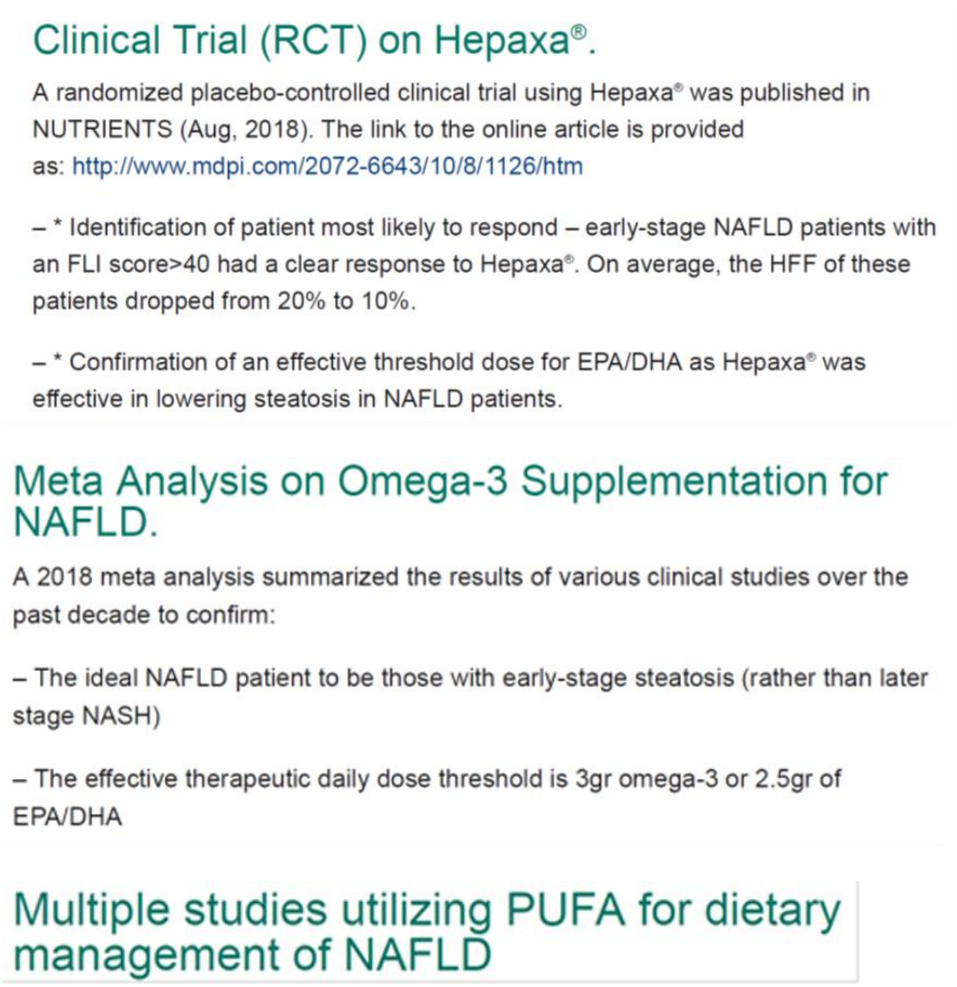
Complaint



c. Hepaxa-USA.com Pages Specific to Hepaxa PD (available online Oct. 2018-Dec. 2019)



d. Hepaxa-USA.com Pages Regarding Clinical Evidence (available online Oct. 2018-Dec. 2019)



Clinical Trial (RCT) on Hepaxa®.

A randomized placebo-controlled clinical trial using Hepaxa® was published in NUTRIENTS (Aug, 2018). The link to the online article is provided as: http://www.mdpi.com/2072-6643/10/8/1126/htm

– * Identification of patient most likely to respond – early-stage NAFLD patients with an FLI score>40 had a clear response to Hepaxa®. On average, the HFF of these patients dropped from 20% to 10%.

– * Confirmation of an effective threshold dose for EPA/DHA as Hepaxa® was effective in lowering steatosis in NAFLD patients.

Meta Analysis on Omega-3 Supplementation for NAFLD.

A 2018 meta analysis summarized the results of various clinical studies over the past decade to confirm:

– The ideal NAFLD patient to be those with early-stage steatosis (rather than later stage NASH)

– The effective therapeutic daily dose threshold is 3gr omega-3 or 2.5gr of EPA/DHA

Multiple studies utilizing PUFA for dietary management of NAFLD

Complaint

Hepaxa® | Clinical Evidence

STUDY	SIZE	DURATION	Liver Fat Reduction vs. Placebo	Liver Enzyme Reduction vs. Placebo	Lipid Levels Improvement vs. Placebo
Capanni et al., 2006	N=56	12 months	✓	✓	✓
Chen et al., 2008	N=46	6 months	✓	✓	✓
Cussons et al., 2009	N=25	2 months	✓	NS	✓
Li et al., 2015	N=78	6 months	✓	✓	✓
Sofi et al., 2010	N=11	12 months	✓	✓	✓
Spadaro et al., 2008	N=36	6 months	✓	✓	✓
Zhu et al., 2008	N=144	6 months	✓	✓	✓

Click for white paper on Adult NAFLD Management

In an RCT, DHA supplementation decreases liver fat and visceral fat, and ameliorates metabolic abnormalities in children with NAFLD. [A]

In an RCT, DHA supplementation improves liver steatosis in children with NAFLD. [B]

In an RCT, DHA supplementation in children decreased the rate of steatosis, elevated ALT and elevated AST in the 12-month treatement in the PUFA group. [C]

Multiple studies utilizing PUFA for dietary management of Pediatric NAFLD

STUDY	STUDY SIZE	STUDY DURATION	Improvement of Liver Fat	Reduction in Liver Enzymes	Change in Insulin/Insulin Resistance	Decrease in Triglycerides
Nobili V et al, 2011, 2013	N=60	24 months	✓	✓	✓	✓
Pacifico L et al, 2015	N=58	6 months	✓	✓	✓	✓
Boyraz M et al., 2015	N=108	12 months	✓	✓	✓	✓
Janczyk et al., 2015	N=64	6 months	NS	✓	NS	NS

Click for white paper on Pediatric NAFLD Management

* * *

Pediatric NAFLD can be reversed.

If NAFLD is addressed early, with adjustment to diet and exercise, many children can naturally reverse their liver fat composition to less than 5%. Doing so can restore their natural liver function and help to improve their overall and long-term health.

However, many children with NAFLD patients have been unsuccessful in making lifestyle changes to the extent needed for better health. In these cases, doctors want to provide extra help. Clinical studies have shown that daily use of poly unsaturated fatty acids (PUFA) like Hepaxa®PD can reduce liver fat and in time reverse steatosis in NAFLD. Hepaxa®PD is designed to help the dietary management of steatosis in children with early stage NAFLD.

* * *

Clinical Evidence for management of Pediatric NAFLD with (PUFA) Hepaxa®PD

Clinical Support (6-24 months)

In a double-blind, placebo controlled trial, DHA supplementation decreases liver and visceral fat, and ameliorates metabolic abnormalities in children with NAFLD.[3]

DHA SIGNIFICANTLY DECREASES the MRI-determined liver fat content independently of BMI-SDS changes in 6 months.
(Average age 10.8)

In a randomized controlled trial, DHA supplementation improves liver steatosis in children with NAFLD.[1]

Groups	Cleared of Fatty Liver	Reverting to Degree 1	Probability of Moderate Steatosis	Probabilty of Degree 3
DHA Groups	10-15%	40-50%	25-35%	Reduced from 60% to <10%
Placebo	0%	20%	45%	Reduced from 60% to 40%

e. BASF Press Release (posted February 22, 2018 at www.basf.com/global/en/media/news-releases/2018/02/p-18-130.html)

BASF launches Hepaxa as first dedicated product in the U.S. to help patients manage Non-Alcoholic Fatty Liver Disease

FLORHAM PARK, NJ, and ANN ARBOR, MI, February 22, 2018 – BASF Corporation is introducing Hepaxa™, a product that can help tens of millions of patients manage Non-Alcoholic Fatty Liver Disease (NAFLD), one of the most common forms of chronic liver disease. Providing highly concentrated and pure eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), Hepaxa is the first product in the U.S. specifically designed to address a buildup of fat in the liver, known as steatosis, in NAFLD patients. Hepaxa will be distributed nationally through DIEM Labs, LLC.

Tony Graetzer
+1-201-704-2670
Send email

Studies have shown that NAFLD patients are deficient in EPA and DHA. Hepaxa increases the levels of these important fatty acids in the blood, which improves the liver´s ability to process excessive fat stored there while inhibiting the conversion of dietary carbohydrates into fat.

A 2017 BASF study has shown that Hepaxa is effective and safe in the dietary management of NAFLD patients. BASF plans to publish the clinical results of this product-specific human intervention trial in the second half of 2018.

Hepaxa is manufactured using a patented purification technology removing persistent organic pollutants and other unwanted lipids such as cholesterol, which are naturally found in all fish oil-based products. Research has shown that one specific pollutant, PCB 153, is particularly harmful to NAFLD patients. The liver function of NAFLD patients is compromised and it is important to avoid additional exposure to unwanted components of traditional fish oil.

“BASF’s launch of Hepaxa is the result of our research and development efforts targeting liver health, where we are capitalizing on our unique scientific competencies,” says Christoph Garbotz, Head of Commercial Management Advanced Health Solutions, BASF. “With NAFLD rapidly becoming a major public health concern worldwide, we are proud to now offer this first-to-market, dedicated solution for NAFLD patients in the U.S.”

“Hepaxa is uniquely positioned to support the dietary management of steatosis in NAFLD patients,” says Tim Prince, Director of Sales at DIEM Labs. “Healthcare providers are continuously looking for an adjunctive treatment to exercise and weight loss therapy to recommend to their patients. Hepaxa can now be used to begin turning around NAFLD in as little as six months.”

Hepaxa is available as a medical food product in the U.S. to NAFLD patients 10 years and older for use under physician supervision. Physicians and healthcare professionals may request clinical support literature and product samples, and patients can gather information to share with their physicians, at www.Hepaxa-USA.com.

f. BASF Press Release (posted Oct. 29, 2018 at www.basf.com/global/en/media/news-releases/2018/10/p-18-356.html)

BASF
We create chemistry

News Release

29 October 2018

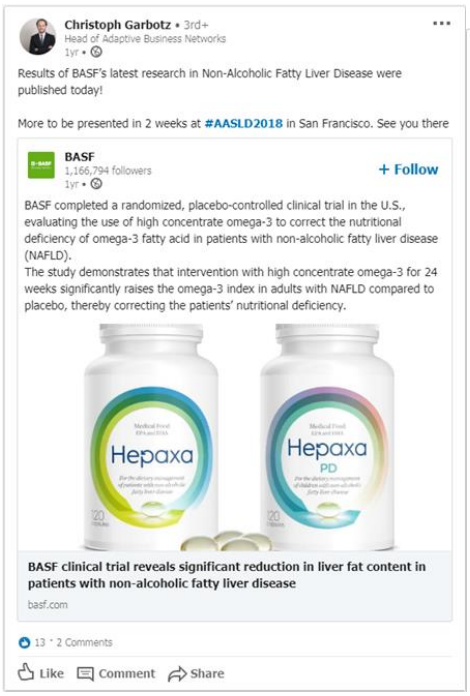
BASF clinical trial reveals significant reduction in liver fat content in patients with non-alcoholic fatty liver disease

Oslo, Norway – October 29, 2018 – BASF AS completed a randomized, placebo-controlled clinical trial in the U.S., newly published in Nutrients, evaluating the use of high concentrate omega-3 to correct the nutritional deficiency of omega-3 fatty acid in patients with non-alcoholic fatty liver disease (NAFLD). Several studies have shown that NAFLD patients have lower levels of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)[i].

The study, covering 176 patients, demonstrates that intervention with high concentrate omega-3 for 24 weeks significantly raises the omega-3 index in adults with NAFLD compared to placebo, thereby correcting the patients' nutritional deficiency. Patients showed reductions of up to 44% in liver fat after placebo correction, providing evidence that clinical management of NAFLD with high concentrate omega-3 has a beneficial outcome on liver fat. This intervention study supports a recently published meta-analysis that concluded that omega-3 fatty acids are associated with significant improvements in liver fat and liver function tests with approximately 3g of EPA and DHA daily.

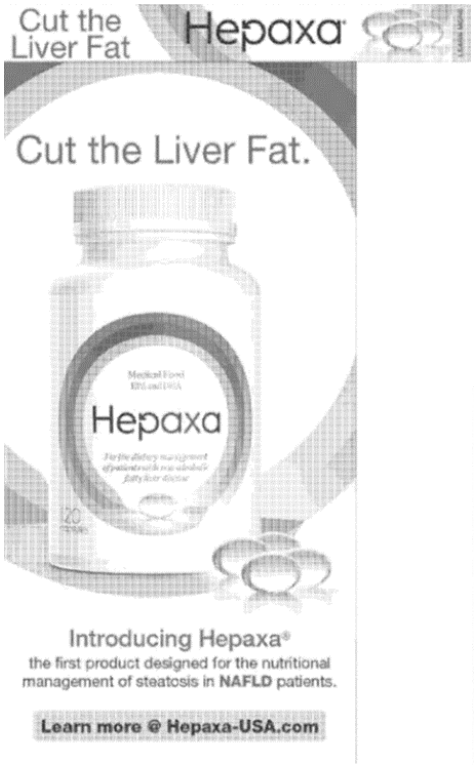
"Science has always been the backbone of all our development work and efforts in the area of liver health, and this study is further evidence that Hepaxa can significantly reduce liver fat content, which is crucial in managing NAFLD." says Derek Tobin, Team Leader for Innovation, Advanced Health Solutions, BASF.

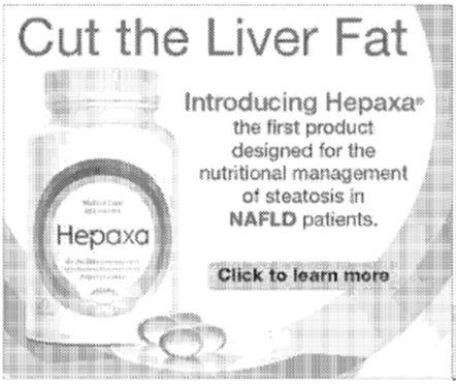
g. LinkedIn Posts



h. Twitter Post

i. Online Banner Ads





9. The clinical trial referred to in Paragraphs 10.E, 10.F, and 10.G. was published as Derek Tobin, et al., Evaluation of a High Concentrate Omega-3 for Correcting the Omega-3 Fatty Acid Nutritional Deficiency in Non-Alcoholic Fatty Liver Disease (CONDIN), 10 Nutrients 1126 (2018). The CONDIN study was a randomized, double-blind human clinical trial designed to evaluate whether Hepaxa raises levels of omega-3 PUFAs in red blood cells and reduces liver fat in adults with NAFLD. For six months, 81 subjects in the treatment arm received Hepaxa and 86 in the control arm took an olive oil placebo. All study participants were advised to reduce calorie intake and to maintain stable physical activity levels. Liver fat was measured using Magnetic Resonance Imaging in 120 subjects, 60 in each arm. At the end of the study, the MRI data showed no statistically significant reduction in liver fat in the Hepaxa patients, as compared to the placebo patients.

10. Due to the CONDIN study's failure to show an effect on liver fat, BASF, DIEM, and the researchers subjected the data to "post hoc" analyses of different subgroups of test subjects, in an attempt to find a positive selling message. A post hoc analysis is a statistical analysis conducted after the data have been collected in hopes of discovering statistical relationships that suggest cause and effect. Unplanned, post hoc subgroup analyses pose a high risk of generating spurious findings and need to be confirmed by further studies. Therefore, post hoc analyses yield results that are exploratory, at best.

11. BASF and DIEM settled on a post hoc analysis that stratified patients by their baseline Fatty Liver Index ("FLI") score. The FLI score derives from an algorithm combining

waist circumference and body mass index with blood serum levels of triglycerides and a specific liver enzyme. The post hoc analysis found that a small subgroup of patients with a baseline FLI over 40 experienced a statistically significant reduction in liver fat after using Hepaxa, as compared to placebo; however, this subgroup included only five Hepaxa patients and twelve placebo patients.

12. Other than the CONDIN study, Respondents have not conducted a human clinical trial on Hepaxa's effect on liver fat. Respondents have not tested Hepaxa PD on children at all. Moreover, there are no competent and reliable human clinical trials of products that are the same as Hepaxa. Other liver fat studies on which Respondents rely tested omega-3 PUFAs from a variety of sources, many of which contained significantly different amounts of DHA or EPA, and/or included omega-3 PUFAs not found in Hepaxa or Hepaxa PD.

Count I
False or Unsubstantiated Efficacy Claims

13. In connection with the advertising, promotion, offering for sale, or sale of Hepaxa and Hepaxa PD, Respondents have represented, directly or indirectly, expressly or by implication, that:

a. Hepaxa reduces liver fat in most adults with NAFLD within six months; and

b. Hepaxa PD reduces liver fat in most children with NAFLD within six months.

14. The representations set forth in Paragraph 13 are false or misleading or were not substantiated at the time the representations were made.

Count II
False Establishment Claim

15. In connection with the advertising, marketing, promotion, offering for sale, or sale of Hepaxa and Hepaxa PD, including through the means described in Paragraph 10, Respondents have represented, directly or indirectly, expressly or by implication, that:

a. Tests prove that Hepaxa reduces liver fat in adults with NAFLD; and

b. Tests prove that Hepaxa PD reduces liver fat in children with NAFLD.

16. In fact:

a. Tests do not prove that Hepaxa reduces liver fat in adults with NAFLD; and

b. Tests do not prove that Hepaxa PD reduces liver fat in children with NAFLD.

17. Therefore, the representations set forth in Paragraph 17 are false or misleading.

Violations of Sections 5 and 12

18. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by the Secretary and its official seal to be affixed hereto, at Washington, DC, this twenty-fourth day of May, 2021.

By the Commission.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Proposed Respondents are:

   a. DIEM Labs, LLC, ("DIEM") a Michigan limited liability company, with its principal office or place of business at 221 Dino Dr., Ann Arbor, MI 48103-9123.

   b. Cai Berg, an officer of DIEM. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of DIEM. His principal office or place of business is the same as that of DIEM.

   c. Tim Prince, an officer of DIEM Labs, LLC. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of DIEM Labs, LLC. His principal office or place of business is the same as that of DIEM.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For the purpose of this Order, the following definitions apply:

A. "**Covered Product**" means Hepaxa, Hepaxa PD, and any other Dietary Supplement, Food, or Drug that contains one or more Omega-3 fatty acids or is promoted by a Respondent or its subsidiary to benefit cardiac, metabolic, or hepatic health or functions, including the prevention, mitigation, treatment, or cure of any disease of such systems.

B. "**Dietary Supplement**" means: (1) any product labeled as a Dietary Supplement or otherwise represented as a Dietary Supplement; or (2) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

C. "**Drug**" means: (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of

disease in humans; (3) articles (other than Food) intended to affect the structure or any function of the body of humans; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include devices or their components, parts, or accessories.

D. "**Essentially Equivalent Product**" means a product that contains the identical ingredients, except for inactive ingredients (e.g., binders, colors, fillers, excipients) in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; *provided that* the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

E. "**Food**" means: (1) any article used for Food or drink for humans; (2) chewing gum; and (3) any article used for components of any such article.

F. "**Respondents**" means means all of the Individual Respondents and the Corporate Respondents, individually, collectively, or in any combination.

1. "**Corporate Respondents**" means DIEM Labs, LLC, and its successors and assigns, including DIEM Direct, LLC.

2. "**Individual Respondents**" means Cai Berg and Tim Prince.

Provisions

II. Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing for Substantiation

IT IS ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation that such product reduces liver fat in adults or children with Non-alcoholic Fatty Liver Disease (NAFLD), or cures, mitigates, or treats any disease, including but not limited to liver disease, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true. For purposes of this Provision, competent and reliable scientific evidence must consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted

by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. Prohibited Claims: Other Health-Related Claims

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, must not make, expressly or by implication, including through the use of a product or program name, endorsement, depiction, or illustration, any representation, other than representations covered under the Provision of this Order entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing for Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this Provision have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

IV. Prohibited Misrepresentations Regarding Tests, Studies, or Other Research

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered

Product, must not misrepresent, in any manner, expressly or by implication, including through the use of any product or program name, endorsement, depiction, or illustration:

A. that any Covered Product is clinically proven to reduce liver fat in adults or children with NAFLD;

B. that any Covered Product is clinically proven to cure, mitigate, or treat any disease;

C. that the health benefits, performance, or safety of any Covered Product is scientifically or clinically proven or otherwise established; or

D. the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research relating to the health benefits, performance, safety, or side effects of any Covered Product.

V. FDA-Approved Claims

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, Respondents' officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them from:

A. for any Drug, making a representation that is approved in labeling for such Drug under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new Drug application approved by the Food and Drug Administration; and

B. for any product, making a representation that is specifically authorized for use in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI. Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. all protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. all documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. all documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. all documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part, by: (1) the Respondent; (2) the Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with the Respondent; (4) any person or entity affiliated with or acting on behalf of the Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by the Respondent, the Respondent must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to the Respondent's size and complexity, the nature and scope of the Respondent's activities, and the sensitivity of the personal information collected from or about the participants.

VII. Monetary Relief

IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $157,318, which Respondents stipulate their counsel, Kane Kessler, P.C., holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

VIII. Additional Monetary Provisions

IT IS FURTHER ORDERED that:

A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondent's practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondent has no right to challenge any activities pursuant to this Provision.

E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that payment is due, the entire amount will immediately become due and payable.

F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.

G. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers), which Respondents have previously submitted to the Commission, may be used for collecting and reporting

on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

IX. Customer Information

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them, must directly or indirectly provide sufficient customer information, including sufficient identification of all resellers, to enable the Commission to efficiently administer consumer redress to purchasers of Hepaxa and Hepaxa PD. If a representative of the Commission requests in writing any information related to redress, Respondents must provide it, in the form prescribed by the Commission, within 14 days.

X. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order.

B. Each Individual Respondent for any business that such Respondent, individually or collectively with any other Respondents, is the majority owner or controls directly or indirectly, and each Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives with managerial responsibilities for conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

XI. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact,

which representatives of the Commission, may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Respondent (which Individual Respondents must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, each Individual Respondent must: (a) identify all his or her telephone numbers and all his or her physical, postal, email and Internet addresses, including all residences; (b) identify all his or her business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For a period of 10 years after the issuance date of the Order, each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of any Corporate Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, each Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity that may affect compliance obligations under the order, including (i) any business for which such Respondent performs services whether as an employee or otherwise, and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re DIEM Labs, LLC.

XII. Recordkeeping

IT IS FURTHER ORDERED that Respondents must create certain records for 10 years after the issuance date of the Order, and retain each such record for 5 years. Specifically, Corporate Respondent and each Individual Respondent for any business relating to a Covered Product that such Respondent, individually or collectively with any other Respondents, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. accounting records showing the revenues from such products;

B. personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. records of all consumer complaints concerning the subject matter of the order and all refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. a copy of each unique advertisement or other marketing material making a representation subject to this Order;

F. for 5 years from the date of the last dissemination of any representation covered by this Order:

1. all materials that were relied upon in making the representation; and

2. all tests, studies, analysis, demonstrations, other research or other such evidence in Respondent's possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

G. for 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communication relate to Respondents' compliance with this Order.

H. for 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents, that demonstrate non-compliance or tend to show any lack of compliance by Respondents with this Order.

XIII. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, the Commission is authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview any employee or other person affiliated with Respondent who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission may use all other lawful means, including posing, through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual

Respondents, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XIV. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order with BASF SE and BASF Corporation ("BASF Respondents"). It also has accepted, subject to final approval, an agreement containing a consent order with DIEM Labs, LLC, and others ("DIEM Respondents"). The proposed consent orders have been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comment received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreements and the comments received,

and will decide whether it should withdraw from one or both of the agreements and take appropriate actions or make final the agreements' proposed orders.

This matter involves Respondents' advertising for Hepaxa and Hepaxa PD capsules containing omega-3 fatty acids. The Commission's proposed complaint alleges that advertising for the Hepaxa products represented that Hepaxa reduces liver fat in most adults with Non-alcoholic Fatty Liver Disease ("NAFLD") within six months, and that Hepaxa PD reduces liver fat in most children with NAFLD within six months. The complaint further alleges that Respondents' advertising represented that tests prove that Hepaxa reduces liver fat in adults with NAFLD and that tests prove that Hepaxa PD reduces liver fat in children with NAFLD. According to the proposed complaint, these claims are false or misleading or were not substantiated at the time the representations were made, in violation of Sections 5 and 12 of the FTC Act.

The proposed orders include injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The proposed orders against the BASF Respondents and DIEM Respondents are substantially similar. In both orders, "Covered Products" is defined as Hepaxa, Hepaxa PD, and any other Dietary Supplement, Food, or Drug that contains one or more omega-3 fatty acids or is promoted by a Respondent or its subsidiary to benefit cardiac, metabolic, or hepatic health or functions, including the prevention, mitigation, treatment, or cure of any disease of such systems.

Part I of the orders prohibits any representation that a Covered Product reduces liver fat in adults or children with Non-alcoholic Fatty Liver Disease (NAFLD), or cures, mitigates, or treats any disease, including but not limited to liver disease, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety, or side effects of any covered product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

Analysis to Aid Public Comment

For purposes of Part II, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III prohibits misrepresentations about tests and studies. Part IV provides Respondents a safe harbor for making claims approved by the Food and Drug Administration ("FDA"). Part V requires that, with regard to any human clinical test or study upon which Respondents rely to substantiate any claim covered by the order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part VI provides for monetary relief, and Part VII describes the procedures and legal rights related those payments. Together, Respondents are paying the full amount of consumer injury, $416,914.00. DIEM Order Part VIII requires the company to provide sufficient customer information to enable the Commission to efficiently administer consumer redress to purchasers of Hepaxa and Hepaxa PD.

DIEM Order Part IX and BASF Order Part VIII require Respondents to submit acknowledgments of receipts of the order. DIEM Order Part X and BASF Order Part IX require the filing of compliance reports with the Commission, including notification to the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. DIEM Order Part XI and BASF Order Part X contain recordkeeping requirements. DIEM Order Part XII and BASF Order XI contain other requirements related to the Commission's monitoring of Respondents' order compliance. Finally, DIEM Order Part XIII and BASF Order Part XII state that the orders will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the orders, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

Complaint

IN THE MATTER OF

HEIDELBERGCEMENT AG, LEHIGH HANSON, INC., LEHIGH CEMENT COMPANY LLC, ELEMENTIA S.A.B. DE C.V., GIANT CEMENT HOLDING, INC., AND KEYSTONE CEMENT COMPANY

FINAL ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

Docket No. 9402; File No. 201 0006
Complaint, May 20, 2021 – Decision, June 4, 2021

This Order addresses the $151 million acquisition by Lehigh Cement Company LLC, a wholly-owned subsidiary of HeidelbergCement AG, of certain assets of Keystone Cement Company, an indirectly wholly-owned subsidiary of Heidelberg. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by significantly reducing competition in the market for cement, the key input in concrete, to customers in eastern Pennsylvania and western New Jersey. On June 3, 2021, Respondents terminated their Asset Purchase Agreement and withdrew the Hart-Scott-Rodino Notification and Report Forms filed for the proposed acquisition. Complaint Counsel and Respondents jointly move to dismiss the complaint as moot. The Order dismisses the complaint without prejudice.

Participants

For the *Commission*: *Michael Barnett, Stephanie C. Bovee, Peter Colwell, Brian A. O'Dea, Christina Perez, James E. Southworth,* and *Ricardo A. Woolery.*

For the *Respondents*: *Lin Kahn, Bruce McDonald,* and *Thomas York, Jones Day; Stephen Pepper, Greenberg Traurig LLP; Andrew Forman, Paul, Weiss, Rifkind, Wharton & Garrison LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act ("FTC Act"), and by virtue of the authority vested in it by the FTC Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents HeidelbergCement AG, Lehigh Hanson, Inc., Lehigh Cement Company LLC (collectively, "Lehigh"), Elementia S.A.B. de C.V. ("Elementia"), Giant Cement Holding, Inc. ("Giant"), and Keystone Cement Company ("Keystone") have executed an acquisition agreement ("Acquisition Agreement") pursuant to which Lehigh will acquire substantially all the assets of Keystone (the "Acquisition") in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, and which if consummated would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby

issues its complaint pursuant to Section 5(b) of the FTC Act, 15 U.S.C. § 45(b), and Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

I.

NATURE OF THE CASE

1. Lehigh proposes to acquire all the assets of Keystone. Today Lehigh and Keystone compete head-to-head to supply cement, the key input in concrete, to customers in eastern Pennsylvania and western New Jersey. For a significant number of customers in this area, Lehigh and Keystone are two of only four competitive sources of cement.

2. Lehigh is by far the largest cement producer in the relevant market today and is one of the largest cement producers in North America. Lehigh owns and operates two cement plants serving customers located in eastern Pennsylvania and western New Jersey. Keystone is one of Lehigh's fiercest competitors for customers in this area, operating a nearby cement plant in Pennsylvania. Intense competition from Keystone has kept market prices down, causing Lehigh to complain that Keystone's [redacted] was negatively impacting Lehigh's sales. In ordinary course documents, Lehigh executives explain that [redacted] in creating [redacted] in the relevant market. Against this backdrop, Lehigh proposes to acquire Keystone in a transaction that Heidelberg executives conclude [redacted] By acquiring Keystone's plant, Lehigh would eliminate competition from Keystone, leading to higher prices for customers.

3. Cement is an essential ingredient of concrete, one of the most important and widely-used building materials in the United States and worldwide across a range of construction applications. Concrete is a fundamental building material used in the construction of homes, schools, hospitals, houses of worship, residential and commercial buildings, as well as highways, bridges, tunnels, mass transit systems, airports, sidewalks, dams, reservoirs, drinking and wastewater pipes, and many other pieces of critical public infrastructure. Due to cement's widespread use in residential, commercial, agricultural, and governmental construction projects, increased cement prices would directly and indirectly impact the pocketbook of many consumers and taxpayers in the relevant market.

4. There is no reasonable substitute for cement. Customer substitution to alternative products would not prevent the post-merger exercise of market power by the combined firm. Nor would more distant suppliers prevent the post-merger exercise of market power by the combined firm. In the cement industry, shipping patterns are regional in nature, as the cost of shipping, as well as customers' requirements for frequent deliveries, make distribution over longer distances impractical and cost-prohibitive. Customers overwhelmingly purchase cement from local sources.

5. Most customers in the relevant market consider only four firms, each of which operate plant(s) in and around the Lehigh Valley in Pennsylvania, to be viable suppliers of cement. These four firms include Lehigh and Keystone, as well as Buzzi Unicem USA Inc.

("Buzzi"), that operates a plant in Stockertown, Pennsylvania, and Lafarge North America, Inc., a subsidiary of LafargeHolcim Ltd ("Lafarge"), that operates a plant in Whitehall, Pennsylvania. Today, these firms account for over [redacted] percent of the cement sold in the relevant market

6. Cement customers in the relevant market have benefited from substantial head-to-head competition between Lehigh and Keystone. Keystone has aggressively used low prices to compete for business, often undercutting prices of Lehigh to win new customers or gain additional business. In many instances, Lehigh responded by [redacted]. Keystone's low prices have also affected market prices for cement in the relevant market, as Keystone's offers of cement at lower prices have defeated attempts by Lehigh and other suppliers to charge higher cement prices. In response to Keystone's aggressive pricing moves, Lehigh and other cement suppliers have also reduced their cement prices for customers.

7. Lehigh recognizes Keystone's disruptive role in the relevant market, identifying Keystone as the [redacted] in the relevant market. Lehigh has monitored Keystone's aggressive sales activity, identifying [redacted] According to Lehigh, competition from Keystone has required it to [redacted]

8. The Acquisition would cement Lehigh's dominant position. Post-Acquisition, Lehigh would control over [redacted] percent of sales in the relevant market. The Acquisition would significantly increase concentration in an already highly concentrated market, making the Acquisition presumptively unlawful under the 2010 U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (the "Merger Guidelines").

9. The Acquisition would eliminate competition between Lehigh and Keystone that has led to lower prices and better terms for customers, bolster Lehigh's position as market leader, and substantially increase market concentration. As a result, it would allow Lehigh unilaterally to raise cement prices or decrease the quality of service provided to customers in these areas.

10. Keystone is a particularly aggressive, low price, and disruptive competitor. By removing Keystone from the market, the Acquisition would also make the relevant market more susceptible to anticompetitive coordination among the remaining cement suppliers.

11. Neither new entry nor expansion by other market participants is likely to be timely or sufficient to prevent the Acquisition's anticompetitive effects. No new plants or terminals have been constructed in the relevant market in over 30 years. There are significant barriers to entry in the market for the production and sale of cement, including substantial sunk costs, environmental and regulatory requirements, economies of scale, and industry expertise.

12. Respondents will not be able to prove verifiable, cognizable efficiencies would result from the Acquisition that would be sufficient to rebut the strong presumption of harm and other evidence of the Acquisition's likely significant anticompetitive effects.

13. As a result, Lehigh's proposed acquisition of Keystone likely would substantially lessen competition for cement in eastern Pennsylvania and western New Jersey in violation of Section 5 of the FTC Act, 15 U.S.C. § 45 and Section 7 of the Clayton Act, 15 U.S.C. § 18.

II.

JURISDICTION

14. Respondents, and each of their relevant operating entities and subsidiaries are, and at all relevant times have been, engaged in commerce or in activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

15. The Acquisition is subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

III.

RESPONDENTS

16. Respondent HeidelbergCement AG ("Heidelberg") is a German corporation headquartered in Heidelberg, Germany. Operating in more than 50 countries, Heidelberg is one of the largest building materials companies in the world. Its core business is the production and distribution of cement and aggregates. In 2020, Heidelberg sold over 122 million metric tons of cement worldwide and generated total revenues of over $20 billion.

17. Respondent Lehigh Hanson, Inc. ("Lehigh Hanson") is a Delaware corporation headquartered in Irving, Texas. Lehigh Hanson is a wholly-owned subsidiary of Heidelberg and is a leading supplier of construction materials in North America. It operates 19 cement plants in North America (including jointly-owned facilities) and sold over 15.5 million metric tons of cement in 2020.

18. Respondent Lehigh Cement Company LLC ("Lehigh Cement") is a Delaware limited liability company headquartered in Irving, Texas. Lehigh Cement is an indirectly wholly-owned subsidiary of Heidelberg. Lehigh Cement is identified as the "Buyer" in the Acquisition Agreement. Lehigh Cement is a leading cement supplier in the United States, serving customers through 13 wholly- and jointly-owned cement plants and a large network of distribution terminals. Lehigh Cement supplies cement to customers located in eastern Pennsylvania and western New Jersey principally from its plants located in or near Nazareth and Evansville, Pennsylvania.

19. Respondent Elementia is a Mexican corporation headquartered in Mexico City, Mexico. Elementia is a leading international building materials company with over 6,000

employees, operations in nine countries, and three business divisions: cement, metal products, and building systems. Elementia indirectly holds a 55 percent ownership interest in Giant, which is the parent of Keystone. Elementia is the ultimate parent entity of Giant and Keystone and, as such, is the legal entity that filed a Premerger Notification and Report Form with the FTC and the Department of Justice for the Acquisition—pursuant to the Hart-Scott-Rodino Antitrust Improvement Act of 1976, 15 U.S.C. § 18a—and responded to the Request for Additional Information and Documentary Material from the Commission.

20. Respondent Giant is a Delaware corporation. It is a holding company that owns Keystone, as well as two other companies that operate cement plants in the United States outside of the relevant geographic market. Giant is a party to the Acquisition Agreement.

21. Respondent Keystone is a Pennsylvania limited liability company headquartered in Bath, Pennsylvania. A wholly-owned subsidiary of Giant, Keystone owns and operates a cement plant and related assets located in East Allen Township (just south of Bath) in Northampton County, Pennsylvania. Keystone has produced cement at this location since 1928. In 2009, Keystone completed a three-year, $230 million modernization and expansion project, making the plant the most modern cement manufacturing facility in the region.

IV.

THE ACQUISITION

22. On September 26, 2019, Heidelberg's indirectly wholly-owned subsidiary Lehigh Cement entered into an Asset Purchase Agreement with Elementia's subsidiaries Giant and Keystone, pursuant to which Lehigh Cement proposes to acquire the assets comprising Keystone's cement manufacturing and distribution business for $151 million, subject to adjustment.

V.

THE RELEVANT PRODUCT MARKET

23. The relevant product market in which to assess the effects of the Acquisition is the production and sale of gray portland cement ("cement"). Cement is an essential ingredient for making concrete, one of the most important building materials in the United States across a range of construction applications. Most cement is purchased to make ready-mix concrete. Delivered to the jobsite in concrete mixer trucks with the familiar revolving drums, ready-mix concrete is used in most residential, commercial, and public construction projects, including buildings, bridges, and highways. Other uses for cement include manufacturing pre-cast concrete products, making mortar for masonry applications, and soil stabilization.

24. The cement manufacturing process is capital-intensive. The elements necessary for making cement include calcium and silica, as well as small amounts of alumina and iron. The main raw material, limestone, is usually extracted from a quarry located near the cement manufacturing plant. The limestone is transported to the cement plant where it is crushed,

combined with other raw materials, and then ground together. The ground material is then introduced into huge rotary furnaces called "kilns" where it is processed at extremely high temperatures to create a lava-like substance called clinker. The red-hot clinker nodules are then cooled and ground with a small amount of gypsum (calcium sulphate) into a fine powder to create cement.

25. Cement customers often specify a certain type of cement based on construction requirements or conditions. Cement manufacturers make different types of cement with slightly different properties formulated to meet defined standards. These cements are classified as Types I through V, according to standards prescribed by the American Society for Testing and Materials. Some cements meet multiple standards. Types I, II (moderate sulfate-resistant), and I/II are general-purpose cements suitable for making concrete for most buildings, pavements, bridges, and other structures, and are the most widely consumed types of cement in the relevant market. Type III cement is used where high early strength is desired. Type III cement is identical in chemical composition to the former types but is ground to a finer consistency, with the result that it achieves full compressive strength at a faster pace when mixed with water. There is little to no demand for Type IV (low heat of hydration) cement or Type V (high sulfate resistance) cement in the relevant market. Another common type of cement is masonry cement, which is a mixture of portland cement, a plasticizer (which makes the mortar more fluid and hence more workable), and other ingredients. Masonry cement is used to make mortar and masonry block.

26. Most cement customers purchase cement in bulk form, usually in trailer loads of about 25 tons. Producers also distribute small amounts of cement in bags containing about 70-94 pounds of cement for resale to building trades professionals and consumers.

27. There is no cost-effective substitute for cement. Other cementitious materials, such as fly ash or ground, granulated blast furnace slag, are not close substitutes for cement and have a negligible impact on the price of cement. Customer substitution to other products would be insufficient to defeat to a small but significant, non-transitory price increase ("SSNIP") imposed by a hypothetical monopolist supplier of cement in the region.

28. Industry participants recognize that cement is a distinct product from other building materials. Cement suppliers do not consider the threat of substitution to any other product when pursuing price increases and consistently calculate market shares only in relation to sales of cement.

VI.

THE RELEVANT GEOGRAPHIC MARKET

29. The relevant geographic market in which to analyze the competitive effects of the Acquisition is no broader than the eastern Pennsylvania and western New Jersey area. A list of the counties that compose the relevant geographic market is included in Appendix A.

30. A hypothetical monopolist that was the only present and future seller of cement in the relevant market could profitably impose a SSNIP on customers located in eastern Pennsylvania and western New Jersey. Competition from more distant suppliers located outside the relevant market would not defeat the price increase because acquiring cement from those more distant plants requires more expensive and less reliable transportation.

31. Several factors serve to limit the distance over which cement can be economically shipped. Cement is a heavy and bulky but relatively low-cost product. As a result, the cost of transporting cement is large in proportion to the cost of cement itself. Transport costs increase proportionally as the distance from the customer to the supplier increases, leading customers to prefer local sources. Other factors that lead customers to purchase cement from local sources are convenience and security of supply. Many customers require frequent shipments of cement (even multiple daily shipments) to maintain their production levels of concrete. Traveling farther to obtain cement could reduce the number of daily trips a customer could make using their own semi-trucks and pneumatic bulk trailers (or force the customer to obtain additional tractor trailers in order to haul a similar volume of cement). Traveling greater distances could also expose a customer to a greater possibility of supply disruptions due to weather or traffic congestion.

32. Cement prices are not posted, but instead are determined through bilateral negotiation between suppliers and customers. As a result, actual transaction prices often vary significantly from customer to customer. In most cases, suppliers and customers negotiate annually to determine the price and terms by which each particular customer will purchase cement for the upcoming year. Usually the quoted cement price is subject to change at any time and is not guaranteed by written contract. When negotiating the price of cement, suppliers are aware of the logistical cost advantage or disadvantage they hold relative to other cement suppliers for sale to a specific customer's location(s). Cement suppliers consider their relative transportation cost advantage or disadvantage when quoting prices to individual customers. In addition, cement suppliers often monitor information regarding their competitor's costs, sales volumes, and capacity utilization. Using all of this information, cement suppliers are able to identify customers that face limited competitive options and are able to target those customers with higher prices.

33. Because cement suppliers can price discriminate based on a customer's location and competitive alternatives, it is analytically appropriate to define relevant geographic markets based on the locations of targeted customers. Although relevant geographic markets could be defined as narrowly as individual customers, it is appropriate and accurate to define a relevant market consisting of customers located in eastern Pennsylvania and western New Jersey because customers in this region of the country face similar competitive conditions.

34. This relevant geographic market conforms to the commercial realities of the cement industry and is consistent with how Lehigh, Keystone, and other cement suppliers conduct their business and assess the markets in which they compete in the ordinary course of business. Industry participants analyze competition in regional markets and view competition in the relevant market as distinct from other markets in which they operate, including, for example, markets in western Pennsylvania, Maryland, and the New York City metropolitan region.

35. The four firms that operate cement plants located in or near Pennsylvania's Lehigh Valley are the only economically feasible options for many customers in the relevant geographic market. Due to the additional cost, time, and inconvenience required to transport cement from more distant suppliers, customer substitution to suppliers located outside of the market would be insufficient to defeat a small but significant non-transitory price increase imposed by a hypothetical monopolist supplier of cement in the region.

VII.

MARKET STRUCTURE AND THE ACQUISITION'S PRESUMPTIVE ILLEGALITY

36. The relevant market is already highly concentrated. In recent years, the relevant market has experienced significant consolidation, including Heidelberg's 2016 acquisition of Italcementi S.p.A., through which Lehigh acquired its cement plant in Nazareth, Pennsylvania.

37. Lehigh and Keystone are now two of only four suppliers that have significant sales in the relevant market. In addition to Lehigh and Keystone, Lafarge and Buzzi produce and distribute cement at plants located in Pennsylvania's Lehigh Valley. These four suppliers account for over [redacted] percent of cement sales in the relevant market. In addition to these four firms, Riverside Construction Materials, a subsidiary of the Silvi Group, imports cement at its terminal in Bristol, Pennsylvania, which it distributes [redacted].

38. The Acquisition would substantially increase concentration levels in this already highly concentrated market. Lehigh is by far the leading cement supplier in the relevant market. If the Acquisition closes, Lehigh will control more than [redacted] percent of cement sales in eastern Pennsylvania and western New Jersey.

39. The Merger Guidelines and courts use the Herfindahl-Hirschman Index ("HHI") to measure market concentration. HHIs are calculated by totaling the squares of the market shares of each firm in the relevant market, both before and after the transaction. A relevant market is "highly concentrated" under the Merger Guidelines if it has an HHI level of 2,500 or more. Under the Merger Guidelines, transactions likely to create or enhance market power are presumptively unlawful. A transaction is presumed likely to create or enhance market power, and is presumptively illegal, if the post-transaction HHI exceeds 2,500 and the transaction increases the HHI by more than 200 points.

40. If consummated, the Acquisition would result in a post-Acquisition HHI of over 3,500 and would increase the HHI by more than 1,000—levels that far exceed the necessary thresholds for presumptive illegality. Accordingly, the Acquisition is presumptively unlawful under the Merger Guidelines and relevant case law.

VIII.

ANTICOMPETITIVE EFFECTS

A.

The Acquisition Would Eliminate Head to Head Competition between Lehigh and Keystone

41. Lehigh and Keystone are close competitors for many cement customers in eastern Pennsylvania and western New Jersey and are two of just four significant suppliers in the relevant market. The Acquisition would significantly reduce competition for cement customers and allow the combined firm to raise prices or reduce output in the relevant market.

42. The significant direct competition between Lehigh and Keystone has benefited cement customers in the relevant market. Many customers in the market request price quotes from both Lehigh and Keystone when negotiating terms for purchasing cement. Keystone has often demonstrated a willingness to offer low prices to win or attempt to win business from Lehigh. Keystone's aggressive pricing has caused Lehigh to lower its cement prices in the relevant market and compete on price more vigorously.

43. Keystone has regularly undercut Lehigh's cement prices in the relevant market. For example, in 2019, Lehigh's sales officials conducted an analysis of [redacted] identifying over [redacted] in which Keystone undercut Lehigh's cement prices for customers, often causing Lehigh [redacted]. Other ordinary course business documents show how Lehigh has responded to direct competition from Keystone by [redacted]. Absent competition from Keystone, Lehigh likely would not need to [redacted].

44. Lehigh recognizes that the completion of the Acquisition will eliminate the opportunity for customers to take advantage of Keystone's lower prices. As [redacted] wrote during the pendency of the Acquisition: [redacted]

45. One of the motivations driving the Acquisition is the perceived defensive value to be attained by removing the competitive threat posed by Keystone. Lehigh executives concluded that, absent the Acquisition, Keystone would [redacted] at Lehigh's expense, and that the Acquisition would prevent Lehigh [redacted].

B.

[redacted] to Curtail [redacted] Output Following the Acquisition

46. If allowed to acquire Keystone, [redacted] would lead to a reduction in output [redacted] and would harm consumers in the relevant market.

C.

The Acquisition Would Increase the Likelihood of Anticompetitive Coordination

47. The Acquisition would increase the likelihood and efficacy of anticompetitive coordination among cement suppliers in the relevant market. Cement suppliers, including the same companies that own facilities in the relevant market, have previously expressly colluded in other geographic markets with similar characteristics. For example, Heidelberg was among six firms fined by the Bundeskartellamt in 2003 for engaging in illegal cartel activity in German cement markets. Following the Acquisition, all of the three remaining significant participants (or their parent companies) in the relevant market—Lehigh, Lafarge, and Buzzi—have been found guilty of illegally coordinating to increase the price of cement in other geographic markets within the last two decades.

48. The relevant market has characteristics that make it vulnerable to coordination. Those characteristics include a highly-concentrated market with limited competitors; a homogeneous product; significant transparency as to the prices, costs, capacities, and strategic initiatives of rival firms; sales that are small, frequent, and usually not made pursuant to long-term contracts; low price elasticity of demand; and evidence of past interdependent behavior by market participants.

49. Competitors commonly track each other's customers, production capacities, costs, sales volumes, and prices. Cement suppliers are often able to obtain information relating to their rivals' prices to individual customers and general price increase announcements that are typically made by each supplier on an annual basis. Post-Acquisition, access to such information will enable Lehigh and the remaining cement suppliers in the relevant market to detect and effectively punish deviations from coordinated schemes or tacit agreements to increase prices, reduce output, or allocate customers.

50. Because cement has no close substitutes Lehigh and the remaining significant suppliers of cement in the relevant market would likely be able to raise cement prices without fear of losing sales to suppliers of other products.

51. In recent years, Keystone has emerged as a particularly aggressive competitor in the relevant market. Keystone, [redacted],

has sought to grow its sales and [redacted] by winning business from other suppliers' customers by offering lower prices.

52. Keystone's aggressive pricing has prevented Lehigh and other suppliers from increasing the price of cement in the relevant market. For example, a Lehigh sales presentation from 2017 described how [redacted] Similarly, in 2018, [redacted] In another example, in April 2019, a Lehigh sales presentation reported, [redacted] Shortly thereafter, Lehigh's management requested that Heidelberg's Managing Board approve its plan to acquire Keystone.

53. The Acquisition would significantly increase concentration in this already highly-concentrated market and would reduce the number of significant competitors from four to three. By reducing the number of competitors, the Acquisition would reduce obstacles to coordination and make it easier for Lehigh and the other two remaining significant cement suppliers to monitor and retaliate against deviations from coordinated schemes or tacit agreements to increase cement prices, reduce output, or allocate customers.

54. Heidelberg's own internal analysis presented to its Managing Board in advance of the Acquisition concluded that the [redacted] and [redacted]

55. By reducing the number of competitors and eliminating Keystone, a firm that plays a disruptive role in the market to the benefit of customers, the Acquisition would likely strengthen existing tendencies among remaining firms to coordinate and enhance the prospects for successful coordination in the future.

IX.

LACK OF COUNTERVAILING FACTORS

A.

Entry Barriers

56. Respondents cannot demonstrate that new entry or expansion by existing firms would be timely, likely, or sufficient to offset the anticompetitive effects of the Acquisition and rebut the presumption that the Acquisition is illegal. To the contrary, the cement industry is characterized by substantial barriers to entry.

57. Construction of a new cement facility would require significant upfront sunk-cost investments and take several years to accomplish. Finding a suitable location, if one is available, and obtaining necessary governmental permits and approvals is difficult and time-consuming and this process alone can take numerous years. Even if a firm could find a suitable location and obtain all necessary governmental approvals, the construction of a cement production facility would take considerable resources and time. For example, Elementia estimated that it would cost approximately [redacted] and require a minimum of [redacted] to construct a new cement plant in eastern Pennsylvania with a capacity similar to Keystone's Bath plant.

58. Entry by constructing a marine terminal is also costly and time-consuming. Securing a suitable site to accommodate ships of sufficient size is difficult. Finding an available location to construct a cement import terminal, obtaining all requisite regulatory approvals and permits, and constructing the facility would likely take more than two years. For example, when [redacted].

59. New entry by means of a truck or rail terminal is unlikely and would be insufficient to prevent the likely anticompetitive effects of the Acquisition. Due to the additional costs of transporting cement to the terminal (as well as terminal operating costs), a new entrant seeking to compete in the relevant market using a truck or rail terminal would be unlikely to be cost competitive, because it would be competing directly against market participants that locally operate lower cost cement plants.

60. Expansion by existing cement suppliers would not be timely, likely, or sufficient to prevent the competitive harm from the Acquisition.

B.

Efficiencies

61. Respondents cannot demonstrate merger-specific cognizable efficiencies sufficient to rebut the strong presumption and evidence of the Acquisition's likely significant anticompetitive effects.

X.

VIOLATION

COUNT I – ILLEGAL AGREEMENT

62. The allegations of Paragraphs 1 through 61 above are incorporated by reference as though fully set forth.

63. The Acquisition Agreement constitutes an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

COUNT II – ILLEGAL ACQUISITION

64. The allegations of Paragraphs 1 through 61 above are incorporated by reference as though fully set forth.

65. The Acquisition, if consummated, may substantially lessen competition in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and is an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the Respondents that the second day of November 2021, at 10 a.m. EST, is hereby fixed as the time, and the Federal Trade Commission offices at 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that this administrative proceeding shall be conducted as though the Commission, in an ancillary proceeding, has also filed a complaint in a United States District Court, seeking relief pursuant to Section 13(b) of the Federal Trade Commission Act, 15 U.S.C. 53(b), as provided by Commission Rule 3.11(b)(4), 16 CFR 3.11(b)(4). You are also notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted. If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the Respondents file their answers. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the Respondents file their answers). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answers, to make certain initial disclosures without awaiting a discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Acquisition challenged in this proceeding violates Section 5 of the Federal Trade Commission Act, as amended, and/or Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Acquisition is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant market, with the ability to offer such products and services as Lehigh and Keystone were offering and planning to offer prior to the Acquisition.

2. A prohibition against any transaction between Respondents that combines their businesses in the relevant market, except as may be approved by the Commission.

3. A requirement that, for a period of time, Respondents provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant market with any other company operating in the relevant markets

4. A requirement to file periodic compliance reports with the Commission.

5. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to restore Keystone as a viable, independent competitor in the relevant markets.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this twentieth day of May 2021.

By the Commission.

Appendix A:

List of Counties in Relevant Geographic Market eastern Pennsylvania and western New Jersey:

Eastern Pennsylvania	Western New Jersey
Berks	Atlantic
Bradford	Burlington
Bucks	Camden
Carbon	Cape May
Centre	Cumberland
Chester	Gloucester
Clinton	Hunterdon
Columbia	Morris
Cumberland	Salem
Dauphin	Somerset
Delaware	Sussex
Juniata	Warren
Lackawanna	
Lancaster	
Lebanon	
Lehigh	
Luzerne	
Lycoming	
Monroe	
Montgomery	
Montour	
Northampton	
Northumberland	
Perry	
Philadelphia	
Pike	
Schuylkill	
Snyder	
Sullivan	
Susquehanna	
Tioga	
Union	
Wayne	
Wyoming	
York	

Final Order

ORDER DISMISSING COMPLAINT

This matter comes before the Commission on Complaint Counsel and Respondents' Joint Motion to Dismiss the Complaint. Having considered the motion,

IT IS HEREBY ORDERED that the Joint Motion to Dismiss the Complaint, dated June 4, 2021, is GRANTED, and the complaint is dismissed without prejudice.

By the Commission.

Complaint

IN THE MATTER OF

CASEY'S GENERAL STORES, INC., STEVEN BUCHANAN, AND BUCK'S INTERMEDIATE HOLDINGS, LLC

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

Docket No. C-4742; File No. 211 0028
Complaint, April 28, 2021 – Decision, June 8, 2021

This consent order addresses the acquisition by Casey's General Stores. Inc. of certain assets of Bucky's Intermediate Holdings, LLC. The complaint alleges that that the Acquisition, if consummated, would violate Section 7 of the Clayton Act and that the Acquisition agreement constitutes a violation of Section 5 of the Federal Trade Commission Act by substantially lessening competition for the retail sale of gasoline in seven local markets in Nebraska and Iowa, and by substantially lessening competition for the retail sale of diesel fuel in four local markets in Nebraska. The consent order requires Respondents to divest certain retail fuel assets in seven local markets in Nebraska and Iowa to Western Oil II, LLC and Danco II, LLC.

Participants

For the *Commission*: *Ashley Masters* and *Nina Thanawala.*

For the *Respondents*: *Wendy K. Arends* and *Mark Tobey, Husch Blackwell LLP; David H. Roe* and *Thomas M. Worthington, McGrath North Mullin & Kratz, PC LLO.*

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Casey's General Stores, Inc. ("Casey's") entered into an agreement to acquire retail fuel outlets and other interests from Respondents Steven Buchanan and Buck's Intermediate Holdings, LLC (collectively, "Bucky's"), that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and that a proceeding in respect thereof would be in the public interest, hereby issues this Complaint, stating its charges as follows.

I. RESPONDENTS

Casey's

1. Respondent Casey's is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Iowa, with its office and principal place of business located at 1 SE Convenience Boulevard, Ankeny, Iowa, 50021.

2. Casey's is, and at all times relevant herein has been, engaged in, among other things, the retail sale of gasoline and diesel fuel in the United States.

3. Casey's and the corporate entities under its control are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

Bucky's

4. Respondent Steven Buchanan is a natural person residing in and doing business under, and by virtue of, the laws of the State of Nebraska, with his office and principal place of business located at 7315 Mercy Road, Omaha, Nebraska 68124.

5. Respondent Buck's Intermediate Holdings, LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Nebraska, with its office and principal place of business located at 7315 Mercy Road, Omaha, Nebraska 68124.

6. Bucky's is, and at all times relevant herein has been, engaged in, among other things, the retail sale of gasoline and diesel fuel in the United States.

7. Bucky's and the corporate entities under its control are, and at all times relevant herein have been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

8. Pursuant to an Equity Purchase Agreement (the "Equity Purchase Agreement") dated November 8, 2020, Casey's proposes to acquire retail outlets and other interests from Bucky's (the "Acquisition"). Casey's proposes to acquire certain interests of the following Bucky's affiliated entities: Buck's Inc., a corporation, Chicago SPE (N), Inc., a corporation, C.T. Jewell Company, Inc., a corporation, Buck's Inc. of Collinsville, a corporation, Buchanan Energy (N), LLC, a limited liability company, Buchanan Energy (S), LLC, a limited liability company, Buck's Intermediate Holdings, LLC, a limited liability company, Steven Buchanan, a natural person, Buck's Holdco, Inc., a corporation, and the other shareholders and members.

9. The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKET

10. The relevant product markets in which to analyze the effects of the Acquisition are the retail sale of gasoline and the retail sale of diesel fuel. Consumers require gasoline for their gasoline-powered vehicles and can purchase gasoline only at retail fuel outlets. Consumers require diesel fuel for their diesel-powered vehicles and can purchase diesel fuel only at retail

fuel outlets. No economic or practical alternative to the retail sale of gasoline or diesel fuel exists.

11. The relevant geographic markets in which to analyze the effects of the Acquisition are seven local markets within the following cities: Omaha, Nebraska; Papillion, Nebraska; and Council Bluffs, Iowa.

12. The relevant geographic markets for retail gasoline and retail diesel fuel are highly localized, ranging up to a few driving miles, depending on local circumstances. Each relevant market is distinct and fact-dependent, reflecting such features as commuting patterns, traffic flows, and outlet characteristics unique to each market. Consumers typically choose between nearby retail fuel outlets with similar characteristics along their planned routes.

IV. MARKET STRUCTURE

13. With regard to the retail sale of gasoline, the Acquisition, if consummated, would reduce the number of competitively constraining independent market participants from four to three in five local markets, and from three to two in two local markets. The Acquisition would result in a highly concentrated market in each of these markets.

14. With regard to the retail sale of diesel fuel, the Acquisition, if consummated, would reduce the number of competitively constraining independent market participants from three to two in four local markets. The Acquisition would result in a highly concentrated market in each of these markets.

V. BARRIERS TO ENTRY

15. Entry into each relevant market would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects arising from the Acquisition. Significant entry barriers include the availability of attractive real estate, the time and cost associated with constructing a new retail fuel outlet, and the time associated with obtaining necessary permits and approvals.

VI. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, as described in Paragraph 8, if consummated, may be to substantially lessen competition or to tend to create a monopoly in each of the relevant markets, with each constituting an independent violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by:

a. increasing the likelihood that Casey's would unilaterally exercise market power in each relevant market; and

b. increasing the likelihood of collusive or coordinated interaction between any remaining competitors in each relevant market.

VII. VIOLATIONS CHARGED

17. The Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Equity Purchase Agreement entered into by Casey's and Bucky's constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

IN WITNESS WHEREOF, the Federal Trade Commission, having caused this Complaint to be signed by the Secretary and its official seal affixed, at Washington, D.C., this twenty-eighth day of April 2021, issues its Complaint against Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission") initiated an investigation of the proposed acquisition by Respondent Casey's General Stores, Inc. of the membership interests of Respondent Buck's Intermediate Holdings, LLC, an entity controlled by Respondent Steven Buchanan (collectively "Respondents"). The Commission's Bureau of Competition prepared and furnished to Respondents the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an agreement ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint, (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission's Rules, and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the said Acts, and that a complaint should issue stating its charges in that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. Now, in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission issues its Complaint, makes the following jurisdictional findings, and issues the following Order to Maintain Assets:

1. Respondent Casey's General Stores, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Iowa with its executive offices and principal place of business located at One SE Convenience Boulevard, Ankeny, Iowa 50021.

2. Respondent Steven Buchanan is a natural person with his office and principal place of business located at 7315 Mercy Road, Omaha, Nebraska 68124.

3. Respondent Buck's Intermediate Holdings, LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the state of Nebraska with its executive offices and principal place of business located at 7315 Mercy Road, Omaha, Nebraska 68124.

4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the Decision and Order, which are incorporated herein by reference and made a part hereof, shall apply:

A. "Casey's" means Casey's General Stores, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Casey's General Stores, Inc. (including Buck's Intermediate Holdings, LLC after the Acquisition), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Buchanan" means Steven Buchanan, a natural person, and all partnerships, joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Steven Buchanan and the respective partners, directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Buck's" means Buck's Intermediate Holdings, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Buck's Intermediate Holdings, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

D. "Decision and Order" means the:

1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance and service of a final Decision and Order by the Commission; and

2. Final Decision and Order issued by the Commission in this matter following the issuance and service of a final Decision and Order by the Commission.

E. "Commission" means the Federal Trade Commission.

F. "Orders" means this Order to Maintain Assets and the Decision and Order.

II. Maintain Assets

IT IS FURTHER ORDERED that that until Respondents fully transfer the Retail Fuel Business and related Retail Fuel Assets to an Acquirer, Respondents shall, subject to their obligations under the Order to Maintain Assets, ensure that each Retail Fuel Business and related Retail Fuel Assets are operated and maintained in the ordinary course of business consistent with past practices, and shall:

A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of the Retail Fuel Business and related Retail Fuel Assets, to minimize the risk of any loss of their competitive potential, to operate them in a manner consistent with applicable laws and regulations, and to prevent their destruction, removal, wasting, deterioration, or impairment (other than as a result of ordinary wear and tear).

B. Not sell, transfer, encumber, or otherwise impair the Retail Fuel Business and related Retail Fuel Assets (other than in the manner prescribed in this Order to Maintain Assets and the Decision and Order) or take any action that lessens their full economic viability, marketability, or competitiveness; and

C. Not terminate the operations of the Retail Fuel Business and related Retail Fuel Assets, and shall conduct or cause to be conducted the operations of the Retail Fuel Business and related Retail Fuel Assets in the ordinary course of business and in accordance with past practice (including regular repair and maintenance efforts) and as may be necessary to preserve the full economic viability, marketability, and competitiveness of the Retail Fuel Business and related Retail Fuel Assets; and

D. Use best efforts to preserve the existing relationships with suppliers, customers, employees, governmental authorities, vendors, landlords, and others having business relationships with the Retail Fuel Business and related Retail Fuel Assets.

Provided, however, that Respondents may take actions that the Acquirer has requested or agreed to in writing and that has been approved in advance by Commission staff, in all cases to facilitate the Acquirer's acquisition of the Retail Fuel Business and related Retail Fuel Assets and consistent with the purposes of this Order to Maintain Assets and the Decision and Order.

III. Transition Assistance

IT IS FURTHER ORDERED that:

A. Until Respondents have transferred all Business Information included in the Retail Fuel Assets, Respondents shall ensure that the Business Information is maintained and updated in the ordinary course of business and shall provide the Acquirer with access to records and information (wherever located and however stored) that Respondents have not yet transferred to the Acquirer, and to employees who possess the records and information.

B. At the option of Acquirer, Respondent Casey's shall provide the Acquirer with Transition Assistance sufficient to (i) transfer efficiently the Retail Fuel Assets to the Acquirer and (ii) allow the Acquirer to operate the acquired Retail Fuel Business and Retail Fuel Assets in a manner that is equivalent in all material respects to the manner in which Respondents did so prior to the Acquisition.

C. Respondent Casey's shall provide Transition Assistance:

1. As set forth in the Divestiture Agreement, or as otherwise reasonably requested by the Acquirer (whether before or after the Divestiture Date);

2. At the price set forth in the Divestiture Agreement, or if no price is set forth, at Direct Cost; and

3. For a period sufficient to meet the requirements of this Paragraph, which shall be, at the option of the Acquirer, for up to 12 months after the Divestiture Date;

Provided, however, that within 15 days after a request by the Acquirer, Respondent Casey's shall file with the Commission a request for prior approval to extend the term for providing Transitional Assistance as the Acquirer requests in order to achieve the purposes of this Order to Maintain Assets and the Decision and Order.

D. Respondent Casey's shall allow the Acquirer to terminate, in whole or part, any Transition Assistance provisions of the Divestiture Agreement upon commercially reasonable notice and without cost or penalty.

E. Respondent Casey's shall not cease providing Transition Assistance due to a breach by the Acquirer of the Divestiture Agreement, and shall not limit any

damages (including indirect, special, and consequential damages) that the Acquirer would be entitled to receive in the event of Respondent Casey's breach of the Divestiture Agreement.

IV. Employees

IT IS FURTHER ORDERED that:

A. Until one year after the Divestiture Date, Respondents shall cooperate with and assist each Acquirer of Retail Fuel Assets to evaluate independently and offer employment to any Retail Fuel Employee.

B. Until one year after the Divestiture Date, Respondent Casey's shall:

1. No later than 10 days after a request from the Acquirer, provide a list of all Retail Fuel Employees and provide Employee Information for each;

2. No later than 10 days after a request from the Acquirer, provide the Acquirer an opportunity to privately interview any of the Retail Fuel Employees outside the presence or hearing of any employee or agent of any Respondent, and to make offers of employment to any of the Retail Fuel Employees;

3. Remove any impediments within the control of Respondents that may deter Retail Fuel Employees from accepting employment with the Acquirer, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by the Acquirer, and shall not make any counteroffer to an Retail Fuel Employee who receives an offer of employment from the Acquirer;

   Provided, however, that nothing in this Order to Maintain Assets shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee;

4. Continue to provide Retail Fuel Employees with compensation and benefits, including regularly scheduled raises and bonuses and the vesting of benefits;

5. Provide reasonable financial incentives for Retail Fuel Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Retail Fuel Employees by the Acquirer; and

6. Not interfere, directly or indirectly, with the hiring or employing by the Acquirer of any Retail Fuel Employee, not offer any incentive to such employees to decline employment with the Acquirer, and not otherwise interfere with the recruitment of any Retail Fuel Employee by the Acquirer.

C. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any Person employed by the Acquirer to terminate his or her employment with the Acquirer; *provided, however*, Respondents may:

1. Hire any such Person whose employment has been terminated by the Acquirer;

2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more Person employed by the Acquirer; or

3. Hire a Person who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of this Paragraph.

V. Confidentiality

IT IS FURTHER ORDERED that:

A. Respondents shall not (x) disclose (including to Respondents' employees) or (y) use for any reason or purpose, any Confidential Information received or maintained by Respondents; *provided, however*, that Respondents may disclose or use such Confidential Information in the course of:

1. Performing its obligations or as permitted under this Order to Maintain Assets, the Decision and Order, or any Divestiture Agreement; or

2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the Retail Fuel Assets or any Retail Fuel Business, or as required by law or regulation, including any applicable securities exchange rules or regulations.

B. If disclosure or use of any Confidential Information, including the pricing of retail fuel that may occur after the Divestiture Date but before the transfer of the Retail Fuel Business to the Acquirer has occurred, is permitted to Respondents' employees or to any other Person under Paragraph V.A of this Order to Maintain Assets, Respondents shall limit such disclosure or use (1) only to the extent such

information is required, (2) only to those employees or Persons who require such information for the purposes permitted under Paragraph V.A, and (3) only after such employees or Persons have signed an agreement to maintain the confidentiality of such information.

C. Respondents shall enforce the terms of this Section V and take necessary actions to ensure that their employees and other Persons comply with the terms of this Section V, including implementing access and data controls, training its employees, and other actions that Respondents would take to protect their own trade secrets and proprietary information.

VI. Additional Obligations

IT IS FURTHER ORDERED that Respondents shall:

A. Respondents shall obtain, no later than the Divestiture Date and at their sole expense, all Consents from Third Parties and all Governmental Authorizations that are necessary to effect the complete transfer and divestiture of the Retail Fuel Assets to the Acquirer and for the Acquirer to operate any aspect of the relevant Retail Fuel Business; p*rovided, however,* that:

1. Respondents may satisfy the requirement to obtain all Consents from third parties by certifying that the Acquirer has entered into equivalent agreements or arrangements directly with the relevant third party that are acceptable to the Commission, or has otherwise obtained all necessary Consents and waivers; and

2. With respect to any Governmental Authorization relating to the Retail Fuel Assets that are not transferable, Respondents shall, to the extent permitted under applicable law, allow the Acquirer to operate the Retail Fuel Assets under Respondents' Governmental Authorization pending the Acquirer's receipt of its own Governmental Authorization, and Respondents shall provide such assistance as the Acquirer may reasonably request in connection with its efforts to obtain such Governmental Authorization.

B. Assist each potential Acquirer to conduct a due diligence investigation of the Retail Fuel Assets and Retail Fuel Business such Acquirer seeks to purchase, including by providing sufficient and timely access to all information customarily provided as part of a due diligence process, and affording each Acquirer and its representatives (including prospective lenders and their representatives) full and free access, during regular business hours, to the personnel, assets, Contracts, Governmental Authorizations, Business Information, and other documents and data relating to the relevant Retail Fuel Business, with such rights of access to be exercised in a manner that does not unreasonably interfere with the operations of Respondents.

VII. Monitor

IT IS FURTHER ORDERED that:

A. At any time after Respondents sign the Consent Agreement, the Commission may appoint a Person to serve as Monitor to observe and report on Respondents' compliance with their obligations as set forth in the Orders.

B. If the Commission determines to appoint a Monitor, the Commission shall select the Monitor subject to the consent of the Respondents, which shall not be unreasonably withheld. Respondents shall be deemed to have consented to the selection of the proposed Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed Monitor.

C. Respondents and the Monitor may enter into an agreement relating to the Monitor's services. Any such agreement:

1. Shall be subject to the approval of the Commission;

2. Shall not limit, and the signatories shall not construe it to limit, the terms of this Section or Section VIII of the Decision and Order ("Monitor Sections"), and to the extent any provision in the agreement varies from or conflicts with any provision in the Monitor Sections, Respondents and the Monitor shall comply with the Monitor Sections; and

3. Shall include a provision stating that the agreement does not limit, and the signatories shall not construe it to limit, the terms of the Orders in this matter, and to the extent any provision in the agreement varies from or conflicts with any provision in the Orders, Respondents and the Monitor shall comply with the Orders.

D. The Monitor shall:

1. Have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;

2. Act in consultation with the Commission or its staff;

3. Serve as an independent third party and not as an employee or agent of Respondents or of the Commission;

4. Serve without bond or other security;

5. At the Monitor's option, employ such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;

6. Enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall also enter into a non-disclosure or other confidentiality agreement with the Commission;

7. Notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict;

8. Report in writing to the Commission concerning Respondents' compliance with this Order to Maintain Assets on a schedule as determined by Commission staff, and at any other time requested by the staff of the Commission; and

9. Unless the Commission or its staff determine otherwise, the Monitor shall serve until Commission staff determines that Respondents have satisfied all obligations under the designated Sections of this Order to Maintain Assets, and files a final report.

E. Respondents shall:

1. Cooperate with and assist the Monitor in performing his or her duties for the purpose of reviewing Respondents' compliance with their obligations under the Orders, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;

2. Not interfere with the ability of the Monitor to perform his or her duties pursuant to the Orders;

3. Pay the Monitor's fees and expenses as set forth in an agreement approved by the Commission, or if such agreement has not been approved, pay the Monitor's customary fees, as well as expenses the Monitor incurs performing his or her duties under the Order, including expenses of any consultants, accountants, attorneys, and other representatives and

assistants that are reasonably necessary to assist the Monitor in carrying out his or her duties and responsibilities;

4. Not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to the Orders; and

5. Indemnify and hold the Monitor harmless against any loss, claim, damage, liability, and expense (including attorneys' fees and out of pocket costs) that arises out of, or is connected with, a claim concerning the performance of the Monitor's duties under the Orders, unless the loss, claim, damage, liability, or expense results from gross negligence or willful misconduct by the Monitor.

F. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement, so long as the agreement does not restrict the Monitor's ability to access personnel, information, and facilities or provide information to the Commission, or otherwise observe and report on the Respondents' compliance with the Orders.

G. If the Monitor resigns or the Commission determines that the Monitor has ceased to act, has failed to act diligently, or is otherwise unable to continue serving as a Monitor due to the existence of a conflict or other reasons, the Commission may appoint a substitute Monitor. The substitute Monitor shall be afforded all rights, powers, and authorities and shall be subject to all obligations of the Monitor Sections of the Orders. The Commission shall select the substitute Monitor, subject to the consent of the Respondents. Respondents:

1. Shall not unreasonably withhold consent to the appointment of the selected substitute Monitor;

2. Shall be deemed to have consented to the selection of the proposed substitute Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed substitute Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Monitor; and

3. May enter into an agreement with the substitute Monitor relating to the substitute Monitor's services that either (a) contains substantially the same terms as the Commission-approved agreement referenced in Paragraph VII.C.; or (b) receives Commission approval.

H. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

VIII. Divestiture Trustee

IT IS FURTHER ORDERED that:

A. If Respondent Casey's has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets as required by the Decision and Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order to Maintain Assets.

B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent Casey's shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Section shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent Casey's to comply with the Orders.

C. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Casey's which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent Casey's has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondent Casey's of the identity of any proposed Divestiture Trustee, Respondent Casey's shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

D. Not later than 10 days after the appointment of a Divestiture Trustee, Respondent Casey's shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestitures required by the Decision and Order. Any failure by Respondent Casey's to comply with a trust agreement approved by the Commission shall be a violation of this Order to Maintain Assets.

E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Section, Respondent Casey's shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by the Decision and Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed;

2. The Divestiture Trustee shall have one year from the date the Commission approves the trustee trust agreement described herein to accomplish the divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of the one year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestitures can be achieved within a reasonable time, the divestiture period may be extended by the Commission, *provided, however,* the Commission may extend the divestiture period only 2 times;

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by the Decision and Order and to any other relevant information, as the Divestiture Trustee may request. Respondent Casey's shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent Casey's shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestitures. Any delays in divestitures caused by Respondent Casey's shall extend the time for divestitures under this Paragraph VIII.E. in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court;

4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent Casey's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestitures shall be made in the manner and to Acquirers that receive the prior approval of the Commission as required by the Decision and Order,

Provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring person for a divestiture, and if the Commission determines to approve more than one such acquiring person for the divestiture, the Divestiture Trustee shall divest to the acquiring

person selected by Respondent Casey's from among those approved by the Commission,

Provided, further, however, that Respondent Casey's shall select such person within 5 days of receiving notification of the Commission's approval;

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent Casey's, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent Casey's, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent Casey's, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by the Decision and Order;

6. Respondent Casey's shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee;

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the Divestiture Assets required to be divested by the Decision and Order;

8. The Divestiture Trustee shall report in writing to Respondent Casey's and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture; and

9. Respondent Casey's may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement,

Provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

F. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

G. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Section.

H. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures and other obligations or action required by the Decision and Order.

IX. Prior Notice

IT IS FURTHER ORDERED that:

A. Respondents Casey's and Buck's shall not, without providing advance written notification to the Commission ("Notification"):

1. Acquire, directly or indirectly, through subsidiaries or otherwise, any leasehold, ownership interest, or any other interest, in whole or in part, in any concern, corporate or non-corporate, or in any assets engaged in the sale of any Fuel Products at a Prior Notice Location, or

2. Enter into any contract with any concern, corporate or non-corporate, engaged in the sale of any Fuel Products at a Prior Notice Location in which Casey's or Buck's will control the retail price of such products.

B. The Notification shall:

1. Be provided on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended, and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification, Notification shall be filed with the Secretary of the Commission, Notification need not be made to the United States Department of Justice, and Notification is required only of the Respondent Casey's and not of any other party to the transaction.

2. Include a description of the proposed acquisition and provide:

   a. A map showing all retail fuel outlets by ownership (*e.g.*, OPIS Corporate Brand) within the relevant Prior Notice Location;

   b. For each retail fuel outlet owned by Respondent Casey's or Buck's within 5 driving miles of the relevant Prior Notice Location, a list of the retail fuel outlets that Respondent Casey's or Buck's monitored at any time within the preceding 12 month period (to the extent such information is available); and

   c. Respondents Casey's and Buck's pricing strategy in relation to each monitored retail fuel outlet identified in response to Paragraph IX.B.2.(b) of this Order to Maintain Assets.

3. Provide the Notification to the Commission at least 30 days prior to consummating the transaction (hereinafter referred to as the "first waiting period"). Further, if, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents Casey's and Buck's shall not consummate the transaction until 30 days after submitting such additional information or documentary material.

4. Early termination of the waiting periods in this Section IX may be requested and, where appropriate, granted by letter from the Bureau of Competition. *Provided, however*, that prior notification shall not be required by this Section for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

X. Compliance Reports

IT IS FURTHER ORDERED that:

A. Respondent Casey's shall:

1. Notify Commission staff via email at bccompliance@ftc.gov of the Acquisition Date and of the Divestiture Date no later than 5 days after the transfer of each Retail Fuel Business location; and

2. Submit the complete Divestiture Agreement to the Commission at ElectronicFilings@ftc.gov and bccompliance@ftc.gov no later than 30 days after the Divestiture Date.

B. Respondents shall file verified written reports ("Compliance Reports") in accordance with the following:

1. Respondents shall submit Compliance Reports 30 days after this Order to Maintain Assets is issued and every 30 days thereafter until this Order to Maintain Assets terminates, and additional Compliance Reports as the Commission or its staff may request.

Provided, however, that Respondent Buchanan shall submit interim Compliance Reports 30 days after this Order to Maintain Assets is issued and every 30 days thereafter only until he has completed his obligations under Sections IV and VI of the Decision and Order.

2. Each compliance report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondents are in compliance with the Orders. Conclusory statements that Respondents have complied with their obligations under the Orders are insufficient. Respondents shall include in their reports, among other information or documentation that may be necessary to demonstrate compliance, a full description of the measures Respondents have implemented or plan to implement to ensure that they have complied or will comply with each paragraph of the Orders.

3. Respondents shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondents' obligations under the Orders and provide copies of these documents to Commission staff upon request.

C. Respondents shall verify each compliance report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondent shall file its compliance reports with the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov, as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a). In addition, Respondent shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

XI. Change in Respondent

IT IS FURTHER ORDERED that Respondent Casey's shall notify the Commission at least 30 days prior to:

A. The proposed dissolution of Casey's General Stores, Inc.;

B. The proposed acquisition, merger, or consolidation of Casey's General Stores, Inc.; or

C. Any other changes in Respondent Casey's, including assignment and the creation, sale, or dissolution of subsidiaries, if such changes may affect compliance obligations arising out of the Orders.

XII. Access

IT IS FURTHER ORDERED that for purposes of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, upon written request and 5 days' notice to the relevant Respondent, made to its principal place of business as identified in this Order to Maintain Assets, registered office of its United States subsidiary, or its headquarters office, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of the Respondent related to compliance with this Order to Maintain Assets, which copying services shall be provided by the Respondent at the request of the authorized representative of the Commission and at the expense of the Respondent; and

B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XIII. Purpose

IT IS FURTHER ORDERED that the purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Retail Fuel Business through its full transfer and delivery to Acquirer; to minimize any risk of loss of competitive potential for the Retail Fuel Business; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Retail Fuel Assets except for ordinary wear and tear.

XIV. Term

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate the day after the Decision and Order in this matter becomes final or the Commission withdraws acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34.

By the Commission.

Appendix A

Retail Fuel Business Locations

Owner	Store No.	Name & Property Address
CGS	2096	Casey's 2301 S. 24th Street Council Bluffs, Iowa 51501
CGS	2886	Casey's 1202 S. 13th Street Omaha, Nebraska 68108
CGS	2985	Casey's 5120 S. 118th Street Omaha, Nebraska 68137
Buchanan	114	Bucky's 11400 S. 72nd Street Papillion, Nebraska 68046
Buchanan	160	Bucky's 6003 Center Street Omaha, Nebraska 68106
Buchanan	172	Bucky's 2901 N. 72nd Street Omaha, Nebraska 68134

Order to Maintain Assets

Appendix B

Prior Notice Location

State	Area	Prior Notice Location
Iowa	Council Bluffs	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 2711 S. 24th Street, Council Bluffs, Iowa 51501.
Nebraska	Omaha	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 2675 S. 13th Street, Omaha, Nebraska 68108.
Nebraska	Omaha	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 4865 S. 108th Street, Omaha, Nebraska 68137.
Nebraska	Papillion	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 9911 S. 71st Avenue, Papillion, Nebraska 68113.
Nebraska	Omaha	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 5920 F Street, Omaha, Nebraska 68117.
Nebraska	Omaha	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 2540 N. 90th Street, Omaha, Nebraska 68134.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of the proposed acquisition by Respondent Casey's General Stores, Inc. of the membership interests of Respondent Buck's Intermediate Holdings, LLC, an entity controlled by Respondent Steven Buchanan (collectively "Respondents"). The Commission's Bureau of Competition prepared and furnished to Respondents the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

Respondents and the Bureau of Competition executed an agreement ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint, (2) a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true, (3) waivers and other provisions as required by the Commission's Rules, and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the said Acts, and that a complaint should issue stating its charges in that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings:

1. Respondent Casey's General Stores, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Iowa with its executive offices and principal place of business located at One SE Convenience Boulevard, Ankeny, Iowa 50021.

2. Respondent Steven Buchanan is a natural person with his office and principal place of business located at 7315 Mercy Road, Omaha, Nebraska 68124.

3. Respondent Buck's Intermediate Holdings, LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the state of Nebraska with its executive offices and principal place of business located at 7315 Mercy Road, Omaha, Nebraska 68124.

4. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent and the proceeding is in the public interest.

ORDER

I. Definitions

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

A. "Casey's" means Casey's General Stores, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Casey's General Stores, Inc. (including Buck's Intermediate Holdings, LLC after the Acquisition), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. "Buchanan" means Steven Buchanan, a natural person, and all partnerships, joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Steven Buchanan and the respective partners, directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Buck's" means Buck's Intermediate Holdings, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Buck's Intermediate Holdings, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

D. "Commission" means the Federal Trade Commission.

E. "Acquirer" means:

1. Western Oil; or

2. Any other Person that the Commission approves to acquire the Retail Fuel Assets pursuant to this Order.

F. "Acquisition" means the proposed acquisition described in the Equity Purchase Agreement by and among Casey's General Stores, Inc., Buck's Inc., Chicago SPE (N), Inc., C.T. Jewell Company, Inc., Buck's Inc. of Collinsville, Buchanan Energy (N), LLC, Buchanan Energy (S), LLC, Buck's Intermediate Holdings, LLC, Steven Buchanan, Buck's Holdco, Inc., and the Other Shareholders and Members As May Join Herein, entered into on November 8, 2020.

G. "Acquisition Date" means the date the Respondents consummate the Acquisition.

H. "Business Information" means books, records, data, and information, wherever located and however stored, used in or related to the Retail Fuel Assets or Retail Fuel Business, including documents, written information, graphic materials, and data and information in electronic format, along with the knowledge of

employees, contractors, and representatives. Business Information includes books, records, data, and information relating to sales, marketing, logistics, products and SKUs, pricing, promotions, advertising, personnel, accounting, business strategy, information technology systems, customers, suppliers, vendors, research and development, underground storage tank ("UST") system registrations and reports, registrations, licenses, and permits (to the extent transferable), operations, and all other information relating to the Retail Fuel Business or Retail Fuel Assets.

I. "Confidential Information" means all Business Information not in the public domain, except for any information that was or becomes generally available to the public other than as a result of disclosure by Respondents.

J. "Consent" means an approval, consent, ratification, waiver, or other authorization.

K. "Contract" means an agreement, contract, lease, license agreement, consensual obligation, promise or undertaking (whether written or oral and whether express or implied), whether or not legally binding with third parties.

L. "Danco II-CB LLC" means a limited liability company organized, existing, and doing business under, and by virtue of the laws of the state of Nebraska, with its office and principal place of business located at 633 West Hwy 20, Valentine, Nebraska 69201.

M. "Direct Cost" means the cost of labor, goods and materials, travel, and other expenditures directly incurred. The cost of any labor included in Direct Cost shall not exceed the hours of labor provided times the then-current average hourly wage rate, including benefits, for the employee providing such labor; *provided, however*, that with respect to the transitional supply of Fuel Products, Fuel Products Cost shall be calculated net of any rebates, Renewable Identification Number sharing, or other discounts or allowances and shall not include any mark-up, profit, overhead, minimum volume penalties, or other upward adjustments by Respondents.

N. "Divestiture Agreement" means:

1. The Purchase Agreement by and among Casey's Marketing Company, Casey's Retail Company, and Danco II-CB, LLC dated March 16, 2021, and all amendments, exhibits, attachments, agreements, and schedules thereto, attached to this Decision and Order as Nonpublic Appendix A; or

2. Any agreement between Respondents (or a Divestiture Trustee appointed pursuant to Section IX of this Order) and an Acquirer to purchase the Retail Fuel Assets, and all amendments, exhibits, attachments, agreements, and schedules thereto.

O. "Divestiture Date" means any date on which Respondents (or a Divestiture Trustee appointed pursuant to Section IX of this Order) consummate the divestiture as required by Section II of this Order.

P. "Divestiture Trustee" means the Person appointed by the Commission pursuant to Section IX of this Order.

Q. "Employee Information" means to the extent permitted by law, the following information summarizing the employment history of each employee that includes:

1. Name, job title or position, date of hire, and effective service date;

2. Specific description of the employee's responsibilities;

3. The employee's base salary or current wages;

4. Most recent bonus paid, aggregate annual compensation for Respondent's last fiscal year, and current target or guaranteed bonus, if any;

5. Written performance reviews for the past three years, if any;

6. Employment status (*i.e.*, active or on leave or disability; full-time or part-time);

7. Any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

8. At the Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the employee.

R. "Equipment" means all tangible personal property (other than Inventories) of every kind owned or leased by Respondents in connection with the operation of the Retail Fuel Business, including, but not limited to all: fixtures, furniture, computer equipment and third-party software, office equipment, telephone systems, security systems, registers, credit card systems, credit card invoice printers and electronic point of sale devices, money order machines and money order stock, shelving, display racks, walk-in boxes, furnishings, signage, canopies, fuel dispensing equipment, UST systems (including all fuel storage tanks, fill holes and fill hole covers and tops, pipelines, vapor lines, pumps, hoses, Stage I and Stage II vapor recovery equipment, containment devices, monitoring equipment, cathodic protection systems, and other elements associated with any of the foregoing), parts, tools, supplies, and all other items of equipment or tangible personal property of any nature or other systems used in the operation of the Retail Fuel Business, together with any express or implied warranty by the manufacturers or sellers or lessors of any item or component part, to the extent

such warranty is transferrable, and all maintenance records and other related documents.

S. "Fuel Products" means refined petroleum gasoline and diesel products.

T. "Governmental Authorization" means a Consent, license, registration, or permit issued, granted, given or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement.

U. "Intellectual Property" means all intellectual property, including: (1) commercial names, all assumed fictional business names, trade names, "doing business as" (d/b/a names), registered and unregistered trademarks, service marks and applications, and trade dress; (2) all patents, patent applications and inventions and discoveries that may be patentable; (3) all registered and unregistered copyrights in both published works and unpublished works; (4) all rights in mask works; (5) all know-how, trade secrets, confidential or proprietary information, customer lists, software, technical information, data, process technology, plans, drawings, and blue prints; (6) and all rights in internet web sites and internet domain names presently used.

V. "Inventories" means all inventories of every kind and nature for retail sale associated with the Retail Fuel Business, including: (1) all Fuel Products, kerosene, and other petroleum-based motor fuels stored in bulk and held for sale to the public; and (2) all usable, non-damaged and non-out-of-date products and items held for sale to the public, including, without limitation, all food-related items requiring further processing, packaging, or preparation and ingredients from which prepared foods are made to be sold.

W. "Monitor" means any Person appointed by the Commission to serve as a monitor pursuant to this Order or the Order to Maintain Assets.

X. "Person" means any individual, partnership, corporation, business trust, limited liability company, limited liability partnership, joint stock company, trust, unincorporated association, joint venture or other entity or a governmental body.

Y. "Prior Notice Location" means any location described in the relevant areas identified in Appendix C of this Order.

Z. "Retail Fuel Assets" means all of Respondents' rights, title, and interest in and to all property and assets, real, personal, or mixed, tangible and intangible, of every kind and description, wherever located, used in, or relating to any Retail Fuel Business, including:

1. All real property interests (including fee simple interests and real property leasehold interests), including all easements, and appurtenances, together

with all buildings and other structures, facilities, and improvements located thereon, owned, leased, or otherwise held;

2. All Equipment, including any Equipment removed from the location of the Retail Fuel Businesses since the date of the announcement of the Acquisition and not replaced;

3. All Inventories;

4. All accounts receivable;

5. All Contracts and all outstanding offers or solicitations to enter into any Contract, and all rights thereunder and related thereto;

6. All Governmental Authorizations and all pending applications therefor or renewals thereof, to the extent transferable;

7. All Business Information; and

8. All intangible rights and property, including going concern value, goodwill, and telephone and telecopy listings;

Provided, *however*, that the Retail Fuel Assets need not include the Retained Assets.

AA. "Retail Fuel Business" means all business activities conducted by Respondents prior to the Acquisition Date at or relating to the locations identified in Appendix B of this Order, including the (1) sale of Fuel Products and (2) the operation of any associated convenience store and other business or service.

BB. "Retail Fuel Employee" means any full-time, part-time, or contract individual employed by Respondents, as applicable, at each Retail Fuel Business, as of and after March 16, 2021.

CC. "Retained Assets" means:

1. Corporate or regional offices;

2. Trade names and trademarks used corporate-wide, and website content, domain names, or e-mail addresses that contain such trade names or trademarks;

3. Intellectual Property;

4. Software that can readily be purchased or licensed from sources other than Respondents and that has not been materially modified (other than through user preference settings);

5. Enterprise software that Respondents used primarily to manage and account for businesses other than the relevant business to be divested;

6. The computer hardware and software, telecommunications equipment, and proprietary signage at each Retail Fuel Business location; and

7. Inventory that an Acquirer agrees not to purchase or that cannot be transferred by law in the applicable jurisdiction.

DD. "Transitional Assistance" means technical services, personnel, assistance, training, the supply of Fuel Products, and other logistical, administrative, and other transitional support as required by the Acquirer and approved by the Commission to facilitate the transfer of the Retail Fuel Assets to the Acquirer, including, but not limited to, services, training, personnel, and support related to: audits, finance and accounting, accounts receivable, accounts payable, employee benefits, payroll, pensions, human resources, information technology and systems, maintenance and repair of facilities and equipment, Fuel Products supply, purchasing, quality control, R&D support, technology transfer, use of Respondents' brands for transitional purposes, operating permits and licenses, regulatory compliance, sales and marketing, customer service, and supply chain management and customer transfer logistics.

EE. "Western Oil" means Danco II-CB LLC and Western Oil II LLC.

FF. "Western Oil II LLC" means a limited liability company organized, existing, and doing business under, and by virtue of the laws of the state of Nebraska, with its office and principal place of business located at 633 West Hwy 20, Valentine, Nebraska 69201.

II. Divestiture

IT IS FURTHER ORDERED that:

A. No later than 10 days after the Acquisition Date, Respondent Casey's shall divest the Retail Fuel Assets, as ongoing businesses, absolutely and in good faith, to Western Oil;

Provided, however, that, if within 12 months after issuing the Order, the Commission determines, in consultation with the Acquirer and the Monitor, should one be appointed, the Acquirer needs one or more Retained Assets to operate the Retail Fuel Assets in a manner that achieves the purposes of the Order, Respondent Casey's shall divest, absolutely and in good faith, such needed Retained Assets to the Acquirer; and

Provided further, however, that if Business Information relating to the Retail Fuel Assets includes information (1) that also relates to other retained businesses of

Respondents and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Retail Fuel Assets or (2) where Respondents have a legal obligation to retain the original copies, then Respondents shall provide only copies of the materials containing such information with appropriate redactions to the Acquirer and shall provide the Acquirer access to the original materials if copies are insufficient for regulatory or evidentiary purposes;

B. If Respondent Casey's has divested the Retail Fuel Assets to Western Oil prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent Casey's that:

1. Western Oil is not acceptable as the acquirer of the Retail Fuel Assets, then Respondent Casey's shall rescind the divestiture to Western Oil within 5 days of notification, and shall divest the Retail Fuel Assets no later than 180 days from the date this Order is issued, as on-going businesses, absolutely and in good faith, at no minimum price, to a Person that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission; or

2. The manner in which the divestiture to Western Oil was accomplished is not acceptable, the Commission may direct Respondent Casey's, or appoint a Divestiture Trustee, to modify the manner of divestiture of the Retail Fuel Assets as the Commission may determine is necessary to satisfy the requirements of this Order.

C. Respondents shall obtain, no later than the Divestiture Date and at their sole expense, all Consents from third parties and all Governmental Authorizations that are necessary to effect the complete transfer and divestiture of the Retail Fuel Assets to the Acquirer and for the Acquirer to operate any aspect of the relevant Retail Fuel Business; *provided, however,* that:

1. Respondents may satisfy the requirement to obtain all Consents from third parties by certifying that the Acquirer has entered into equivalent agreements or arrangements directly with the relevant third party that are acceptable to the Commission, or has otherwise obtained all necessary Consents and waivers; and

2. With respect to any Governmental Authorization relating to the Retail Fuel Assets that are not transferable, Respondents shall, to the extent permitted under applicable law, allow the Acquirer to operate the Retail Fuel Assets under Respondents' Governmental Authorization pending the Acquirer's receipt of its own Governmental Authorization, and Respondents shall provide such assistance as the Acquirer may reasonably request in connection with its efforts to obtain such Governmental Authorization.

D. Respondents shall assist each potential Acquirer to conduct a due diligence investigation of the Retail Fuel Assets and Retail Fuel Business such Acquirer seeks to purchase, including by providing sufficient and timely access to all information customarily provided as part of a due diligence process, and affording each Acquirer and its representatives (including prospective lenders and their representatives) full and free access, during regular business hours, to the personnel, assets, Contracts, Governmental Authorizations, Business Information, and other documents and data relating to the relevant Retail Fuel Business, with such rights of access to be exercised in a manner that does not unreasonably interfere with the operations of Respondents.

III. Divestiture Agreement

IT IS FURTHER ORDERED that:

A. The Divestiture Agreement shall be incorporated by reference into this Order and made a part hereof, and any failure by Respondent Casey's to comply with the terms of the Divestiture Agreement shall constitute a violation of this Order;

Provided, however, that the Divestiture Agreement shall not limit, or be construed to limit, the terms of this Order. To the extent any provision in the Divestiture Agreement varies from or conflicts with any provision in the Order such that Respondent Casey's cannot fully comply with both, Respondent Casey's shall comply with the Order.

B. Respondent Casey's shall not modify or amend the terms of the Divestiture Agreement after the Commission issues the Order without the prior approval of the Commission, except as otherwise provided in Commission Rule 2.41(f)(5), 16 C.F.R. § 2.41(f)(5).

IV. Transitional Assistance

IT IS FURTHER ORDERED that:

A. Until Respondents have transferred all Business Information included in the Retail Fuel Assets, Respondents shall ensure that the Business Information is maintained and updated in the ordinary course of business and shall provide the Acquirer with access to records and information (wherever located and however stored) that Respondents have not yet transferred to the Acquirer, and to employees who possess the records and information.

B. At the option of Acquirer, Respondent Casey's shall provide the Acquirer with Transition Assistance sufficient to (i) transfer efficiently the Retail Fuel Assets to the Acquirer and (ii) allow the Acquirer to operate the acquired Retail Fuel Business and Retail Fuel Assets in a manner that is equivalent in all material respects to the manner in which Respondents did so prior to the Acquisition.

C. Respondent Casey's shall provide Transition Assistance:

1. As set forth in the Divestiture Agreement, or as otherwise reasonably requested by the Acquirer (whether before or after the Divestiture Date);

2. At the price set forth in the Divestiture Agreement, or if no price is set forth, at Direct Cost; and

3. For a period sufficient to meet the requirements of this Paragraph, which shall be, at the option of the Acquirer, for up to 12 months after the Divestiture Date;

Provided, however, that within 15 days after a request by the Acquirer, Respondent Casey's shall file with the Commission a request for prior approval to extend the term for providing Transitional Assistance as the Acquirer requests in order to achieve the purposes of this Order.

D. Respondent Casey's shall allow the Acquirer to terminate, in whole or part, any Transition Assistance provisions of the Divestiture Agreement upon commercially reasonable notice and without cost or penalty.

E. Respondent Casey's shall not cease providing Transition Assistance due to a breach by the Acquirer of the Divestiture Agreement, and shall not limit any damages (including indirect, special, and consequential damages) that the Acquirer would be entitled to receive in the event of Respondent Casey's breach of the Divestiture Agreement.

V. Employees

IT IS FURTHER ORDERED that:

A. Until one year after the Divestiture Date, Respondents shall cooperate with and assist each Acquirer of Retail Fuel Assets to evaluate independently and offer employment to any Retail Fuel Employee.

B. Until one year after the Divestiture Date, Respondent Casey's shall:

1. No later than 10 days after a request from the Acquirer, provide a list of all Retail Fuel Employees and provide Employee Information for each;

2. No later than 10 days after a request from the Acquirer, provide the Acquirer an opportunity to privately interview any of the Retail Fuel Employees outside the presence or hearing of any employee or agent of any Respondent, and to make offers of employment to any of the Retail Fuel Employees;

3. Remove any impediments within the control of Respondents that may deter Retail Fuel Employees from accepting employment with the Acquirer, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by the Acquirer, and shall not make any counteroffer to an Retail Fuel Employee who receives an offer of employment from the Acquirer;

   Provided, however, that nothing in this Order shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee;

4. Continue to provide Retail Fuel Employees with compensation and benefits, including regularly scheduled raises and bonuses and the vesting of benefits;

5. Provide reasonable financial incentives for Retail Fuel Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Retail Fuel Employees by the Acquirer; and

6. Not interfere, directly or indirectly, with the hiring or employing by the Acquirer of any Retail Fuel Employee, not offer any incentive to such employees to decline employment with the Acquirer, and not otherwise interfere with the recruitment of any Retail Fuel Employee by the Acquirer.

C. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any Person employed by the Acquirer to terminate his or her employment with the Acquirer; *provided, however*, Respondents may:

1. Hire any such Person whose employment has been terminated by the Acquirer;

2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more Person employed by the Acquirer; or

3. Hire a Person who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of this Paragraph.

VI. Asset Maintenance

IT IS FURTHER ORDERED that that until Respondent Casey's fully transfers each Retail Fuel Business and related Retail Fuel Assets to the Acquirer, Respondent Casey's shall, subject to its obligations under the Order to Maintain Assets, ensure that each Retail Fuel Business and related Retail Fuel Assets are operated and maintained in the ordinary course of business consistent with past practices, and shall:

A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of the Retail Fuel Business and related Retail Fuel Assets, to minimize the risk of any loss of their competitive potential, to operate them in a manner consistent with applicable laws and regulations, and to prevent their destruction, removal, wasting, deterioration, or impairment (other than as a result of ordinary wear and tear).

B. Not sell, transfer, encumber, or otherwise impair the Retail Fuel Business and related Retail Fuel Assets (other than in the manner prescribed in this Order and the Order to Maintain Assets) or take any action that lessens their full economic viability, marketability, or competitiveness; and

C. Not terminate the operations of the Retail Fuel Business and related Retail Fuel Assets, and shall conduct or cause to be conducted the operations of the Retail Fuel Business and related Retail Fuel Assets in the ordinary course of business and in accordance with past practice (including regular repair and maintenance efforts) and as may be necessary to preserve the full economic viability, marketability, and competitiveness of the Retail Fuel Business and related Retail Fuel Assets; and

D. Use best efforts to preserve the existing relationships with suppliers, customers, employees, governmental authorities, vendors, landlords, and others having business relationships with the Retail Fuel Business and related Retail Fuel Assets.

Provided, however, that Respondents may take actions that the Acquirer has requested or agreed to in writing and that has been approved in advance by Commission staff, in all cases to facilitate the Acquirer's acquisition of the Retail Fuel Business and related Retail Fuel Assets and consistent with the purposes of this Order and the Order to Maintain Assets.

VII. Confidentiality

IT IS FURTHER ORDERED that:

A. Respondents shall not (x) disclose (including to Respondents' employees) or (y) use for any reason or purpose, any Confidential Information received or maintained by Respondents; *provided, however,* that Respondents may disclose or use such Confidential Information in the course of:

1. Performing its obligations or as permitted under this Order, the Order to Maintain Assets, or any Divestiture Agreement; or

2. Complying with financial reporting requirements, obtaining legal advice, prosecuting or defending legal claims, investigations, or enforcing actions threatened or brought against the Retail Fuel Assets or any Retail Fuel Business, or as required by law or regulation, including any applicable securities exchange rules or regulations.

B. If disclosure or use of any Confidential Information, including the pricing of retail fuel that may occur after the Divestiture Date but before the transfer of the Retail Fuel Business to the Acquirer has occurred, is permitted to Respondents' employees or to any other Person under Paragraph VII.A of this Order, Respondents shall limit such disclosure or use (1) only to the extent such information is required, (2) only to those employees or Persons who require such information for the purposes permitted under Paragraph VII.A, and (3) only after such employees or Persons have signed an agreement to maintain the confidentiality of such information.

C. Respondents shall enforce the terms of this Section VII and take necessary actions to ensure that their employees and other Persons comply with the terms of this Section VII, including implementing access and data controls, training its employees, and other actions that Respondents would take to protect their own trade secrets and proprietary information.

VIII. Monitor

IT IS FURTHER ORDERED that:

A. At any time after Respondents sign the Consent Agreement, the Commission may appoint a Person to serve as Monitor to observe and report on Respondents' compliance with their obligations as set forth in the Orders.

B. If the Commission determines to appoint a Monitor, the Commission shall select the Monitor subject to the consent of the Respondents, which shall not be unreasonably withheld. Respondents shall be deemed to have consented to the selection of the proposed Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed Monitor.

C. Respondents and the Monitor may enter into an agreement relating to the Monitor's services. Any such agreement:

1. Shall be subject to the approval of the Commission;

2. Shall not limit, and the signatories shall not construe it to limit, the terms of this Section or Section VII of the Order to Maintain Assets ("Monitor Sections"), and to the extent any provision in the agreement varies from or conflicts with any provision in the Monitor Sections, Respondents and the Monitor shall comply with the Monitor Sections; and

3. Shall include a provision stating that the agreement does not limit, and the signatories shall not construe it to limit, the terms of the Orders in this matter, and to the extent any provision in the agreement varies from or conflicts with any provision in the Orders, Respondents and the Monitor shall comply with the Orders.

D. The Monitor shall:

1. Have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;

2. Act in consultation with the Commission or its staff;

3. Serve as an independent third party and not as an employee or agent of Respondents or of the Commission;

4. Serve without bond or other security;

5. At the Monitor's option, employ such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;

6. Enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall also enter into a non-disclosure or other confidentiality agreement with the Commission;

7. Notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict;

8. Report in writing to the Commission concerning Respondents' compliance with this Order on a schedule as determined by Commission staff, and at any other time requested by the staff of the Commission; and

9. Unless the Commission or its staff determine otherwise, the Monitor shall serve until Commission staff determines that Respondents have satisfied all obligations under the designated Sections of this Order, and files a final report.

E. Respondents shall:

1. Cooperate with and assist the Monitor in performing his or her duties for the purpose of reviewing Respondents' compliance with their obligations under the Orders, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;

2. Not interfere with the ability of the Monitor to perform his or her duties pursuant to the Orders;

3. Pay the Monitor's fees and expenses as set forth in an agreement approved by the Commission, or if such agreement has not been approved, pay the Monitor's customary fees, as well as expenses the Monitor incurs performing his or her duties under the Order, including expenses of any consultants, accountants, attorneys, and other representatives and assistants that are reasonably necessary to assist the Monitor in carrying out his or her duties and responsibilities;

4. Not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to the Orders; and

5. Indemnify and hold the Monitor harmless against any loss, claim, damage, liability, and expense (including attorneys' fees and out of pocket costs) that arises out of, or is connected with, a claim concerning the performance of the Monitor's duties under the Orders, unless the loss, claim, damage, liability, or expense results from gross negligence or willful misconduct by the Monitor.

F. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement, so long as the agreement does not restrict the Monitor's ability to access personnel, information, and facilities or provide information to the Commission, or otherwise observe and report on the Respondents' compliance with the Orders.

G. If the Monitor resigns or the Commission determines that the Monitor has ceased to act, has failed to act diligently, or is otherwise unable to continue serving as a

Monitor due to the existence of a conflict or other reasons, the Commission may appoint a substitute Monitor. The substitute Monitor shall be afforded all rights, powers, and authorities and shall be subject to all obligations of the Monitor Sections of the Orders. The Commission shall select the substitute Monitor, subject to the consent of the Respondents. Respondents:

1. Shall not unreasonably withhold consent to the appointment of the selected substitute Monitor;

2. Shall be deemed to have consented to the selection of the proposed substitute Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed substitute Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Monitor; and

3. May enter into an agreement with the substitute Monitor relating to the substitute Monitor's services that either (a) contains substantially the same terms as the Commission-approved agreement referenced in Paragraph VIII.C.; or (b) receives Commission approval.

H. The Commission may on its own initiative or at the request of the Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

IX. Divestiture Trustee

IT IS FURTHER ORDERED that:

A. If Respondent Casey's has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order.

B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent Casey's shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Section shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondent Casey's to comply with this Order.

C. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Casey's which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent Casey's has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondent Casey's of the identity of any proposed Divestiture Trustee, Respondent Casey's shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

D. Not later than 10 days after the appointment of a Divestiture Trustee, Respondent Casey's shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestitures required by this Order. Any failure by Respondent Casey's to comply with a trust agreement approved by the Commission shall be a violation of this Order.

E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Section, Respondent Casey's shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed;

2. The Divestiture Trustee shall have one year from the date the Commission approves the trustee trust agreement described herein to accomplish the divestitures, which shall be subject to the prior approval of the Commission. If, however, at the end of the one year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestitures can be achieved within a reasonable time, the divestiture period may be extended by the Commission, *provided, however,* the Commission may extend the divestiture period only 2 times;

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent Casey's shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent Casey's shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestitures. Any delays in divestitures caused by Respondent Casey's shall extend the time for divestitures under this Paragraph IX.E. in an

amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court;

4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent Casey's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestitures shall be made in the manner and to Acquirers that receive the prior approval of the Commission as required by this Order,

   Provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring person for a divestiture, and if the Commission determines to approve more than one such acquiring person for the divestiture, the Divestiture Trustee shall divest to the acquiring person selected by Respondent Casey's from among those approved by the Commission,

   Provided, further, however, that Respondent Casey's shall select such person within 5 days of receiving notification of the Commission's approval;

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent Casey's, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent Casey's, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent Casey's, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order;

6. Respondent Casey's shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities,

or expenses result from gross negligence or willful misconduct by the Divestiture Trustee;

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the Divestiture Assets required to be divested by this Order;

8. The Divestiture Trustee shall report in writing to Respondent Casey's and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture; and

9. Respondent Casey's may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement,

Provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

F. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

G. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Section.

H. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestitures and other obligations or action required by this Order.

X. Prior Notice

IT IS FURTHER ORDERED that:

A. Respondents Casey's and Buck's shall not, without providing advance written notification to the Commission ("Notification"):

1. Acquire, directly or indirectly, through subsidiaries or otherwise, any leasehold, ownership interest, or any other interest, in whole or in part, in any concern, corporate or non-corporate, or in any assets engaged in the sale of any Fuel Products at a Prior Notice Location, or

2. Enter into any contract with any concern, corporate or non-corporate, engaged in the sale of any Fuel Products at a Prior Notice Location in which Casey's or Buck's will control the retail price of such products.

B. The Notification shall:

1. Be provided on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended, and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification, Notification shall be filed with the Secretary of the Commission, Notification need not be made to the United States Department of Justice, and Notification is required only of the Respondent Casey's and not of any other party to the transaction.

2. Include a description of the proposed acquisition and provide:

a. A map showing all retail fuel outlets by ownership (*e.g.*, OPIS Corporate Brand) within the relevant Prior Notice Location;

b. For each retail fuel outlet owned by Respondent Casey's or Buck's within 5 driving miles of the relevant Prior Notice Location, a list of the retail fuel outlets that Respondent Casey's or Buck's monitored at any time within the preceding 12 month period (to the extent such information is available); and

c. Respondents Casey's and Buck's pricing strategy in relation to each monitored retail fuel outlet identified in response to Paragraph X.B.2.(b) of this Order.

3. Provide the Notification to the Commission at least 30 days prior to consummating the transaction (hereinafter referred to as the "first waiting period"). Further, if, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents Casey's and Buck's shall not consummate the transaction until 30 days after submitting such additional information or documentary material.

4. Early termination of the waiting periods in this Section X may be requested and, where appropriate, granted by letter from the Bureau of Competition. *Provided, however*, that prior notification shall not be required by this Section for a transaction for which notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

XI. Compliance Reports

IT IS FURTHER ORDERED that:

A. Respondent Casey's shall:

1. Notify Commission staff via email at bccompliance@ftc.gov of the Acquisition Date and of the Divestiture Date no later than 5 days after the transfer of each Retail Fuel Business location; and

2. Submit the complete Divestiture Agreement to the Commission at ElectronicFilings@ftc.gov and bccompliance@ftc.gov no later than 30 days after the Divestiture Date.

B. Respondents shall file verified written reports ("Compliance Reports") in accordance with the following:

1. Respondents shall submit:

a. Interim Compliance Reports 30 days after this Order is issued and every 30 days thereafter until Respondents have fully complied with the provisions of Sections II and IV of this Order;

b. Annual Compliance Reports one year after the date this Order is issued and annually thereafter for the next nine years on the anniversary of that date; and

c. Additional Compliance Reports as the Commission or its staff may request.

Provided, however, that Respondent Buchanan shall submit interim Compliance Reports 30 days after this Order is issued and every 30 days thereafter only until he has completed his obligations under Sections IV and VI of this Order.

2. Each Compliance Report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondents are in compliance with the Order. Conclusory statements that Respondents have complied with their obligations under the Order are insufficient. Respondents shall include in their reports, among other information or documentation that may be necessary to demonstrate compliance, a full description of the measures Respondents have implemented or plan to implement to ensure that they have complied or will comply with each paragraph of this Order.

3. For a period of 5 years after filing a Compliance Report, each Respondent shall retain all material written communications with each party identified in each Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondent's obligations under this Order during the period covered by such Compliance Report. Respondent shall provide copies of these documents to Commission staff upon request.

C. Respondents shall verify each compliance report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondent shall file its compliance reports with the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov, as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a). In addition, Respondent shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

XII. Change in Respondent

IT IS FURTHER ORDERED that Respondent Casey's shall notify the Commission at least 30 days prior to:

A. The proposed dissolution of Casey's General Stores, Inc.;

B. The proposed acquisition, merger, or consolidation of Casey's General Stores, Inc.; or

C. Any other changes in Respondent Casey's, including assignment and the creation, sale, or dissolution of subsidiaries, if such changes may affect compliance obligations arising out of the Order.

XIII. Access

IT IS FURTHER ORDERED that for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and 5 days' notice to the relevant Respondent, made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters office, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the

request of the authorized representative of the Commission and at the expense of the Respondent; and

B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XIV. Purpose

IT IS FURTHER ORDERED that the purpose of this Order is to remedy the harm to competition the Commission alleged in its Complaint and to ensure the Acquirer can operate the Retail Fuel Business in a manner equivalent in all material respects to the manner in which Respondents operated the Retail Fuel Business prior to the Acquisition.

XV. Term

IT IS FURTHER ORDERED that this Order shall terminate 10 years from the date it is issued.

By the Commission.

Nonpublic Appendix A

Divestiture Agreement

[Redacted From the Public Record Version, But Incorporated By Reference]

Decision and Order

Appendix B

Retail Fuel Business Locations

Owner	Store No.	Name & Property Address
Casey's	2096	Casey's 2301 S. 24th Street Council Bluffs, Iowa 51501
Casey's	2886	Casey's 1202 S. 13th Street Omaha, Nebraska 68108
Casey's	2985	Casey's 5120 S. 118th Street Omaha, Nebraska 68137
Buchanan	114	Bucky's 11400 S. 72nd Street Papillion, Nebraska 68046
Buchanan	160	Bucky's 6003 Center Street Omaha, Nebraska 68106
Buchanan	172	Bucky's 2901 N. 72nd Street Omaha, Nebraska 68134

Appendix C

Prior Notice Locations

State	Area	Prior Notice Location
Iowa	Council Bluffs	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 2711 S. 24th Street, Council Bluffs, Iowa 51501.
Nebraska	Omaha	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 2675 S. 13th Street, Omaha, Nebraska 68108.
Nebraska	Omaha	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 4865 S. 108th Street, Omaha, Nebraska 68137.
Nebraska	Papillion	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 9911 S. 71st Avenue, Papillion, Nebraska 68113.
Nebraska	Omaha	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 5920 F Street, Omaha, Nebraska 68117.
Nebraska	Omaha	Any location within a 3 mile driving distance (calculated as the shortest route from such location by Google maps) of 2540 N. 90th Street, Omaha, Nebraska 68134.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

I. Introduction

The Federal Trade Commission ("Commission") has accepted for public comment, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Casey's General Stores. Inc. (Casey's") and Bucky's Intermediate Holdings, LLC and Steven Buchanan ("Bucky's" and collectively, the "Respondents"). The Consent Agreement is designed to remedy the anticompetitive effects that likely would result from Casey's proposed acquisition of retail fuel assets from Bucky's.

Under the terms of the proposed Decision and Order ("Order") contained in the Consent Agreement, Respondents must divest certain retail fuel assets in seven local markets in Nebraska and Iowa. Respondents must complete the divestiture within 10 days after the closing of the acquisition. The Commission and Respondents have agreed to an Order to Maintain Assets that requires Respondents to operate and maintain each divestiture outlet in the normal course of business through the date the upfront buyers acquire the divested assets.

The Commission has placed the Consent Agreement on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the proposed Order final.

II. The Respondents

Respondent Casey's, a publicly traded company headquartered in Ankeny, Iowa, owns and operates roughly 2,200 retail fuel outlets and convenience stores in 16 Midwestern states, primarily Iowa, Missouri and Illinois. Casey's convenience stores operate under the Casey's name, and its retail fuel outlets sell under unbranded fuel banners.

Respondent Bucky's is a family-owned chain of retail fuel outlets and convenience stores headquartered in Omaha, Nebraska. It has approximately 170 stores in its network, including 94 company operated sites, and currently operates the largest chain of convenience stores in the Omaha metro area, under the Bucky's name, with additional stores in Chicago, Illinois. Bucky's retail fuel outlets sell under a variety of third-party branded and unbranded fuel banners.

III. The Proposed Acquisition

On November 8, 2020, Casey's entered into an agreement to acquire certain retail and wholesale fuel assets from Bucky's and related entities (the "Acquisition"). The Commission's Complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and that the Acquisition agreement constitutes a violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition for the retail sale of gasoline in seven local markets in Nebraska and Iowa, and by substantially lessening competition for the retail sale of diesel fuel in four local markets in Nebraska.

IV. The Retail Sale of Gasoline and Diesel Fuel

The Commission alleges that the relevant product markets in which to analyze the Acquisition are the retail sale of gasoline and the retail sale of diesel fuel. Consumers require gasoline for their gasoline-powered vehicles and can purchase gasoline only at retail fuel outlets. Likewise, consumers require diesel fuel for their diesel-powered vehicles and can purchase diesel fuel only at retail fuel outlets. The retail sale of gasoline and the retail sale of diesel fuel constitute separate relevant markets because the two are not interchangeable. Vehicles that run on gasoline cannot run on diesel fuel, and vehicles that run on diesel fuel cannot run on gasoline.

The Commission alleges that the relevant geographic markets in which to assess the competitive effects of the Acquisition with respect to the retail sale of gasoline are seven local markets in and around the following cities: Omaha, Nebraska; Papillion, Nebraska, and Council Bluffs, Iowa. The relevant geographic markets in which to assess the competitive effects of the Acquisition with respect to the retail sale of diesel fuel are four local markets in and around the following cities: Omaha, Nebraska and Papillion, Nebraska.

The geographic markets for retail gasoline and retail diesel fuel are highly localized, depending on the unique circumstances of each area. Each relevant market is distinct and fact-dependent, reflecting many considerations, including commuting patterns, traffic flows, and outlet characteristics. Consumers typically choose between nearby retail fuel outlets with similar characteristics along their planned routes. The geographic markets for the retail sale of diesel fuel are similar to the corresponding geographic markets for retail gasoline, as many diesel fuel consumers exhibit preferences and behaviors similar to those of gasoline consumers.

The Acquisition would substantially lessen competition in each of these local markets, resulting in seven highly concentrated markets for the retail sale of gasoline and three highly concentrated markets for the retail sale of diesel fuel. Retail fuel outlets compete on price, store format, product offerings, and location, and pay close attention to competitors in close proximity, on similar traffic flows, and with similar store characteristics. In each of the local gasoline and diesel fuel retail markets, the Acquisition would reduce the number of competitively constraining independent market participants to three or fewer. The combined entity would be able to raise prices unilaterally in markets where Casey's and Bucky's are close competitors. Absent the Acquisition, Casey's and Bucky's would continue to compete head to head in these local markets.

Moreover, the Acquisition would enhance the incentives for interdependent behavior in local markets where only two or three competitively constraining independent market participants would remain. Two aspects of the retail fuel industry make it vulnerable to such coordination. First, retail fuel outlets post their fuel prices on price signs that are visible from the street, allowing competitors easily to observe each other's fuel prices. Second, retail fuel outlets regularly track their competitors' fuel prices and change their own in response. These repeated interactions give retail fuel outlets familiarity with how their competitors price and how changing prices affect fuel sales.

Entry into each relevant market would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects arising from the Acquisition. Significant entry barriers include the availability of attractive real estate, the time and cost associated with constructing a new retail fuel outlet, and the time associated with obtaining necessary permits and approvals.

V. The Consent Agreement

The proposed Order would remedy the Acquisition's likely anticompetitive effects by requiring Casey's to divest certain Casey's and Bucky's retail fuel assets to Western Oil II, LLC and Danco II, LLC (collectively "Western Oil") in each local market. Western Oil is an

experienced operator or supplier of retail fuel sites and will be a new entrant into the local markets.

The proposed Order requires that the divestiture be completed no later than 10 days after Casey's consummates the Acquisition. The proposed Order further requires Casey's and Bucky's to maintain the economic viability, marketability, and competitiveness of each divestiture asset until the divestiture to Western Oil is complete.

In addition to requiring outlet divestitures, the proposed Order requires Respondents to provide the Commission notice before acquiring retail fuel assets within a fixed distance of any Casey's outlet in a market involving a divestiture for ten years. The prior notice provision is necessary because an acquisition in close proximity to divested assets likely would raise the same competitive concerns as the Acquisition and may fall below the Hart-Scott-Rodino Act premerger notification thresholds.

The Consent Agreement contains additional provisions designed to ensure the effectiveness of the relief. For example, Respondents have agreed to an Order to Maintain Assets that will issue at the time the proposed Consent Agreement is accepted for public comment. The Order to Maintain Assets requires Respondents to operate and maintain each divestiture outlet in the normal course of business, through the date the Respondents complete the divestiture. The proposed Order also includes a provision that allows the Commission to appoint an independent third party as a Monitor to oversee the Respondents' compliance with the requirements of the Order.

The purpose of this analysis is to facilitate public comment on the Consent agreement, and the Commission does not intend this analysis to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

AMAZON.COM, INC.,
AND
AMAZON LOGISTICS, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4746; File No. 192 3123
Complaint, June 9, 2021 – Decision, June 9, 2021

This consent order addresses Amazon.com, Inc.'s operation of Amazon Flex, a gig economy program through which consumers can become "drivers" for Amazon and, using their own vehicles, deliver products and groceries to Amazon customers. The complaint alleges that Amazon has violated Section 5 of the Federal Trade Commission Act by misrepresenting to both customers and drivers that it would give drivers 100% of customer tips in addition to the pay Amazon offered. The consent order prohibits Amazon from misrepresenting to any consumer, including both customers and drivers: (a) the income a driver is likely to earn, (b) the amount Amazon will pay drivers, (c) that Amazon will give drivers customer tips in addition to Amazon's contribution to drivers' earnings, (d) the percentage or amount of any customer tip a driver will receive, or (e) that any amount customers pay is a tip.

Participants

For the *Commission*: *Elizabeth C. Scott, Claire Stewart,* and *Guy G. Ward.*

For the *Respondents*: *James Howard, David Maas, Chris Renner*, and *Steve Rummage, Davis Wright Tremaine LLP; Maureen K. Ohlhausen* and *Andrew George, Baker Botts LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Amazon.com, Inc., a corporation, and Amazon Logistics, Inc., a corporation (collectively, "Amazon" or "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Amazon.com, Inc. is a Delaware corporation with its principal office or place of business at 410 Terry Avenue North, Seattle, Washington, 98126.

2. Respondent Amazon Logistics, Inc. is a Delaware Corporation with its principal office or place of business at 410 Terry Avenue North, Seattle, Washington, 98126. Amazon Logistics, Inc. is a wholly owned subsidiary of Amazon.com, Inc.

3. Respondents advertise and sell products, using drivers to deliver them.

4. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Respondents' Business Activities

5. Amazon offers various products, including books, electronics, household goods, apparel, groceries, and other items that consumers purchase online through Amazon websites and smartphone applications.

6. In 2015, Amazon launched Amazon Flex, a service through which consumers can sign up as drivers to deliver products to Amazon customers. Amazon pays drivers for making deliveries, and for some deliveries, allows customers to tip their drivers.

7. Amazon consistently has represented both to Amazon Flex drivers and to customers that it will pass on 100% of tips to drivers. In fact, for a period of over two and a half years, without consumers' permission, Amazon secretly used nearly a third of customer tips to subsidize its own pay to drivers.

8. Amazon continued to divert drivers' tips during this time despite hundreds of driver complaints about the practice, critical media reports, and internal recognition that its conduct was a "reputation tinderbox." Through these practices, Amazon ultimately pocketed over $61 million in tips meant for drivers.

Amazon Flex

9. In 2015, Amazon launched Amazon Flex, through which it hires drivers (also known as "delivery partners") to deliver products for Amazon. At various times relevant to this complaint, Amazon offered to pay drivers to deliver packages to customers of its various services, including Amazon.com, Prime Now (household items), AmazonFresh (groceries), and Amazon Restaurants (restaurant meals).

10. To qualify to be a driver for Amazon Flex, consumers must be over twenty-one years of age with a car and a valid driver's license. They also must install the Amazon Flex App (the "App") on their smartphones. Among other things, the App includes Amazon's terms of service for drivers and answers to frequently asked questions ("FAQs").

11. According to Amazon's terms of service, Amazon Flex drivers are treated as independent contractors who must pay for their own gas, insurance, vehicle repairs, and other expenses.

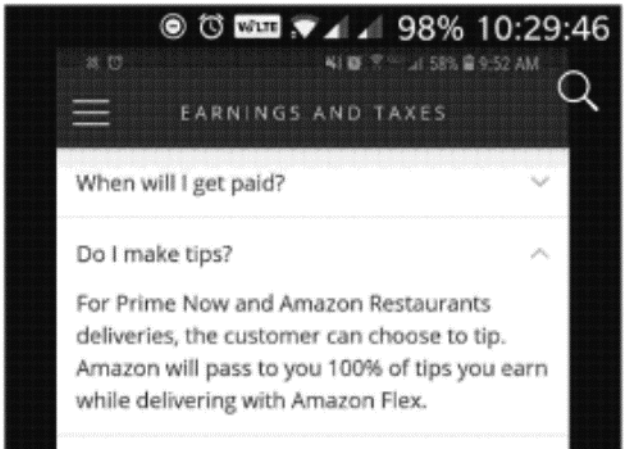
Amazon's Representations to Prospective Drivers About Tips and Pay

12. Through widely disseminated advertisements, websites, and the App, Amazon has represented that Amazon Flex drivers will receive 100% of customer tips.

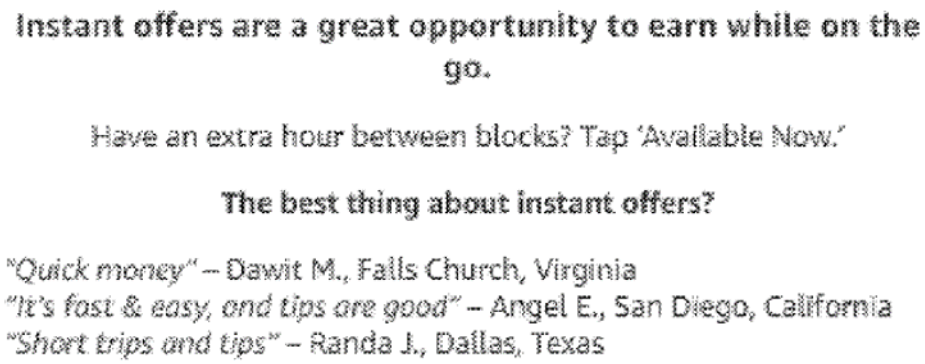
13. For example, the FAQs in the Amazon Flex App answer the question "Will I receive tips?" by promising that drivers will receive 100% of their tips:

> For Prime Now, AmazonFresh, and store deliveries, the customer can choose to tip. **You will receive 100% of the tips you earn** while delivering with Amazon Flex.

14. An earlier version of the FAQs promised that Amazon "will pass to you 100% of tips you earn," as shown in the following screenshot from May 2018:



15. Amazon's recruitment ads also promoted the benefits of tip-eligible deliveries, including quotes from drivers describing tips as one of the "best thing[s]" about "Instant Offers," one of the delivery options within Amazon Flex:



16. When drivers enroll in Amazon Flex, they are required to accept terms of service that make similar representations about driver tips, promising that Amazon will pay drivers "service fees in the amounts indicated in the Amazon Flex app at the time of acceptance" and separately guaranteeing that drivers will receive 100% of their tips. Amazon's original terms of service for Amazon Flex, for example, promised to "provide [drivers] with any tips you earn" (emphasis added):

> Depending on the location in which the Services are provided and the product or business to which the Services relate, Amazon's customers may be able to provide a tip in connection with the fulfillment of their orders and **Amazon will provide you with any tips you earn**.
>
> Amazon's current terms of service, effective September 22, 2016, promise that "Amazon will pass through any tips payable to you."

17. In conjunction with its representations about drivers receiving 100% of customer tips, Amazon also regularly advertises on its website and in recruitment ads on platforms such as Google and Craigslist that Amazon Flex drivers will earn an hourly rate of $18 to $25.

18. The following is a typical recruitment ad for Amazon Flex promoting driver earnings of $18 to $25 per hour:

Amazon Flex is expanding in your area for a limited time!

Earn $18-25/hr delivering packages with Amazon.
All you need is a car, an iPhone or Android smartphone, and some free time.
This is a great opportunity to be your own boss: deliver when you want and make some extra cash.

GET STARTED NOW

Why Amazon Flex?

Flexible hours: Schedule ahead or pick up any available delivery block of time
Great pay: Make $18-25/hr
Available work: Delivery opportunities available 7 days a week

To get started:

You must be 21 years old
Have a car and a valid driver's license
Have an iPhone or Android smartphone

19. Amazon's FAQs on its website promoted the benefits of tip-eligible deliveries, noting that drivers could earn up to $18-$25 per hour delivering for Amazon, and could "make more" by making deliveries that are eligible for tips:

Earnings

How much will I earn delivering with Amazon Flex?
Delivering with Amazon Flex, you may earn up to $18 - $25 an hour. Amazon pays by the delivery block.

How can I make more delivering with Amazon Flex?
Use a large vehicle: You can earn more by driving a larger vehicle, like an SUV or van that can fit more packages, to make you eligible to receive offers for longer delivery routes.
Earn more during our busiest times: During peak delivery times, delivery blocks may be offered at higher rates. A notification will alert you that increased rates are available.
Make deliveries eligible for tips: Customers are given the opportunity to tip you when ordering from Prime Now, AmazonFresh, and Amazon Restaurants.

20. Based on Amazon's representations, drivers expect that they will earn the hourly rate Amazon promised plus 100% of customer tips.

Amazon's Specific Delivery Offers to Amazon Flex Drivers

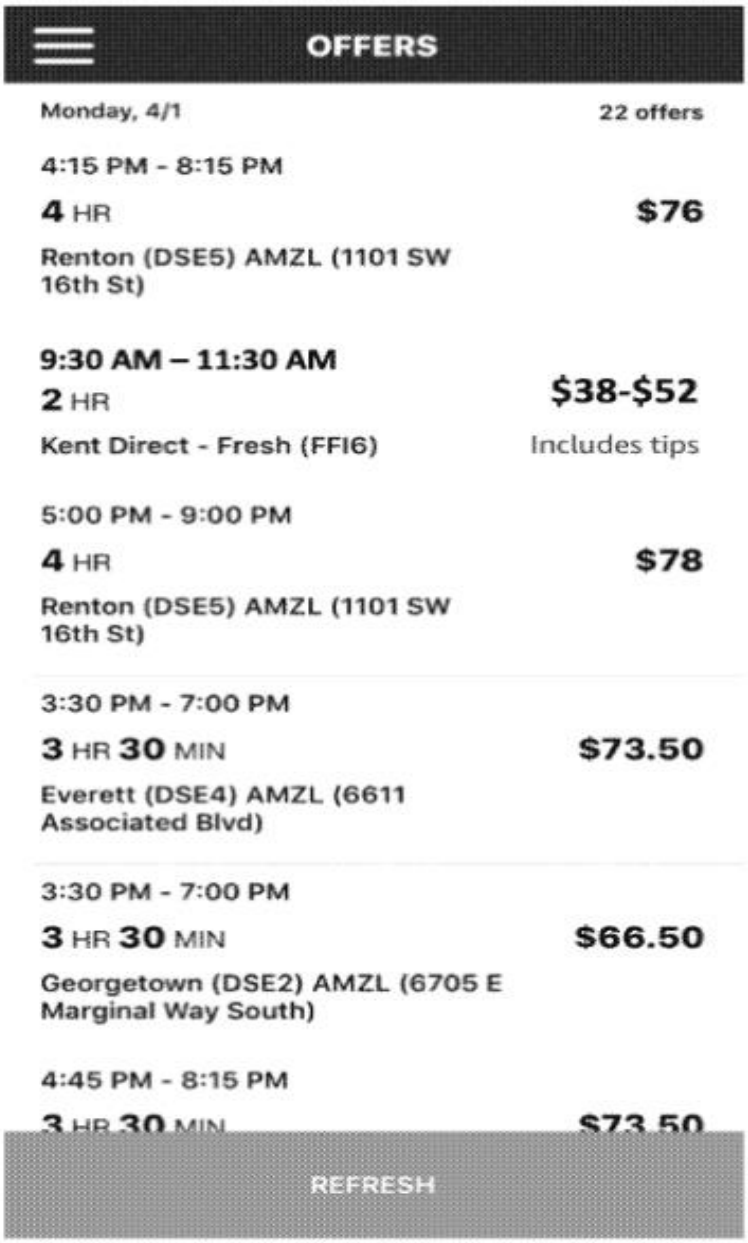
21. Once hired, Amazon Flex drivers can use the App to view and accept specific delivery gigs, known as "delivery blocks." Each delivery block consists of a certain number of deliveries to be completed within a certain period of time, typically one to four hours. The App's "Offers" screen displays the available delivery blocks, the duration of each block, and the payment offered to the driver for the block.

22. Amazon decides which delivery blocks are eligible for tips. At the outset of the Amazon Flex program, only Prime Now deliveries were eligible for tips, but Amazon expanded its tip-eligible deliveries over time to also include AmazonFresh and Amazon Restaurants.

23. For deliveries that are not tip-eligible, Amazon offers drivers a flat rate.

24. For deliveries that are tip-eligible, Amazon offers drivers a range of payment to complete the delivery block. Amazon typically offers a range of $18 to $25 per hour, or multiples thereof, sometimes more in certain areas, and treats the bottom of this pay range as the guaranteed minimum payment the driver will receive for completing the delivery block.

25. For example, below is a representative screenshot of several delivery blocks Amazon offered:

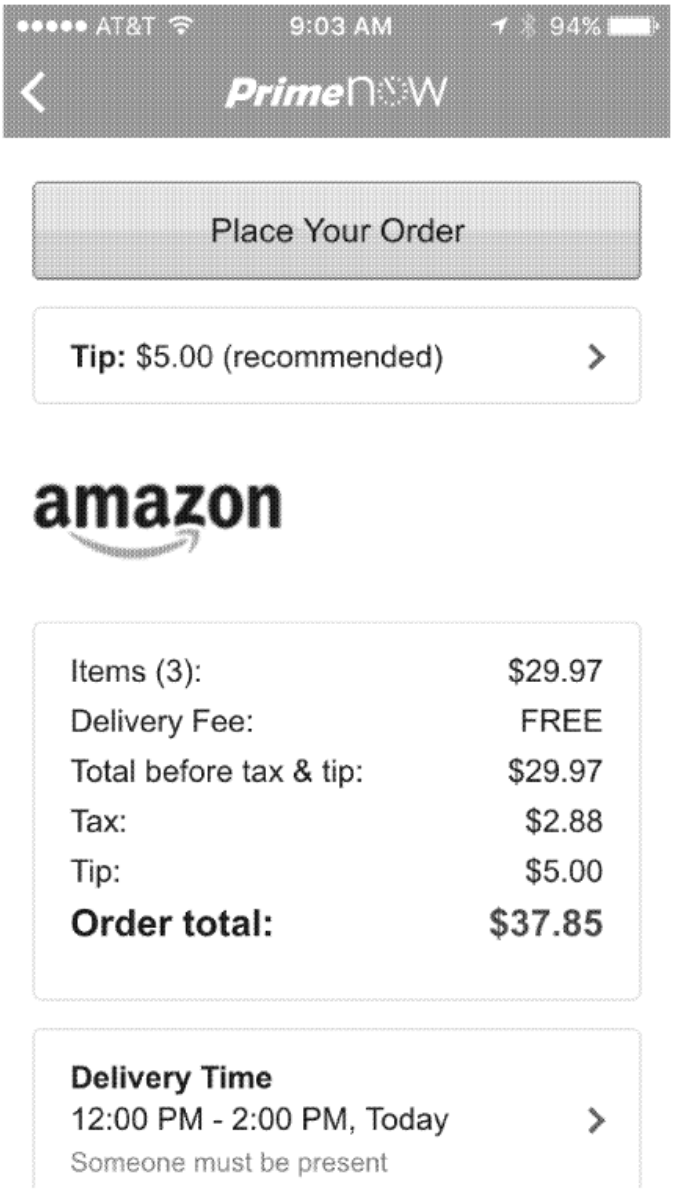


In the above example, only the second delivery block is eligible for tips. The first block offers the driver $76 for four hours. The second block offers the driver a range of $38 to $52 for two hours and, because that block is eligible for tips, displays the phrase “Includes tips” below the range.

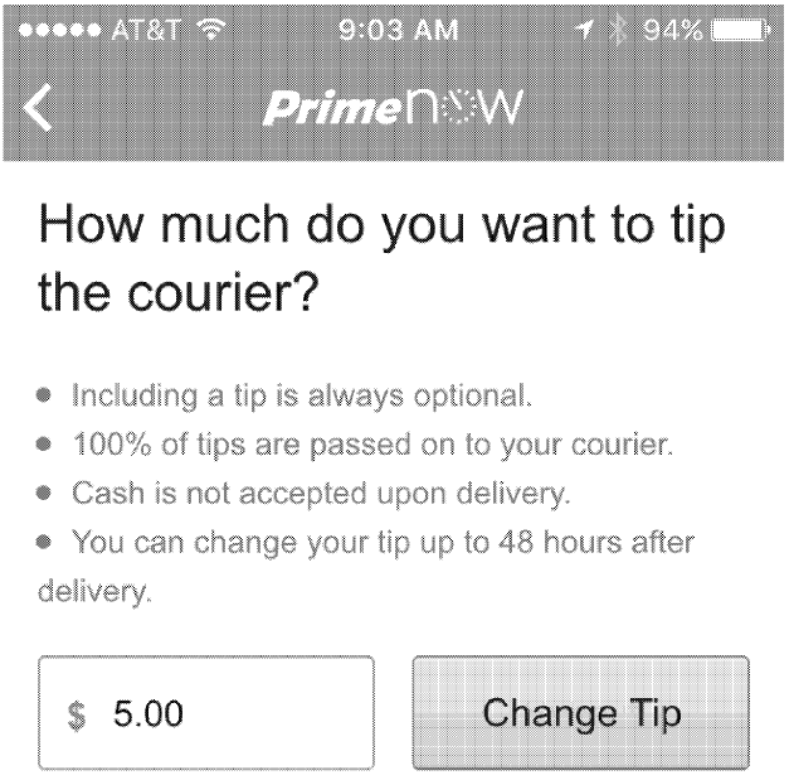
Amazon's Claims to Customers About Tips

26. Apart from its representations to drivers, Amazon also assures customers who place orders for delivery through the Amazon Flex program that 100% of their tips will be passed on to drivers. When an Amazon customer places an order that is eligible for tips through an Amazon website or mobile application (for example, the Prime Now App), the customer encounters a screen displaying the order that includes a prepopulated tip for the driver.

27. An example of a screen displaying an order that includes a prepopulated tip for the driver is shown below:



28. When customers click on the recommended tip amount, the next screen explains that "100% of tips are passed on to your courier." The screen also indicates that "Cash is not accepted upon delivery," thereby encouraging customers to leave tips through the App:



29. Amazon experimented with different prepopulated tip percentages or amounts to determine which ones generate the highest tips. Amazon referred to this internally as its "Get More Tip$ Project."

Amazon Used Customer Tips to Subsidize its Payments to Drivers

30. Contrary to Amazon's representations to its drivers and customers that it would provide drivers 100% of customer tips, Amazon used tens of millions of dollars in customer tips to subsidize its payments to drivers. Amazon concealed from drivers the amount that customers had tipped for their deliveries.

31. At the outset of the Amazon Flex program, from 2015 through late 2016, Amazon paid drivers at least $18 per hour plus 100% of customer tips, as represented to drivers at the time of enrollment. During that period, Amazon also displayed to drivers the amount they had been tipped.

32. Beginning in late 2016, however, Amazon made changes to the program to reduce its costs. At that point, Amazon implemented what it called "variable base pay" for Amazon Flex drivers on a rolling basis in various locations across the country. Under the variable base pay

approach, for over two and a half years, Amazon secretly reduced its own contribution to drivers' pay to an algorithmically set, internal "base rate" using data it collected about average tips in the area. The base rate varied by location and sometimes varied within the same market. But this algorithmically set "base rate" often was below the $18-$25 per hour range that Amazon had promised at the time of drivers' enrollment and in specific block offers.

33. Under this approach, rather than provide drivers 100% of tips in addition to the range it offered drivers in a delivery block, Amazon treated the bottom of the range as its guaranteed minimum payment and often used drivers' tips to meet that minimum. For example, for a one-hour block offering $18-$25, if Amazon's base rate in the particular location was $12, and the customer left a $6 tip for the driver, then Amazon paid the driver only $12 and used the full customer tip of $6 to reach its minimum payment of $18 to the driver. In the App, Amazon then displayed driver earnings as the combined total of its base rate and any customer tip—it did not separately display to drivers the amount of any customer tip.

34. This practice contradicted Amazon's representation to drivers and consumers' expectations that drivers would receive 100% of customer tips on top of their offered pay. Through variable base pay, Amazon harmed both its drivers and its customers. Drivers received less than Amazon promised them for completing delivery blocks, and customers paid over $61 million in tips meant for drivers that Amazon instead diverted to subsidize its own labor costs.

Amazon's Efforts to Conceal its Unlawful Practices

35. When it instituted variable base pay, Amazon decided not to seek drivers' consent or otherwise notify them that it was changing its compensation practices. Amazon did not inform drivers or the media about the changes. At the same time, Amazon also did not change the earnings claims it had been making to drivers since the inception of the Amazon Flex program, nor did it adjust its promises to customers or drivers that 100% of customer tips would be passed on to drivers.

36. In planning for the transition to variable base pay, Amazon discussed internally how to handle the change to variable base pay with drivers and "what level of detail about earnings to show" drivers. Amazon considered different versions of earnings display screens that showed or concealed the breakdown between Amazon's "base rate" and tips.

37. Ultimately, when it implemented variable base pay, Amazon decided to obscure from drivers that it was reducing their pay, and began reporting their earnings as a single lump sum that hid any distinction between customer tips and pay from Amazon. Based on the information Amazon provided, drivers could not tell whether Amazon had contributed its minimum for the delivery block or a lesser amount, nor could drivers tell the amount of any customer tip.

38. Amazon knew that its new compensation policies would reduce some drivers' earnings. Rather than seek to modify its terms of service with its drivers or inform them of the policy change, Amazon instead chose to conceal the change and to respond only to individual drivers who questioned their reduced compensation. As one Amazon employee explained it, the

company "did not want to communicate any pricing changes to [drivers], so we are only 'reacting' to any questions." In fact, Amazon prepared canned responses to questions it anticipated receiving from drivers, including "Is Amazon taking our tips?" and "Why did I only receive the minimum payment?" Amazon's canned responses continued to reiterate that its "earnings commitment to delivery partners has not changed—delivery partners still earn $18-25 per hour including 100% of customer tips," which only obscured that Amazon was diverting drivers' tips to its own use.

39. Although Amazon continued promising drivers 100% of their tips, some drivers suspected that Amazon was no longer making good on this promise. Following the implementation of variable base pay, Amazon received hundreds of complaints and inquiries from drivers expressing concern about reduced earnings and asking whether Amazon was breaking its promise to pass through 100% of their tips.

40. Many drivers reported to Amazon that they were expecting to receive 100% of their tips in addition to the rate Amazon promised. For example, one driver asked "what happened to drivers receiving 100% of all tips?" Another driver asked for clarification because he "thought [drivers] were paid $18-$24/hr plus 100% of the tip," and asked if drivers were "still getting paid $18 per hour plus 100% of [their] tips." Other complaints stated that "amazon [wa]s supposed to pay 18.00 minimum Base pay with 100% tips" and that drivers had "not been getting 100% of the tip." Drivers also asked Amazon for breakdowns of tips and its own payout for each delivery, including one who said he expected "to make 100% of [his] money tips as amazon promised." Drivers also questioned Amazon's representations to customers, including one who pointed out that "amazon states 100% of that tip goes to the driver when in fact it sounfs [sic] like the customer is paying the operaring [sic] cost of a delivery for amazon and not a tip like they are told."

41. In May 2018, a driver sent an email to Amazon with the subject line, "My tips not being given to me????" The driver complained that he was "supposed to get 100% of [his] tips," but had not received a $5 tip that a customer showed him in the App. The driver stated that he was "shocked" and "just felt cheated as also [his] friend did as a customer." The driver added that the customer "said he would follow up with Amazon because he also felt cheated saying he did not leave a tip for Amazon that it was for me the driver." The driver attached to his email a screenshot of Amazon's FAQs stating that "Amazon will pass to you 100% of tips you earn."

42. When drivers complained, Amazon sent them the canned email responses it had prepared. These canned emails stated that Amazon was providing drivers "100% of customer tips" and did not explain that Amazon had changed its practices by paying drivers less than promised and making up the difference with their tips.

43. After implementation of variable base pay, Amazon Flex drivers also posted complaints on social media about Amazon reducing their pay or "stealing" their tips. Amazon employees monitored and circulated these complaints internally.

44. Amazon employees also acknowledged internally that Amazon was using customer tips to subsidize its minimum payments to drivers, and that these subsidies were saving

Amazon millions of dollars at the drivers' expense. In August 2018 emails, Amazon employees referred to the issue as "a huge PR risk for Amazon" and warned of "an Amazon reputation tinderbox."

45. In late 2018 and early 2019, news articles suggested that Amazon was secretly using customer tips to fund guaranteed payments to drivers. On February 5, 2019, a reporter emailed Amazon to ask whether it employed such a practice, explaining, "there's a concern that it constitutes consumer fraud because the people leaving tips aren't made aware that the tip will cover a guaranteed minimum payment, or that by leaving a tip, they could be lowering the fraction of that minimum payment that is covered by the company." Amazon dodged the question, responding that "our pay commitment to delivery partners has not changed since we launched the Amazon Flex program – delivery partners still earn $18-$25 per hour, including 100% of tips – and on average drivers earn over $20/hour." Simultaneously, however, an Amazon employee acknowledged internally that the reporter was "definitely zero'ing [sic] in on the right question."

46. Despite taking customer tips to subsidize its own advertised minimum pay in numerous markets, Amazon continued to misrepresent in its terms of service and FAQs that it would pass through 100% of tips to drivers. Amazon also continued to advertise the same pay range of $18-$25 on multiple platforms and the opportunity to "make more" through tip-eligible deliveries. And Amazon continued urging customers to "tip the courier" while assuring them that "100% of tips are passed on to your courier."

47. Amazon continued these practices for over two and a half years despite hundreds of complaints from drivers, critical media reports, and internal recognition that it was misguiding consumers.

Amazon's Changes After Learning of the FTC's Investigation

48. Amazon changed its practices only after learning it was under investigation by the FTC. On May 23, 2019, the FTC issued a civil investigative demand ("CID") to Amazon seeking information and records relating to Amazon Flex, including Amazon's representation that Amazon Flex drivers receive 100% of their tips. The CID informed Amazon that the FTC was investigating whether Amazon had "deceived consumers regarding compensation of Amazon Flex Drivers, in violation of the FTC Act, 15 U.S.C. § 45, and whether Commission action to obtain monetary relief would be in the public interest."

49. On August 22, 2019, Amazon announced to its current drivers an "Updated Earnings Experience," which was similar to the original compensation program that had been in effect from 2015 through late 2016 at the start of the Amazon Flex program. After the August 2019 announcement, Amazon began separately displaying in the App the amount it would pay drivers and the tips for each delivery block. According to Amazon, it now pays drivers the full amount offered in a delivery block and, separately, passes on customer tips. In announcing the change, Amazon stated that, "For deliveries that give customers the option to tip, you always receive 100% of the tips."

Count I
Deceptive Tipping Claims

50. In numerous instances in connection with the Amazon Flex delivery service, Respondents have represented, directly or indirectly, expressly or by implication, that Amazon would give drivers 100% of customer tips in addition to the pay Amazon offered.

51. In fact, in numerous instances in which Respondents have made this representation, Amazon has not given drivers 100% of customer tips in addition to the pay Amazon offered. Therefore, the representation is false or misleading.

Violations of Section 5

52. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this 9th day of June, 2021, has issued this Complaint against Respondents.

By the Commission.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent

Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

   a. Respondent Amazon.com, Inc., a Delaware corporation with its principal office or place of business at 410 Terry Avenue North, Seattle, Washington, 98126.

   b. Respondent Amazon Logistics, Inc., a Delaware corporation with its principal office or place of business at 410 Terry Avenue North, Seattle, Washington, 98126. Amazon Logistics, Inc. is a wholly owned subsidiary of Amazon.com, Inc.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "Respondents" means Amazon.com, Inc., and Amazon Logistics.com, Inc., and their successors and assigns, individually or collectively, or in any combination.

B. "Driver" means someone, regardless of employment status with Respondents, who provides delivery services by accepting individual offers to make a single delivery or set of deliveries to Respondents' customers.

Provisions

I. Prohibited Misrepresentations

IT IS ORDERED that Respondents, and Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with any delivery program or service using Drivers, must not misrepresent, expressly or by implication:

A. The income a Driver is likely to earn;

B. The amount Respondents will pay Drivers;

C. That Respondents will give Drivers customer tips in addition to Respondents' contribution to Drivers' earnings;

D. The percentage or amount of any customer tip a Driver will receive; or

E. That any amount customers pay is a tip.

II. Prohibition Against Unauthorized Use of Tips

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with any delivery program or service using Drivers, must not change the extent to which they use a Driver's tips toward the Respondents' contribution to the Driver's earnings without first obtaining express informed consent from the Driver.

III. Monetary Relief

IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $61,710,583, which Respondents stipulate their undersigned counsel holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 8 days of the effective date of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

C. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

D. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

E. The facts alleged in the Complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

F. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct

redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondents have no right to challenge any activities pursuant to this Provision.

IV. Driver Information

IT IS FURTHER ORDERED that Respondents must directly or indirectly provide sufficient Driver information to enable the Commission to efficiently administer consumer redress to Drivers. Respondents represent that they have provided this redress information to the Commission. If a representative of the Commission requests in writing any information related to redress, Respondents must provide it, in the form prescribed by the Commission representative, within 14 days.

V. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 3 years after the issuance date of this Order, each Respondent must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members of Respondents; (2) all employees, agents, and representatives of Respondents managing conduct related to the subject matter of this Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

VI. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which each Respondent must:

1. identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent;

2. identify all of that Respondent's businesses that could violate this Order by all of their names, telephone numbers, and physical, postal, email, and Internet addresses;

3. describe the activities of each business, including changes to and representations about Drivers' tips or compensation, the means of advertising, marketing, and sales, and the involvement of any other Respondent;

4. describe in detail whether and how that Respondent is in compliance with each Provision of this Order; and

5. provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

B. For 10 years after the issuance date of this Order, each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. any designated point of contact; or

2. the structure of any Respondent or any entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal

Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "In re Amazon.com, Inc., FTC File No. 1923123."

VII. Recordkeeping

IT IS FURTHER ORDERED that Respondents must create certain records for 10 years after the issuance date of the Order, and retain each such record for 5 years. Specifically, each Respondent, in connection with any delivery program or service using Drivers, must create and retain the following records:

A. accounting records showing the revenues from all goods or services sold;

B. personnel records showing, for each Driver and each person who participates in conduct related to the subject matter of the Order, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. records of all consumer complaints related to Drivers' tips or earnings, whether received directly or indirectly, such as through a third party, and any response;

D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission; and

E. a copy of each unique advertisement or other marketing material concerning the subject matter of this Order.

VIII. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the

Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

IX. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate on June 9, 2041, or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Concurring Statement

JOINT STATEMENT OF COMMISSIONER NOAH JOSHUA PHILLIPS AND ACTING CHAIRWOMAN REBECCA KELLY SLAUGHTER

The internet-enabled gig economy is substantial and continues to grow. According to one study, U.S. families earning income from the internet-enabled gig economy rose from under 2% of the sample in 2013 to 4.5% by early 2018, with more than 5 million U.S. households earning some income from this type of work by 2018.[1] Another study estimates worldwide transaction volume of $204 billion in 2018, which will more than double to $455 billion by 2023.[2]

Consumer demand for the services offered by the gig economy surely contributes to this growth. But it would not be possible without the contributions of drivers, shoppers, designers, and other gig workers, whether seeking supplemental income or relying on one gig or a patchwork of gigs to get by.

The impact of the internet-enabled gig economy on workers is a matter of robust debate in Congress, state legislatures, popular referenda, academia, and elsewhere. The two authors of this joint statement may not agree on every aspect of this debate, including whether this novel business model is, on net, beneficial for consumers and workers.

Where we do agree—and what this case reflects—is that the platforms that facilitate this gig economy must treat their workers fairly and non-deceptively, just as they must consumers, and that the Federal Trade Commission should work to ensure that they do. That is why this case resolving our investigation into Amazon.com, Inc. and its subsidiary Amazon Logistics, Inc.'s (collectively, "Amazon") treatment of delivery drivers is so important.

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1 *See* Diana Farrell, Fiona Greig & Amar Hamoudi, *The Online Platform Economy in 2018: Drivers, Workers, Sellers and Lessors*, JPMorgan Chase & Co. Institute (2018) at 23, https://www.jpmorganchase.com/content/dam/jpmc/jpmorgan-chase-and-co/institute/pdf/institute-ope-2018.pdf. Particularly because of high turnover, with many workers spending only a few months participating, estimates of the gig economy are difficult and inconsistent. Another study estimated that there were 1.6 million American workers in the internet-enabled gig economy in 2017, or 1% of the entire workforce, still a substantial number. *See* U.S. Bureau of Labor Statistics, *Electronically mediated work: new questions in the Contingent Worker Supplement*, U.S. Dep't of Labor (Sept. 2018), https://www.bls.gov/opub/mlr/2018/article/electronically-mediated-work-new-questions-in-the-contingent-worker-supplement htm.

2 *See* Mastercard & Kaiser Associates, *The Global Gig Economy: Capitalizing on a ~$500 Billion Opportunity* (May 2019) at 2, https://newsroom.mastercard.com/wp-content/uploads/2019/05/Gig-Economy-White-Paper-May-2019.pdf. Another study estimated that spending on gig platforms was increasing 43% year-on-year in 2018. *See* Uber, *Working Together: Priorities to enhance the quality and security of independent work in the United States* (Aug. 10, 2020) at 5, https://ubernewsroomapi.10upcdn.com/wp-content/uploads/2020/08/Working-Together-Priorities.pdf ("Uber Report") (citing Staffing Industry Analysts, The Gig Economy and Human Cloud Landscape (2019)). By way of example, the number of Uber drivers in the U.S. has grown from 160,000 in 2014 to 1 million in 2020. *See* Jonathan V. Hall & Alan B. Krueger, *An Analysis of the Labor Market for Uber's Driver-Partners in the United States* at 1 (Princeton U. Indus. Relations Section, Working Paper No. 587, Jan. 2015), https://dataspace.princeton.edu/bitstream/88435/dsp010z708z67d/5/587.pdf; Uber Report.

Concurring Statement

The conduct alleged in the complaint is outrageous. According to the complaint, Amazon recruited delivery drivers (and, possibly, attracted customers) by promising that drivers would collect all the tips awarded them by Amazon customers. At a certain point, it decided to divert thirty percent of those tips from drivers to the company to subsidize the amounts it had committed to paying its drivers. The complaint alleges that Amazon then went to great lengths to ensure that no one would figure out what it was doing, by changing the way it presented earnings to drivers and drafting misleading answers for service representatives to give to drivers upset at being short-changed.

Our settlement with Amazon ensures that these drivers will get back every dollar that was promised, every dollar that a customer chose to give as a tip for their service. That is a good result for an enforcement action under the FTC Act, the law we apply today. But we believe that, given the importance of candor and fairness to workers in the gig economy, our current authorities could be improved. Congress can give us direct penalty authority to deter deception aimed at workers in the internet-enabled gig economy and rulemaking authority under the Administrative Procedure Act to address systemic and unfair practices that harm those workers.

Clear rules and the threat of substantial civil penalties can deter wrongdoing. The authors of this statement do not always agree on the proper scope of rulemaking and penalty authority, but we do agree here. Authorizing the FTC to assess penalties to deter similar lawbreaking will help gig workers and make labor markets more efficient. The internet-enabled gig economy is new, innovative, and growing. We believe that the modest reforms we propose here can help gig workers have a fairer shake at getting their benefit of the bargain from that growth, too.

STATEMENT OF COMMISSIONER ROHIT CHOPRA

Today, the FTC is sanctioning Amazon.com (NASDAQ: AMZN) for expanding its business empire by cheating its workers. In 2015, Amazon launched Flex, a package delivery service that was widely seen as a challenge to FedEx and UPS.[1] To recruit drivers, the company promised to pay them a minimum of $18 to $25 an hour, plus tips.[2] But once the service was off the ground, in late 2016, Amazon changed course. The Commission's complaint charges that the company secretly began cutting its payments to drivers, and siphoning their tips to make up the difference.[3] In total, Amazon stole nearly one-third of drivers' tips to pad its own bottom line.

1 *See* Laura Stevens, *Amazon Drives Deeper Into Package Delivery*, WALL STREET J. (June 28, 2018), https://www.wsj.com/articles/amazon-drives-deeper-into-package-delivery-1530158460.

2 Compl., In the Matter of Amazon, Inc., Fed. Trade Comm'n File 1923123, ¶¶ 17-20.

3 *Id.* ¶¶ 30-34.

This theft did not go unnoticed by Amazon's drivers, many of whom expressed anger and confusion to the company. But, rather than coming clean, Amazon took elaborate steps to mislead its drivers and conceal its theft, sending them canned responses that repeated the company's lies. The complaint charges that Amazon executives chose not to alter the practice, instead viewing drivers' complaints as a "PR risk," which they sought to contain through deception.[4]

Amazon's scheme ended after it was exposed, but it likely produced significant benefits for the company. First, by promising a higher base pay initially, Amazon was likely able to recruit drivers more quickly, particularly as the company tried to stand up Amazon Flex in time for the holiday season.[5] Second, and most directly, Amazon's bait-and-switch allowed the company to pocket more than $60 million in workers' tips.[6] And finally, by allegedly misleading its workers about their earnings, the company made it less likely that drivers would seek better opportunities elsewhere, helping Amazon attract and retain workers in its quest to dominate.[7]

By the time this scheme was exposed in late 2019, Amazon Flex was far more established. In fact, that same year, the company quietly disclosed that it was slashing drivers' minimum pay by more than 15 percent, relative to what it promised in 2015.[8] This conduct raises serious questions about how Amazon amassed and wielded its market power. Fortunately, today's action to redress the company's victims does not prevent the FTC or state attorneys general from assessing whether Amazon has engaged in a broader pattern of unfair practices in violation of the antitrust laws.

Today's order provides substantial redress to the families victimized by Amazon's anticompetitive deception. However, this cannot be the only action we take to protect workers and families from dominant middlemen. The FTC will also need to carefully examine whether

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4 *Id.* ¶ 35-47.

5 Shortly after launching Flex, Amazon noted that it was trying to "ramp quickly" in anticipation of the holiday season, Prime Day, and other periods of high demand. *See* Becky Yerak, *Uber for packages? Amazon looking for drivers to deliver goods*, CHICAGO TRIBUNE (Oct. 9, 2015), https://www.chicagotribune.com/business/ct-amazon-flex-chicago-1009-biz-20151009-story html.

6 Compl., *supra* note 2, ¶ 8.

7 During the period of the alleged lawbreaking, gig workers were reportedly in high demand. *See* Christopher Mims, *In a Tight Labor Market, Gig Workers Get Harder to Please*, WALL STREET J. (May 4, 2019), https://www.wsj.com/articles/in-a-tight-labor-market-gig-workers-get-harder-to-please-11556942404.

8 After Amazon's scheme was exposed, the company indicated that it would begin paying drivers a minimum of $15 per hour. *See* Chaim Gartenberg, *Amazon will no longer use tips to pay delivery drivers' base salaries*, THE VERGE (Aug. 22, 2019), https://www.theverge.com/2019/8/22/20828550/amazon-delivery-drivers-tips-end-base-salaries-flex. This was a significant reduction from the $18 promised in 2015, particularly when adjusted for cost of living.

tech platforms are engaging in anticompetitive conduct that hoodwinks workers and crushes law-abiding competitors.[9]

The Commission has historically taken a lax approach to worker abuse, entering no-consequences settlements even in naked wage-fixing matters that are criminal in nature.[10] Despite broad pronouncements about a commitment to policing markets for anticompetitive conduct that harms workers,[11] the FTC has done little. I hope that today's action turns the page on this era of inaction.

I also agree with Acting Chairwoman Slaughter and Commissioner Phillips that preying on workers justifies punitive measures far beyond the restitution provided here, and I believe the FTC should act now to deploy dormant authorities to trigger civil penalties and other relief in cases like this one.[12]

Companies should succeed only when they compete, not when they cheat or abuse their power. While Amazon.com is one of the largest, most powerful, and most feared firms in the world, the company cannot be above the law. Regulators and enforcers in the United States and around the globe can no longer turn a blind eye.

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9 I have previously outlined certain steps that regulators can take to address anticompetitive practices in labor markets. Comment Submission of Commissioner Chopra to Department of Justice Initiative on Labor Market Competition (Sept. 18, 2019), https://www ftc.gov/public-statements/2019/09/comment-submission-commissioner-chopra-department-justice-initiative-labor.

10 In 2019, the FTC agreed to a no-consequences settlement with respondents charged with blatant wage-fixing. *See* Dissenting Statement of Commissioner Rohit Chopra In the Matter of Your Therapy Source, Neeraj Jindal and Sheri Yarbray, Fed. Trade Comm'n File No. 1710134 (Oct. 31, 2109), https://www.ftc.gov/public-statements/2019/10/dissenting-statement-commissioner-rohit-chopra-matter-your-therapy-source. Respondent Neeraj Jindal was later indicted by the United States Department of Justice. Press Release, U.S. Dep't of Justice, Former Owner of Health Care Staffing Company Indicted for Wage Fixing (Dec. 10, 2020), https://www.justice.gov/opa/pr/former-owner-health-care-staffing-company-indicted-wage-fixing.

11 *See, e.g.*, Press Release, Fed. Trade Comm'n, FTC and DOJ Release Guidance for Human Resource Professionals on How Antitrust Law Applies to Employee Hiring and Compensation (Oct. 20, 2016), https://www.ftc.gov/news-events/press-releases/2016/10/ftc-doj-release-guidance-human-resource-professionals-how.

12 Under its status quo approach, the FTC does not seek civil penalties for this type of abuse. But this can change. In the short term, the Commission can deploy its Penalty Offense Authority to apprise market participants, using existing administrative orders, that it is a penalty offense to recruit workers based on false earnings claims. *See Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority* (Oct. 29, 2020), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256. The Commission can also codify existing precedent into a Restatement Rulemaking to trigger penalties and damages for this type of fraud. *See* Statement of Commissioner Rohit Chopra Regarding the Report to Congress on Protecting Older Consumers, Fed. Trade Comm'n File No. P1444400 (Oct. 19, 2020) https://www.ftc.gov/public-statements/2020/10/statement-commissioner-rohit-chopra-regarding-report-congress-protecting. Such a rule would impose no burden on market participants, while ensuring real deterrence for practices that undercut workers and competitors.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order from Amazon.com, Inc. and Amazon Logistics, Inc. ("Amazon"). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

Amazon operates Amazon Flex, a gig economy program through which consumers can become "drivers" for Amazon and, using their own vehicles, deliver products and groceries to Amazon customers. Amazon pays drivers for making deliveries, and for some types of deliveries, allows customers to tip the drivers via the app or website used to place the order. Amazon consistently represents to both drivers and customers that it passes on 100% of customer tips to drivers. However, from late 2016 through August 2019, Amazon withheld nearly a third of the tips meant for drivers, about $61 million in total, despite its representations that it would provide drivers 100% of customer tips. Amazon continued diverting drivers' tips in this way for over two and a half years despite hundreds of complaints from drivers and critical media reports. Amazon changed its practices only after the FTC issued a Civil Investigative Demand to the company in May 2019.

The Commission's proposed complaint alleges that Amazon has violated Section 5 of the FTC Act. In particular, the proposed complaint alleges that Amazon misrepresented to both customers and drivers that it would give drivers 100% of customer tips in addition to the pay Amazon offered.

The proposed order includes equitable monetary relief and injunctive provisions to prevent Amazon from engaging in the same or similar acts or practices in the future. Part I of the proposed order prohibits Amazon from misrepresenting to any consumer, including both customers and drivers: (a) the income a driver is likely to earn, (b) the amount Amazon will pay drivers, (c) that Amazon will give drivers customer tips in addition to Amazon's contribution to drivers' earnings, (d) the percentage or amount of any customer tip a driver will receive, or (e) that any amount customers pay is a tip. Part II of the proposed order prohibits Amazon from changing the extent to which it uses a driver's tips toward Amazon's contribution to the driver's earnings without first obtaining express informed consent from the driver.

Part III of the proposed order requires Amazon to pay $61,710,583, the full amount of tips that Amazon improperly withheld from drivers. Part IV of the proposed order requires Amazon to provide sufficient information about drivers to enable the Commission to efficiently administer redress to drivers.

Parts V through VIII of the proposed order are reporting and compliance provisions. Part V requires acknowledgments of the order. Part VI requires Amazon to notify the Commission of changes in corporate status for 10 years and mandates that the company submit an initial compliance report to the Commission. Part VII requires Amazon to create certain documents

relating to its compliance with the order for 10 years and to retain those documents for a 5-year period. Part VIII mandates that the company make available to the Commission information or subsequent compliance reports, as requested.

Finally, Part IX states that the proposed order will remain in effect for 20 years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

Complaint

IN THE MATTER OF

FLO HEALTH, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4747; File No. 192 3133
Complaint, June 17, 2021 – Decision, June 17, 2021

This consent order addresses Flo Health, Inc.'s mobile application called the Flo Period & Ovulation Tracker, which collects and stores menstruation and fertility information about millions of users worldwide. The complaint alleges that Flo Health violated of Section 5(a) of the Federal Trade Commission Act by misrepresenting their use and disclosure of consumer's personal information, and compliance with the Privacy Shield Principles of Notice, Choice, Accountability for Onward Transfers, and Purpose Limitation. The consent order requires Flo Health to ask any party other than Flo Health, its service providers, or subcontractors, that has received "Health Information" about "Covered App Users" to destroy such information; and prohibits Flo Health from making false or deceptive statements regarding: (1) the purposes for which Flo Health or any entity to whom it discloses, collects, maintains, or uses personal information, including identifiable health information; (2) the extent to which consumers may exercise control over Flo Health's access, collection, maintenance, use, disclosure, or deletion of such information; (3) the extent to which Flo Health complies with any privacy, security, or compliance program, including the Privacy Shield; and (4) the extent to which Flo Health collects, maintains, uses, discloses, deletes, or permits or denies access to any Covered Information, or the extent to which Flo Health protects the availability, confidentiality, or integrity of Covered Information.

Participants

For the *Commission*: *Elisa Jillson* and *Miles Plant.*

For the *Respondents*: *David Kantrowitz* and *Brenda Sharton, Goodwin Procter LLP.*

COMPLAINT

The Federal Trade Commission ("FTC"), having reason to believe that Flo Health, Inc., a corporation ("Respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Flo Health, Inc. ("Flo Health") is a Delaware corporation with its principal office or place of business at 1013 Centre Road, Suite 403-B, Wilmington, Delaware 19805.

2. Respondent has developed, advertised, offered for sale, sold, and distributed the Flo Period & Ovulation Tracker, a mobile application ("app") powered by artificial intelligence that functions as an ovulation calendar, period tracker, and pregnancy guide ("Flo App").

3. Millions of women use the Flo App, giving Respondent details of their menstruations and gynecological health on the promise that the app will help predict ovulation and aid in pregnancy and childbirth. These users trust Respondent with intimate details of their reproductive health because Respondent repeatedly promised to protect the information and keep

it secret. Indeed, Respondent's privacy policies stated, time and again, that Respondent would not share users' health details with anyone.

4. In fact, beginning in 2016, Respondent handed users' health information out to numerous third parties, including Google, LLC ("Google"); Google's separate marketing service, Fabric ("Fabric"); Facebook, Inc., through its Facebook Analytics tool ("Facebook"); marketing firm AppsFlyer, Inc. ("AppsFlyer"); and analytics firm Flurry, Inc. ("Flurry"). And Respondent took no action to limit what these companies could do with the users' information. Rather, they merely agreed to each company's standard terms of service. By doing so, Respondent gave these third parties the ability to use Flo App users' personal health information expansively, including for advertising.

5. Respondent shared women's personal health information with these third parties for years, while at the same time promising them privacy. It was not until February 2019, when the Wall Street Journal revealed the practice, that Respondent halted sharing the data. Indeed, Respondent stopped sharing users' health information with Facebook the day after the exposé.

6. Upon learning that Respondent had turned some data related to their menstruations, pregnancies, and childbirths over to these third parties, hundreds of users wrote to Respondent, stating that they were "outraged," "incredibly upset," "disturbed," "appalled," and "very angry." Indeed, they felt "victimized" and "violated" by Respondent's actions.

7. The acts and practices of Respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Flo App

8. Since at least 2016, Respondent has made the Flo App available to users for free download from the Apple App Store and the Google Play Store. In the product description available on the Apple App Store, Respondent describes the Flo App as "a smart and simple period tracker, helpful pregnancy week by week app, accurate ovulation and fertility calendar and PMS symptoms tracker for women all over the world."

9. The Flo App is one of the most popular health and fitness apps available to consumers. Since 2016, more than 100 million users have downloaded the Flo App, including more than 16 million users across the United States and more than 19 million users in the European Union ("EU") and Switzerland. In 2019, the Flo App was the most downloaded health and fitness app in the Apple App store, and was the "App of the Day" in the Apple App Store in over 30 countries.

10. During the relevant time period, Respondent contracted with dozens of third-party firms to provide, among other things, various marketing and analytics services in connection with the Flo App. These firms included Facebook's analytics division, Google's analytics division, Fabric, AppsFlyer, and Flurry. Respondent did not contractually limit how these third

parties could use data they received from the Flo App. In fact, the Terms of Service governing the agreements permitted the third parties to use the data for their own purposes.

11. Respondent encourages women to input vast quantities of health information into the Flo App: "Log your menstruation days in a handy period calendar, ovulation and fertility tracker, schedule menstrual cycle reminders, record moods and PMS symptoms, use a due date calculator, follow a pregnancy calendar ...." By doing so, Respondent tells users, you can "take full control of your health."

12. By encouraging millions of women to input extensive information about their bodies and mental and physical health, Respondent has collected personal information about consumers, including name, email address, date of birth, place of residence, dates of menstrual cycles, when pregnancies started and ended, menstrual and pregnancy-related symptoms, weight, and temperature.

Respondent's Repeated Deceptive Statements to Flo App Users About Health Data

13. Between 2017 and 2019, Respondent repeatedly promised users that the Flo App would keep their health data private, and that Respondent would only use Flo App users' data to provide the Flo App's services. Many users entrusted Respondent with their health information in part because they believed that Respondent would treat it according to Respondent's privacy policies.

14. Specifically, in privacy policies in effect between August 28, 2017 and February 19, 2019, Respondent explained that it "may share certain" personal data with third parties, but only for purposes of operating and servicing the Flo App. The privacy policies defined "personal data" broadly to include "information about your health." However, the privacy policies then asserted that any information shared with third parties "**exclud[ed] information regarding your marked cycles, pregnancy, symptoms**, notes and other information that is entered by you and that you do not elect to share." (emphasis added).

15. In the privacy policies described in Paragraph 14, Respondent also promised that third parties could not use Flo App users' personal information "for any other purpose except to provide services in connection with the App."

16. In addition to stating that Respondent would not share "information regarding your marked cycles, pregnancy, [or] symptoms ..." with any third parties (as described in Paragraph 14), privacy policies in effect between May 28, 2018 and February 19, 2019 specifically promised that Respondent would not disclose "any data related to health" to either AppsFlyer or Flurry.

a. "AppsFlyer is a mobile marketing platform. We may share certain non-identifiable information about you and some Personal Data **(but never any data related to health)** in order to carry out marketing activities and provide you better and more targeted, tailor-made service." (emphasis added)

b. "We may share certain non-identifiable information about you and some Personal Data **(but never any data related to health)** with Flurry." (emphasis added)

17. The privacy policies described in Paragraph 16 also singled out Facebook, Google, and Fabric, claiming that these third parties would only receive "non-personally identifiable information," "Personal Data like device identifiers," or "device identifiers." Specifically, Respondent's privacy policies stated as follows:

a. "We use Facebook Analytics and Google Analytics tools to track installs of our App. Normally, Facebook and Google collect **only non-personally identifiable information,** though some **Personal Data like device identifiers** may be transferred to Facebook ...." (emphasis added).

b. "**Fabric may use device identifiers** that are stored on your mobile device and allow us to analyze your use of the App in order to improve our app feature [sic]." (emphasis added).

For Years, Respondent Disclosed Health Data About Millions of App Users to Facebook, Google, and Other Third Parties

18. Like most app developers, Respondent tracks "Standard App Events," records of routine app functions, such as launching or closing the app, as well as "Custom Apps Events," records of user-app interactions unique to the Flo App. For example, when a user enters menstruation dates, Respondent records the user's interaction with that feature as a Custom App Event. Respondent analyzes Custom App Events to improve the Flo App's functionality and identify which features are likely to interest new users.

19. Respondent gave each Custom App Event a descriptive title. For example, when a user enters the week of her pregnancy, Respondent records the Custom App Event "R_PREGNANCY_WEEK_CHOSEN." When a user selects a feature to receive menstruation reminders in the "wanting to get pregnant branch" of the app, Respondent records the Custom App Event "P_ACCEPT_PUSHES_PERIOD." Consequently, many of Respondent's Custom App Events convey information about users' menstruation, fertility, or pregnancies.

20. Despite its repeated representations between 2017 and 2019 that it would keep users' health data secret, Respondent disclosed health information to various third parties. In fact, as far back as June 2016, Respondent integrated into the Flo App software development tools, known as software development kits ("SDKs"), from the numerous third-party marketing and analytics firms mentioned above, including Facebook, Flurry, Fabric, AppsFlyer, and Google. These SDKs gathered the unique advertising or device identifiers and Custom App Events of the millions of Flo App users. By including sensitive health information in the titles of the Custom App Events, Respondent conveyed the health information of millions of users to these third parties for years. This directly contradicted Respondent's statements in its privacy policies that it would not divulge such information. Specifically, Respondent disclosed Custom App Event information to:

a. Facebook from June 2016 to February 2019;

b. Flurry from June 2016 to February 2019;

c. Fabric from November 2016 to February 2019;

d. AppsFlyer from May 2018 to February 2019; and

e. Google from September 2018 to February 2019.

21. Besides breaking promises to Flo App users, Respondent's disclosures violated several of the third parties' own terms of service or use—terms to which Respondent had agreed:

a. Facebook's Business Tools Terms stated: "**You will not share Customer Data with us that you know or reasonably should know ... includes health**, financial information, or other categories of sensitive information (including any information defined as sensitive under applicable law)." (emphasis added).

b. AppsFlyer's Terms of Use stated: "**AppsFlyer strictly prohibits you from using the Services to collect or otherwise enable the collection of any Restricted Data**. You hereby warrant that you shall not configure the Codes or Services to collect any Restricted Data through the Services." The Terms of Use defined "Restricted Data" to include "**any health information**." (emphasis added).

22. Despite representing in the privacy policies described in Paragraphs 14 and 15 that it would restrict how third parties could use Flo App users' personal data, Respondent merely agreed to these third parties' stock terms of service, several of which permitted the third party to use any information obtained from Flo App users for the third party's own purposes, including, in certain cases, for advertising and product improvement:

a. Facebook's Business Tools Terms stated: "We use [aggregated] Event Data to personalize the features and content (including ads and recommendations) we show people on and off our Facebook Company Products .... We may also use Event Data ... for research and development purposes, and to ... improve the Facebook Company Products." That "Event Data" includes Custom App Events.

b. Google Analytics's Terms of Service stated: "Google and its wholly owned subsidiaries may retain and use ... information collected in [Flo Health's] use of the service."

c. AppsFlyer's Terms of Use stated: "You hereby allow AppsFlyer to collect, store, use and process Customer Data," where "Customer Data"

was defined to include "data concerning the characteristics and activities" of app users.

d. The Fabric Software and Services Agreement stated: "[Flo Health] acknowledges and agrees that Google [Fabric] may use Usage Data for its own business purposes," where "Usage Data" was defined to mean "all information, data and other content, not including any [identifying data], received by Google related to [Flo Health]'s use of the Fabric Technology.

23. As a result, at least one of these third parties (Facebook) used Flo App event data (which Facebook did not know included users' personal and health data) for its own purposes, including its own research and development purposes.

24. On February 22, 2019, the *Wall Street Journal* reported that it was able to intercept unencrypted identifying health information transmitted by the Flo App to Facebook. The Wall Street Journal reported that this information included a unique advertising identifier, the user's intention to get pregnant, and when the user was having her period.

25. Following publication of the *Wall Street Journal's* story, Respondent received more than 300 complaints from Flo App users about the unauthorized disclosures of health information to Facebook. For example, users stated:

a. "I'm absolutely [sic] disgusted at this invasion of my most personal information."

b. "This is private personal data and I feel disgusted that you are now making this data available to third parties."

c. "Why would you EVER think it is ok to share that personal, private information with a third [sic] party?"

26. More than 100 Flo App users asked Respondent to delete their accounts and/or data or told the company they were deleting, or would delete, the Flo App.

Respondent's Violation of the Privacy Shield Principles

27. Respondent has been a participant in the EU-U.S. Privacy Shield ("Privacy Shield") and the U.S.-Swiss Privacy Shield framework since August 12, 2018. In privacy policies effective from August 6, 2018 through the present, Respondent has represented that it participates in the EU-U.S. Privacy Shield framework and the U.S.-Swiss Privacy Shield framework. Specifically, since August 6, 2018, Respondent's privacy policies have stated: "[W]e comply with the EU-U.S. Privacy Shield Framework and Swiss-U.S. Privacy Shield Framework as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of personal information transferred from the EU and Switzerland to the United States. We have certified to the Department of Commerce that we adhere to the Privacy Shield Principles."

28. The Department of Commerce ("Commerce") and the European Commission negotiated the Privacy Shield to provide a mechanism for companies to transfer personal data from the European Union to the United States in a manner consistent with the requirements of European Union law on data protection. Enacted in 1995, the European Union Data Protection Directive (the "Directive") set forth European Union requirements for the protection of personal data. Among other things, it required European Union Member States to implement legislation that prohibits the transfer of personal data outside the European Union, with exceptions, unless the European Commission has made a determination that the recipient jurisdiction's laws ensure the protection of such personal data. This determination commonly referred to as meeting the European Union's "Adequacy Standard."

29. The European Union has since enacted a new data protection regime, the General Data Protection Regulation ("GDPR"), which took effect as of May 25, 2018, and contains similar provisions on data transfers. The GDPR explicitly recognizes European Commission adequacy determinations in effect as of that date. Unlike the Directive, the GDPR is directly applicable and generally does not require member states to enact implementing legislation.

30. To satisfy the European Union Adequacy Standard for certain commercial transfers, Commerce and the European Commission negotiated the Privacy Shield, which the European Commission determined was adequate by written decision in July 2016, and took effect August 1, 2016. Thus, the Privacy Shield allows for the lawful transfer of personal data from the European Union to those companies in the United States that participate in Privacy Shield.

31. The Swiss-U.S. Privacy Shield Framework is identical to the EU-U.S. Privacy Shield Framework and is consistent with the requirements of the Swiss Federal Act on Data Protection.

32. To join the EU-U.S. and/or Swiss-U.S. Privacy Shield Framework, a company must self-certify to Commerce that it complies with the Privacy Shield Principles, and to related requirements that have been deemed to meet the European Union's Adequacy Standard. Participating companies must annually re-certify their compliance.

33. The Privacy Shield expressly provides that, while decisions by organizations to "enter the Privacy Shield are entirely voluntary, effective compliance is compulsory: organizations that self-certify to the Department and publicly declare their commitment to adhere to the Principles **must comply fully** with the Principles." (emphasis added).

34. Companies under the jurisdiction of the FTC are eligible to join the EU-U.S. and/or Swiss-U.S. Privacy Shield Framework. Both frameworks warn companies that claim to have self-certified to the Privacy Shield Principles that failure to comply or otherwise to "fully implement" the Privacy Shield Principles "is enforceable under Section 5 of the Federal Trade Commission Act."

Respondent's Failure to Provide Adequate Notice for Third-Party Use of Health Information for Advertising and Other Purposes

35. Privacy Shield Principle 1, "Notice," requires organizations to inform individuals about, among other things, "the type or identity of third parties to which it discloses personal information, and the purposes for which it does so." Principle 1(a)(vi). It provides further: "This notice must be provided in clear and conspicuous language when individuals are first asked to provide personal information to the organization or as soon thereafter as is practicable, but in any event before the organization uses such information for a purpose other than that for which it was originally collected or processed by the transferring organization or discloses it for the first time to a third party." Principle 1(b).

36. Respondent did not provide notice in clear and conspicuous language about the purposes for which it disclosed health information to third parties. When users in the European Union, Switzerland, Norway, Lichtenstein, and Iceland opened the Flo App for the first time, they were greeted by a "Welcome" screen that provided that by using the Flo App, the user consented to Respondent's aforementioned privacy policies and terms of use.

37. However, as described in Paragraphs 20-23, Respondent disclosed users' health information to numerous third parties authorized to use the data for advertising (among other uses). At no point did Respondent inform users that their health data could be used for these third parties' purposes.

Respondent's Failure to Provide Adequate Choice for Third-Party Use of Health Information for Advertising, Product Improvement, and Other Purposes

38. Privacy Shield Principle 2, "Choice," requires organizations to "offer individuals the opportunity to choose (opt out) whether their personal information is ... to be used for a purpose that is materially different from the purpose(s) for which it was originally collected or subsequently authorized by the individuals." Principle 2(a).

39. The Choice Principle specifies further: "Individuals must be provided with clear, conspicuous, and readily available mechanisms to exercise choice." *Id.*

40. This Principle also requires opt-in consent for disclosures of "sensitive information *(i.e.,* personal information specifying medical or health conditions ...)." Principle 2(c). Specifically, Principle 2(c) requires that "organizations must obtain affirmative express consent (opt in) from individuals if such information is to be [] disclosed to a third party ..." *Id.*

41. Respondent did not offer users the opportunity to opt out of whether their personal information would be used for a materially different purpose than the purposes for which it was originally collected or subsequently authorized. Specifically, Respondent told App users that their health information would only be used to provide the Flo App functions.

Respondent did not offer Flo App users the opportunity to opt out of the use of their health information by third parties for advertising, product improvement, and other purposes.

42. Respondent did not obtain Flo App users' affirmative express opt-in consent for disclosures of health information to third parties, including Facebook, Google, Flurry, Fabric, and AppsFlyer. To the contrary, as described in Paragraphs 13-14 and 16, Respondent reassured Flo App users that the Flo App would **not** disclose health information to third parties.

43. Respondent did not offer individuals a clear, conspicuous, and readily available mechanism to exercise choice. The aforementioned privacy policy provided misleading information, which prevented users from exercising choice.

Respondent's Failure to Provide for Accountability for Onward Transfers

44. Privacy Shield Principle 3, "Accountability for Onward Transfer," requires organizations that transfer personal data to a third party acting as an agent to, among other things, "(i) transfer such data only for limited and specified purposes, (ii) ascertain that the agent is obligated to provide at least the same level of privacy protection as is required by the Principles, [and] (iii) take reasonable and appropriate steps to ensure that the agent effectively processes the personal information transferred in a manner consistent with the organization's obligations under the Principles." Principle 3(b).

45. To the extent Respondent considered AppsFlyer, Fabric, Facebook, Flurry, and Google to be its agents, Respondent violated Principle 3 because it did not transfer Flo App users' health data to third parties acting as Respondent's agents only for limited and specified purposes. To the contrary, as described in Paragraphs 20 and 22, Respondent transferred health information to numerous third parties that Respondent considered its agents under broad contracts that permitted use of the data received for wide-ranging purposes, including the third parties' advertising and product improvement.

46. Respondent also violated Principle 3 because it did not obligate third parties that Respondent considered its agents to provide the same level of privacy protection as is required by the Principles. Specifically, Respondent transferred users' health information to AppsFlyer, Fabric, Facebook, Flurry, and Google, without requiring these third parties to provide the same level of privacy protection for this data as is required by the Principles.

47. Respondent also violated Principle 3 because it did not take reasonable and appropriate steps to ensure processing of users' information consistent with the Principles. Specifically, as described in Paragraph 22, Respondent did not require third parties it considered agents, including Facebook, Google, Fabric, and AppsFlyer, to sign any contract acknowledging that they could or would receive Flo App users' health information or requiring processing consistent with the sensitivity of this information. To the contrary, as described in Paragraph 21, Respondent agreed to terms of service that specifically prohibited disclosures of health information to Facebook and AppsFlyer.

48. As a result, these third parties were not even aware that they had received Flo App users' health data and, therefore, could not process the data in a manner consistent with its sensitivity.

Respondent's Failure to Abide by the Principle of Purpose Limitation

49. Privacy Shield Principle 5, "Data Integrity and Purpose Limitation," provides, in part: "An organization may not process personal information in a way that is incompatible with the purposes for which it has been collected or subsequently authorized by the individual." Principle 5(a).

50. Respondent collected health information from Flo App users for the purpose of providing the Flo App's functions. By disclosing Flo App users' health information to third parties under contracts that permitted those third parties to use the data for advertising, product improvement and other purposes, Respondent processed Flo App users' health information in a way that was incompatible with the purposes for which it has been collected.

Count I
Privacy Misrepresentation – Disclosures of Health Information

51. As described in Paragraphs 13-14 and 16, Respondent represented, directly or indirectly, expressly or by implication, that the Flo App would not disclose, without consumers' consent, their health information to third parties in general, and to AppsFlyer and Flurry in particular.

52. In fact, as set forth in Paragraph 20, Respondent did disclose consumers' health information to Facebook, Google, Fabric, Flurry, and AppsFlyer. Therefore, the representations set forth in Paragraph 51 are false or misleading.

Count II
Privacy Misrepresentation – Disclosures Beyond Identifiers

53. As described in Paragraph 17, Respondent represented, directly or indirectly, expressly or by implication, that it would only disclose non-personally identifiable information, device identifiers, and personal data "like device identifiers" to Fabric, Google, and Facebook.

54. In fact, as set forth in Paragraph 20, Respondent did not only disclose non-personally identifiable information, device identifiers, and personal data "like device identifiers" to Fabric, Google, and Facebook. Respondent also conveyed users' health information to Google, Facebook, and Fabric. Therefore, the representations set forth in Paragraph 53 are false or misleading.

Count III
Privacy Misrepresentation – Failure to Limit Third-Party Use

55. As described in Paragraphs 14-15, Respondent represented, directly or indirectly, expressly or by implication, that third parties could not use Flo App users' personal information "for any other purpose except to provide services in connection with the App."

56. In fact, as set forth in Paragraph 22, third parties could use Flo App users' personal information for purposes other than providing services in connection with the app. Respondent entered into agreements with third parties Facebook, Google, AppsFlyer, and Fabric that permitted them to use Flo App users' personal information for the third parties' own purposes, including for advertising and product improvement. Furthermore, as set forth in Paragraph 23, from June 2016 to February 2019, at least one third party (Facebook) used the Flo App users' personal information for its own purposes, including its own research and development purposes. Therefore, the representations set forth in Paragraph 55 are false or misleading.

Count IV
Misrepresentation Regarding Notice

57. As described in Paragraph 27, Respondent has represented, directly or indirectly, expressly or by implication, that it adheres to the Privacy Shield Framework Principles, including the principle of Notice.

58. In fact, as described in Paragraphs 36-37, Respondent did not adhere to the Privacy Shield Principle of Notice. Therefore, the representation set forth in Paragraph 57 is false or misleading.

Count V
Misrepresentation Regarding Choice

59. As described in Paragraph 27, Respondent has represented, directly or indirectly, expressly or by implication, that it adheres to the Privacy Shield Framework Principles, including the principle of Choice.

60. In fact, as described in Paragraphs 41-43, Respondent did not adhere to the Privacy Shield Principle of Choice. Therefore, the representation set forth in Paragraph 59 is false or misleading.

Count VI
Misrepresentation Regarding Accountability for Onward Transfers

61. As described in Paragraph 27, Respondent has represented, directly or indirectly, expressly or by implication, that it adheres to the Privacy Shield Framework Principles, including the principle of Accountability for Onward Transfers.

62. In fact, as described in Paragraphs 45-48, Respondent did not adhere to the Privacy Shield Principle of Accountability for Onward Transfers. Therefore, the representation set forth in Paragraph 61 is false or misleading.

Count VII
Misrepresentation Regarding Data Integrity and Purpose Limitation

63. As described in Paragraph 27, Respondent has represented, directly or indirectly, expressly or by implication, that it adheres to the Privacy Shield Framework Principles, including the principle of Data Integrity and Purpose Limitation.

64. In fact, as described in Paragraph 50, Respondent did not adhere to the Privacy Shield Principle of Data Integrity and Purpose Limitation. Therefore, the representation set forth in Paragraph 63 is false or misleading.

Violations of Section 5

65. The acts and practices of Respondent as alleged in this complaint constitute unfair or deceptive acts or practices, in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this 17th day of June 2021, has issued this complaint against Respondent.

By the Commission.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondent named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondent a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondent with violations of the Federal Trade Commission Act.

Respondent and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondent that it neither admits nor denies any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, it admits the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondent has violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of thirty (30) days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondent is Flo Health, Inc. ("Flo Health"), a Delaware corporation with its principal office or place of business at 1013 Centre Road, Suite 403-B, Wilmington, Delaware 19805.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "Clearly and Conspicuously" means that a required disclosure is difficult to miss *(i.e.*, easily noticeable) and easily understandable by ordinary consumers, including in all of the following ways:

   1. In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure ("triggering representation") is made through only one means.

   2. A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

   3. An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to hear it easily and understand it.

4. In any communication using an interactive electronic medium, such as the Internet or software, the disclosure must be unavoidable.

5. The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the triggering representation appears.

6. The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.

7. The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.

8. When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, "ordinary consumers" includes reasonable members of that group.

B. "Covered App User" means any individual who downloaded and used Respondent's mobile application Flo Period & Ovulation Tracker between June 30, 2016 and February 23, 2019.

C. "Covered Incident" means any instance in which Respondent discloses Health Information to a Third Party without first receiving that consumer's affirmative express consent.

D. "Covered Information" means information from or about an individual consumer, including but not limited to: (a) a first and last name; (b) a physical address; (c) an email address or other online contact information, such as a user identifier or a screen name; (d) a telephone number; (e) a Social Security number; (f) a driver's license or other government-issued identification number; (g) a financial institution account number; (h) credit or debit card information; (i) a persistent identifier, such as a customer number held in a "cookie," a static Internet Protocol ("IP") address, a mobile device ID, or processor serial number; (j) Health Information; or (k) any information combined with any of (a) through (j) above.

E. "Health Information" means individually identifiable information from or about an individual consumer relating to health, including but not limited to information concerning fertility, menstruation, sexual activity, pregnancy, and childbirth.

F. "Respondent" means Flo Health, a corporation, and its successors and assigns.

G. "Third Party" means any individual or entity other than: (1) Respondent; (2) a service provider of Respondent that: (i) uses or receives Covered Information collected by or on behalf of Respondent for and at the direction of the Respondent and no other individual or entity, (ii) does not disclose the data, or any

individually identifiable information derived from such data, to any individual or entity other than Respondent or a subcontractor to such service provider bound to data processing terms no less restrictive than terms to which the service provider is bound, and (iii) does not use the data for any other purpose; or (3) any entity that uses Covered Information only as reasonably necessary: (i) to comply with applicable law, regulation, or legal process, (ii) to enforce Respondent's terms of use, or (iii) to detect, prevent, or mitigate fraud or security vulnerabilities.

Provisions

I. Prohibition against Misrepresentations about Information Privacy

IT IS ORDERED that Respondent, Respondent's officers, agents, employees, and attorneys, and all other persons in active concert or participation with either of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with any product or service must not misrepresent in any manner, expressly or by implication:

A. the purposes for which Respondent or any entity to whom it discloses Covered Information collects, maintains, uses, or discloses Covered Information;

B. the extent to which consumers may exercise control over Respondent's collection, maintenance, use, disclosure, or deletion of Covered Information, and the steps a consumer must take to implement such controls;

C. the extent to which Respondent is a member of, adheres to, complies with, is certified by, is endorsed by, or otherwise participates in any privacy, security, or any other compliance program sponsored by a government or any self-regulatory or standard-setting organization, including the EU-U.S. Privacy Shield and the U.S.-Swiss Privacy Shield framework; and

D. the extent to which Respondent collects, maintains, uses, discloses, deletes, or permits or denies access to any Covered Information, or the extent to which Respondent protects the availability, confidentiality, or integrity of any Covered Information.

II Data Deletion

IT IS FURTHER ORDERED that, on or before thirty (30) days after the date of the filing of this Order, Respondent and Respondent's officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, must instruct any Third Party that has received Health Information from Respondent belonging to any Covered App User to destroy such information.

III. Notice to Users

IT IS FURTHER ORDERED that on or before fourteen (14) days after the date of the filing of this Order, Respondent must post Clearly and Conspicuously on Respondent's website, https://flo.health/, an exact copy of the notice attached hereto as Exhibit A ("Notice") and email the Notice to all Covered App Users, *provided however*, that if Respondent does not have email information for any Covered App User, Respondent must send the Notice to that Covered App User through Respondent's primary means of communicating with that user (such as a notification within Respondent's mobile application). Respondent shall not include with the Notice any other information, documents, or attachments.

IV. Notice and Affirmative Express Consent

IT IS FURTHER ORDERED that Respondent and Respondent's officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, in connection with any product or service, prior to disclosing any consumer's Health Information to any Third Party, must:

A. Clearly and Conspicuously disclose to the consumer, separate and apart from any "privacy policy," "terms of use" page, or other similar document: (1) the categories of Health Information that will be disclosed to such Third Parties, (2) the identities of such Third Parties, and (3) all purposes for Respondent's disclosure of such Health Information, including how it may be used by each Third Party; and

B. obtain the consumer's affirmative express consent.

V. Compliance Review

IT IS FURTHER ORDERED that, within 180 days after the issuance date of this Order, Respondent must obtain an outside review of certain of its practices (the "Compliance Review"):

A. The Compliance Review must be completed by a qualified, objective, independent third- party professional, who: (1) uses procedures and standards generally accepted in the profession; (2) conducts an independent review of compliance with the EU-U.S. Privacy Shield Framework Principles (the "Principles"), attached hereto as Exhibit B; and (3) retains all documents relevant to the Compliance Review for five (5) years after completion and will provide such documents to the Commission within ten (10) days of receipt of a written request from a representative of the Commission. No documents may be withheld on the basis of a claim of confidentiality, proprietary or trade secrets, work product protection, attorney-client privilege, statutory exemption, or any similar claim.

B. Respondent shall provide the Associate Director of Enforcement for the Bureau of Consumer Protection at the Commission with the name, affiliation, and resume of

each person selected to conduct the Compliance Review, which the Associate Director shall have the authority to approve in his sole discretion.

C. The reporting period for the Compliance Review must cover the first 180 days after the issuance date of the Order.

D. The Compliance Review must (1) determine whether Respondent has maintained compliance with the Principles attached hereto as Exhibit B; (2) determine whether Respondent's privacy practices are consistent with its privacy policy; (3) determine whether Respondent adequately informs individuals about the mechanisms through which they may pursue complaints regarding Respondent's privacy practices; (4) identify any gaps or weaknesses in the privacy practices assessed; and (5) identify specific evidence (including, but not limited to, documents reviewed, sampling and technical testing performed, and interviews conducted) examined to make such determinations and identifications, and explain why the evidence examined is sufficient to justify the findings. No finding of the Compliance Review shall rely solely on assertions or attestations by Respondent's management. The Compliance Review shall be signed by the lead professional who performs the review and shall state that he or she conducted an independent review of Respondent's privacy practices, and did not rely solely on assertions or attestations by Respondent's management.

E. Unless otherwise directed by a Commission representative in writing, Respondent must submit the Compliance Review to the Commission within ten (10) days after the Compliance Review has been completed via email to DEbrief@ftc.gov or by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "In re Flo Health, Inc., LLC, FTC File No. 1923133."

VI. Cooperation with Compliance Reviewer

IT IS FURTHER ORDERED that Respondent, whether acting directly or indirectly, in connection with the Compliance Review required by Provision V of this Order, must disclose all material facts to the individual(s) conducting the Compliance Review (the "Reviewer"), and must not misrepresent in any manner, expressly or by implication, any fact material to the Reviewer's determination whether Respondent (1) has maintained compliance with the Principles attached hereto as Exhibit B; (2) has engaged in privacy practices consistent with its privacy policy; (3) adequately informs individuals about the mechanisms through which they may pursue complaints regarding Respondent's privacy practices; or (4) has any gaps or weaknesses in its privacy practices.

VII. Certification

IT IS FURTHER ORDERED that, in connection with Provisions I through VI of this Order, Respondent must:

A. Within 180 days after the issuance date of this Order, provide the Commission with a certification from a senior corporate manager, or, if no such senior corporate manager exists, a senior officer of Respondent responsible for Respondent's privacy practices that Resondent: (1) has established, implemented, and maintained the requirements of this Order; and (2) is not aware of any material noncompliance that has not been (a) corrected or (b) disclosed to the Commission. The certification must be based on the personal knowledge of the senior corporate manager, senior officer, or subject matter experts upon whom the senior corporate manager or senior officer reasonably relies in making the certification.

B. Unless otherwise directed by a Commission representative in writing, submit the certification to the Commission pursuant to this Order via email to DEbrief@ftc.gov or by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "In re Flo Health, Inc., LLC, FTC File No. 1923133."

VIII. Covered Incident Reports

IT IS FURTHER ORDERED that Respondent, within thirty (30) days after that Respondent's discovery of a Covered Incident, must submit a report to the Commission. The report must include, to the extent possible:

A. The date, estimated date, or estimated date range when the Covered Incident occurred;

B. A description of the facts relating to the Covered Incident, including the causes and scope of the Covered Incident, if known;

C. The number of consumers whose information was affected;

D. The acts that Respondent has taken to date to remediate the Covered Incident and protect Health Information from further disclosure, exposure or access, and protect affected individuals from identity theft or other harm that may result from the Covered Incident; and

E. A representative copy of any materially different notice sent by Respondent to consumers or to any U.S. federal, state, or local government entity.

Unless otherwise directed by a Commission representative in writing, all Covered Incident reports to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "In re Flo Health, Inc., LLC, FTC File No. 1923133."

IX. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondent obtain acknowledgments of receipt of this Order:

A. Respondent, within ten (10) days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For five (5) years after the issuance date of this Order, Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order, and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within ten (10) days after the effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Respondent delivered a copy of this Order, Respondent must obtain, within thirty (30) days, a signed and dated acknowledgment of receipt of this Order.

X. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondent makes timely submissions to the Commission:

A. Sixty (60) days after the issuance date of this Order, and annually thereafter for five (5) more years, Respondent must submit a compliance report, sworn under penalty of perjury, in which Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the services offered, what Covered Information is collected, and how Covered Information is used and disclosed to third parties; (d) describe in detail whether and how Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

B. Respondent must submit a compliance notice, sworn under penalty of perjury, within fourteen (14) days of any change in: (a) any designated point of contact or (b) the structure of Respondent or any entity Respondent has any ownership

interest in or control directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

C. Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against Respondent within fourteen (14) days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Flo Health, Inc., a corporation.

XI. Recordkeeping

IT IS FURTHER ORDERED that Respondent must create certain records for twenty (20) years after the issuance date of the Order, and retain each such records for five (5) years, unless otherwise specified below. Specifically, Respondent must create and retain the following records:

A. accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name, addresses, telephone numbers, job title or position, dates of service, and (if applicable) the reason for termination;

C. copies or records of all consumer complaints and refund requests sent to Respondent, and any response;

D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. a copy of each unique advertisement or other marketing material making a representation subject to this Order;

F. a copy of each widely disseminated representation by Respondent that describes the extent to which Respondent maintains or protects the privacy, security and confidentiality of any Covered Information, including any representation concerning a change in any website or other service controlled by Respondent that relates to the privacy, security, and confidentiality of Covered Information;

G. for five (5) years after the date of preparation of the Compliance Review required by this Order, all materials relied upon to prepare the Compliance Review, whether prepared by or on behalf of Respondent, including all plans, reports, studies, reviews, audits, audit trails, policies, training materials, assessments, and any other materials concerning Respondent's compliance with related Provisions of this Order, for the compliance period covered by the Compliance Review.

XII. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondent's compliance with this Order:

A. Within ten (10) days of receipt of a written request from a representative of the Commission, Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with Respondent. Respondent must permit representatives of the Commission to interview anyone affiliated with Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondent or any individual or entity affiliated with Respondent, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

XIII. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate twenty (20) years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than twenty (20) years;

B. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Exhibit A

Dear [Customer]:

Between June 1, 2016 and February 23, 2019, the company that makes the Flo Period & Ovulation Tracker app sent an identifying number related to you and information about your period and pregnancy to companies that help us measure and analyze trends, usage, and activities on the app, including the analytics divisions of Facebook, Flurry, Fabric, and Google. No information was shared with the social media divisions of these companies. We did not share your name, address, or birthday with anyone at any time.

We do not currently, and will not, share any information about your health with any company unless we get your permission. We recently entered into a settlement with the Federal Trade Commission, the nation's consumer protection agency, to resolve allegations that sharing this information was inconsistent with the promises we made to you. Learn more about the settlement at [to be determined]. This page also includes links to resources for consumers to help them evaluate the risks and benefits of sharing information with health apps.

If you have any questions or concerns, please contact us at privacy@flo.health.

Exhibit B

EU-U.S. PRIVACY SHIELD FRAMEWORK PRINCIPLES ISSUED BY THE U.S. DEPARTMENT OF COMMERCE

I. OVERVIEW

1. While the United States and the European Union share the goal of enhancing privacy protection, the United States takes a different approach to privacy from that taken by the European Union. The United States uses a sectoral approach that relies on a mix of legislation, regulation, and self-regulation. Given those differences and to provide organizations in the United States with a reliable mechanism for personal data transfers to the United States from the European Union while ensuring that EU data subjects continue to benefit from effective safeguards and protection as required by European legislation with respect to the processing of their personal data when they have been transferred to non-EU countries, the Department of Commerce is issuing these Privacy Shield Principles, including the Supplemental Principles (collectively "the Principles") under its statutory authority to foster, promote, and develop international commerce (15 U.S.C. § 1512). The Principles were developed in consultation with the European Commission, and with industry and other stakeholders, to facilitate trade and commerce between the United States and European Union. They are intended for use solely by organizations in the United States receiving personal data from the European Union for the purpose of qualifying for the Privacy Shield and thus benefitting from the European Commission's adequacy decision[1]. The Principles do not affect the application of national provisions implementing Directive 95/46/EC ("the Directive") that apply to the processing of personal data in the Member States. Nor do the Principles limit privacy obligations that otherwise apply under U.S. law.

2. In order to rely on the Privacy Shield to effectuate transfers of personal data from the EU, an organization must self-certify its adherence to the Principles to the Department of Commerce (or its designee) ("the Department"). While decisions by organizations to thus enter the Privacy Shield are entirely voluntary, effective compliance is compulsory: organizations that self-certify to the Department and publicly declare their commitment to adhere to the Principles must comply fully with the Principles. In order to enter the Privacy Shield, an organization must (a) be subject to the investigatory and enforcement powers of the Federal Trade Commission (the "FTC"), the Department of Transportation or another statutory body that will effectively ensure compliance with the Principles *(other U.S. statutory bodies recognized by the EU may be included as an annex in the future)*; (b) publicly declare its commitment to comply with the Principles; (c) publicly

[1] Provided that the Commission Decision on the adequacy of the protection provided by the EU-U.S. Privacy Shield applies to Iceland, Liechtenstein and Norway, the Privacy Shield Package will cover both the European Union, as well as these three countries. Consequently, references to the EU and its Member States will be read as including Iceland, Liechtenstein and Norway.

disclose its privacy policies in line with these Principles; and (d) fully implement them. An organization's failure to comply is enforceable under Section 5 of the Federal Trade Commission Act prohibiting unfair and deceptive acts in or affecting commerce (15 U.S.C. § 45(a)) or other laws or regulations prohibiting such acts.

3. The Department of Commerce will maintain and make available to the public an authoritative list of U.S. organizations that have self-certified to the Department and declared their commitment to adhere to the Principles ("the Privacy Shield List"). Privacy Shield benefits are assured from the date that the Department places the organization on the Privacy Shield List. The Department will remove an organization from the Privacy Shield List if it voluntarily withdraws from the Privacy Shield or if it fails to complete its annual re-certification to the Department. An organization's removal from the Privacy Shield List means it may no longer benefit from the European Commission's adequacy decision to receive personal information from the EU. The organization must continue to apply the Principles to the personal information it received while it participated in the Privacy Shield, and affirm to the Department on an annual basis its commitment to do so, for as long as it retains such information; otherwise, the organization must return or delete the information or provide "adequate" protection for the information by another authorized means. The Department will also remove from the Privacy Shield List those organizations that have persistently failed to comply with the Principles; these organizations do not qualify for Privacy Shield benefits and must return or delete the personal information they received under the Privacy Shield.

4. The Department will also maintain and make available to the public an authoritative record of U.S. organizations that had previously self-certified to the Department, but that have been removed from the Privacy Shield List. The Department will provide a clear warning that these organizations are not participants in the Privacy Shield; that removal from the Privacy Shield List means that such organizations cannot claim to be Privacy Shield compliant and must avoid any statements or misleading practices implying that they participate in the Privacy Shield; and that such organizations are no longer entitled to benefit from the European Commission's adequacy decision that would enable those organizations to receive personal information from the EU. An organization that continues to claim participation in the Privacy Shield or makes other Privacy Shield-related misrepresentations after it has been removed from the Privacy Shield List may be subject to enforcement action by the FTC, the Department of Transportation, or other enforcement authorities.

5. Adherence to these Principles may be limited: (a) to the extent necessary to meet national security, public interest, or law enforcement requirements; (b) by statute, government regulation, or case law that creates conflicting obligations or explicit authorizations, provided that, in exercising any such authorization, an organization can demonstrate that its non-compliance with the Principles is limited to the extent

necessary to meet the overriding legitimate interests furthered by such authorization; or (c) if the effect of the Directive or Member State law is to allow exceptions or derogations, provided such exceptions or derogations are applied in comparable contexts. Consistent with the goal of enhancing privacy protection, organizations should strive to implement these Principles fully and transparently, including indicating in their privacy policies where exceptions to the Principles permitted by (b) above will apply on a regular basis. For the same reason, where the option is allowable under the Principles and/or U.S. law, organizations are expected to opt for the higher protection where possible.

6. Organizations are obligated to apply the Principles to all personal data transferred in reliance on the Privacy Shield after they enter the Privacy Shield. An organization that chooses to extend Privacy Shield benefits to human resources personal information transferred from the EU for use in the context of an employment relationship must indicate this when it self-certifies to the Department and conform to the requirements set forth in the Supplemental Principle on Self-Certification.

7. U.S. law will apply to questions of interpretation and compliance with the Principles and relevant privacy policies by Privacy Shield organizations, except where such organizations have committed to cooperate with European data protection authorities ("DPAs"). Unless otherwise stated, all provisions of the Principles apply where they are relevant.

8. Definitions:

   a. "Personal data" and "personal information" are data about an identified or identifiable individual that are within the scope of the Directive, received by an organization in the United States from the European Union, and recorded in any form.

   b. "Processing" of personal data means any operation or set of operations which is performed upon personal data, whether or not by automated means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure or dissemination, and erasure or destruction.

   c. "Controller" means a person or organization which, alone or jointly with others, determines the purposes and means of the processing of personal data.

9. The effective date of the Principles is the date of final approval of the European Commission's adequacy determination.

II. PRINCIPLES

1. NOTICE

a. An organization must inform individuals about:

i. its participation in the Privacy Shield and provide a link to, or the web address for, the Privacy Shield List,

ii. the types of personal data collected and, where applicable, the entities or subsidiaries of the organization also adhering to the Principles,

iii. its commitment to subject to the Principles all personal data received from the EU in reliance on the Privacy Shield,

iv. the purposes for which it collects and uses personal information about them,

v. how to contact the organization with any inquiries or complaints, including any relevant establishment in the EU that can respond to such inquiries or complaints,

vi. the type or identity of third parties to which it discloses personal information, and the purposes for which it does so,

vii. the right of individuals to access their personal data,

viii. the choices and means the organization offers individuals for limiting the use and disclosure of their personal data,

ix. the independent dispute resolution body designated to address complaints and provide appropriate recourse free of charge to the individual, and whether it is: (1) the panel established by DPAs, (2) an alternative dispute resolution provider based in the EU, or (3) an alternative dispute resolution provider based in the United States,

x. being subject to the investigatory and enforcement powers of the FTC, the Department of Transportation or any other U.S. authorized statutory body,

xi. the possibility, under certain conditions, for the individual to invoke binding arbitration,

xii. the requirement to disclose personal information in response to lawful requests by public authorities, including to meet national security or law enforcement requirements, and

xiii. its liability in cases of onward transfers to third parties.

b. This notice must be provided in clear and conspicuous language when individuals are first asked to provide personal information to the organization or as soon thereafter as is practicable, but in any event before the organization uses such information for a purpose other than that for which it was originally collected or processed by the transferring organization or discloses it for the first time to a third party.

2. CHOICE

a. An organization must offer individuals the opportunity to choose (opt out) whether their personal information is (i) to be disclosed to a third party or (ii) to be used for a purpose that is materially different from the purpose(s) for which it was originally collected or subsequently authorized by the individuals. Individuals must be provided with clear, conspicuous, and readily available mechanisms to exercise choice.

b. By derogation to the previous paragraph, it is not necessary to provide choice when disclosure is made to a third party that is acting as an agent to perform task(s) on behalf of and under the instructions of the organization. However, an organization shall always enter into a contract with the agent.

c. For sensitive information (*i.e.*, personal information specifying medical or health conditions, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership or information specifying the sex life of the individual), organizations must obtain affirmative express consent (opt in) from individuals if such information is to be (i) disclosed to a third party or (ii) used for a purpose other than those for which it was originally collected or subsequently authorized by the individuals through the exercise of opt-in choice. In addition, an organization should treat as sensitive any personal information received from a third party where the third party identifies and treats it as sensitive.

3. ACCOUNTABILITY FOR ONWARD TRANSFER

a. To transfer personal information to a third party acting as a controller, organizations must comply with the Notice and Choice Principles. Organizations must also enter into a contract with the third-party controller that provides that such data may only be processed for limited and specified purposes consistent with the consent provided by the individual and that the recipient will provide the same level of protection as the Principles and will notify the organization if it makes a determination that it can no longer meet this obligation. The contract shall provide that when such a determination is made the third party controller ceases processing or takes other reasonable and appropriate steps to remediate.

b. To transfer personal data to a third party acting as an agent, organizations must: (i) transfer such data only for limited and specified purposes; (ii)

ascertain that the agent is obligated to provide at least the same level of privacy protection as is required by the Principles; (iii) take reasonable and appropriate steps to ensure that the agent effectively processes the personal information transferred in a manner consistent with the organization's obligations under the Principles; (iv) require the agent to notify the organization if it makes a determination that it can no longer meet its obligation to provide the same level of protection as is required by the Principles; (v) upon notice, including under (iv), take reasonable and appropriate steps to stop and remediate unauthorized processing; and (vi) provide a summary or a representative copy of the relevant privacy provisions of its contract with that agent to the Department upon request.

4. SECURITY

a. Organizations creating, maintaining, using or disseminating personal information must take reasonable and appropriate measures to protect it from loss, misuse and unauthorized access, disclosure, alteration and destruction, taking into due account the risks involved in the processing and the nature of the personal data.

5. DATA INTEGRITY AND PURPOSE LIMITATION

a. Consistent with the Principles, personal information must be limited to the information that is relevant for the purposes of processing.[2] An organization may not process personal information in a way that is incompatible with the purposes for which it has been collected or subsequently authorized by the individual. To the extent necessary for those purposes, an organization must take reasonable steps to ensure that personal data is reliable for its intended use, accurate, complete, and current. An organization must adhere to the Principles for as long as it retains such information.

b. Information may be retained in a form identifying or making identifiable[3] the individual only for as long as it serves a purpose of processing within the meaning of 5a. This obligation does not prevent organizations from processing personal information for longer periods for the time and to the

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[2] Depending on the circumstances, examples of compatible processing purposes may include those that reasonably serve customer relations, compliance and legal considerations, auditing, security and fraud prevention, preserving or defending the organization's legal rights, or other purposes consistent with the expectations of a reasonable person given the context of the collection.

[3] In this context, if, given the means of identification reasonably likely to be used (considering, among other things, the costs of and the amount of time required for identification and the available technology at the time of the processing) and the form in which the data is retained, an individual could reasonably be identified by the organization, or a third party if it would have access to the data, then the individual is "identifiable."

extent such processing reasonably serves the purposes of archiving in the public interest, journalism, literature and art, scientific or historical research, and statistical analysis. In these cases, such processing shall be subject to the other Principles and provisions of the Framework. Organizations should take reasonable and appropriate measures in complying with this provision.

6. ACCESS

a. Individuals must have access to personal information about them that an organization holds and be able to correct, amend, or delete that information where it is inaccurate, or has been processed in violation of the Principles, except where the burden or expense of providing access would be disproportionate to the risks to the individual's privacy in the case in question, or where the rights of persons other than the individual would be violated.

7. RECOURSE, ENFORCEMENT AND LIABILITY

a. Effective privacy protection must include robust mechanisms for assuring compliance with the Principles, recourse for individuals who are affected by non-compliance with the Principles, and consequences for the organization when the Principles are not followed. At a minimum such mechanisms must include:

i. readily available independent recourse mechanisms by which each individual's complaints and disputes are investigated and expeditiously resolved at no cost to the individual and by reference to the Principles, and damages awarded where the applicable law or private-sector initiatives so provide;

ii. follow-up procedures for verifying that the attestations and assertions organizations make about their privacy practices are true and that privacy practices have been implemented as presented and, in particular, with regard to cases of non-compliance; and

iii. obligations to remedy problems arising out of failure to comply with the Principles by organizations announcing their adherence to them and consequences for such organizations. Sanctions must be sufficiently rigorous to ensure compliance by organizations.

b. Organizations and their selected independent recourse mechanisms will respond promptly to inquiries and requests by the Department for information relating to the Privacy Shield. All organizations must respond expeditiously to complaints regarding compliance with the Principles referred by EU Member State authorities through the Department. Organizations that have chosen to cooperate with DPAs, including organizations that process human resources data, must respond directly to

such authorities with regard to the investigation and resolution of complaints.

c. Organizations are obligated to arbitrate claims and follow the terms as set forth in Annex I, provided that an individual has invoked binding arbitration by delivering notice to the organization at issue and following the procedures and subject to conditions set forth in Annex I.

d. In the context of an onward transfer, a Privacy Shield organization has responsibility for the processing of personal information it receives under the Privacy Shield and subsequently transfers to a third party acting as an agent on its behalf. The Privacy Shield organization shall remain liable under the Principles if its agent processes such personal information in a manner inconsistent with the Principles, unless the organization proves that it is not responsible for the event giving rise to the damage.

e. When an organization becomes subject to an FTC or court order based on non-compliance, the organization shall make public any relevant Privacy Shield-related sections of any compliance or assessment report submitted to the FTC, to the extent consistent with confidentiality requirements. The Department has established a dedicated point of contact for DPAs for any problems of compliance by Privacy Shield organizations. The FTC will give priority consideration to referrals of non-compliance with the Principles from the Department and EU Member State authorities, and will exchange information regarding referrals with the referring state authorities on a timely basis, subject to existing confidentiality restrictions.

III. SUPPLEMENTAL PRINCIPLES

1. Sensitive Data

a. An organization is not required to obtain affirmative express consent (opt in) with respect to sensitive data where the processing is:

i. in the vital interests of the data subject or another person;

ii. necessary for the establishment of legal claims or defenses;

iii. required to provide medical care or diagnosis;

iv. carried out in the course of legitimate activities by a foundation, association or any other non-profit body with a political, philosophical, religious or trade-union aim and on condition that the processing relates solely to the members of the body or to the persons who have regular contact with it in connection with its purposes and that the data are not disclosed to a third party without the consent of the data subjects;

v. necessary to carry out the organization's obligations in the field of employment law; or

vi. related to data that are manifestly made public by the individual.

2. Journalistic Exceptions

a. Given U.S. constitutional protections for freedom of the press and the Directive's exemption for journalistic material, where the rights of a free press embodied in the First Amendment of the U.S. Constitution intersect with privacy protection interests, the First Amendment must govern the balancing of these interests with regard to the activities of U.S. persons or organizations.

b. Personal information that is gathered for publication, broadcast, or other forms of public communication of journalistic material, whether used or not, as well as information found in previously published material disseminated from media archives, is not subject to the requirements of the Privacy Shield Principles.

3. Secondary Liability

a. Internet Service Providers ("ISPs"), telecommunications carriers, and other organizations are not liable under the Privacy Shield Principles when on behalf of another organization they merely transmit, route, switch, or cache information. As is the case with the Directive itself, the Privacy Shield does not create secondary liability. To the extent that an organization is acting as a mere conduit for data transmitted by third parties and does not

determine the purposes and means of processing those personal data, it would not be liable.

4. Performing Due Diligence and Conducting Audits

a. The activities of auditors and investment bankers may involve processing personal data without the consent or knowledge of the individual. This is permitted by the Notice, Choice, and Access Principles under the circumstances described below.

b. Public stock corporations and closely held companies, including Privacy Shield organizations, are regularly subject to audits. Such audits, particularly those looking into potential wrongdoing, may be jeopardized if disclosed prematurely. Similarly, a Privacy Shield organization involved in a potential merger or takeover will need to perform, or be the subject of, a "due diligence" review. This will often entail the collection and processing of personal data, such as information on senior executives and other key personnel. Premature disclosure could impede the transaction or even violate applicable securities regulation. Investment bankers and attorneys engaged in due diligence, or auditors conducting an audit, may process information without knowledge of the individual only to the extent and for the period necessary to meet statutory or public interest requirements and in other circumstances in which the application of these Principles would prejudice the legitimate interests of the organization. These legitimate interests include the monitoring of organizations' compliance with their legal obligations and legitimate accounting activities, and the need for confidentiality connected with possible acquisitions, mergers, joint ventures, or other similar transactions carried out by investment bankers or auditors.

5. The Role of the Data Protection Authorities

a. Organizations will implement their commitment to cooperate with European Union data protection authorities ("DPAs") as described below. Under the Privacy Shield, U.S. organizations receiving personal data from the EU must commit to employ effective mechanisms for assuring compliance with the Privacy Shield Principles. More specifically as set out in the Recourse, Enforcement and Liability Principle, participating organizations must provide: (a)(i) recourse for individuals to whom the data relate; (a)(ii) follow up procedures for verifying that the attestations and assertions they have made about their privacy practices are true; and (a)(iii) obligations to remedy problems arising out of failure to comply with the Principles and consequences for such organizations. An organization may satisfy points (a)(i) and (a)(iii) of the Recourse, Enforcement and Liability Principle if it adheres to the requirements set forth here for cooperating with the DPAs.

b. An organization commits to cooperate with the DPAs by declaring in its Privacy Shield self-certification submission to the Department of Commerce (*see* Supplemental Principle on Self-Certification) that the organization:

i. elects to satisfy the requirement in points (a)(i) and (a)(iii) of the Privacy Shield Recourse, Enforcement and Liability Principle by committing to cooperate with the DPAs;

ii. will cooperate with the DPAs in the investigation and resolution of complaints brought under the Privacy Shield; and

iii. will comply with any advice given by the DPAs where the DPAs take the view that the organization needs to take specific action to comply with the Privacy Shield Principles, including remedial or compensatory measures for the benefit of individuals affected by any non-compliance with the Principles, and will provide the DPAs with written confirmation that such action has been taken.

c. Operation of DPA Panels

i. The cooperation of the DPAs will be provided in the form of information and advice in the following way:

1. The advice of the DPAs will be delivered through an informal panel of DPAs established at the European Union level, which will *inter alia* help ensure a harmonized and coherent approach.

2. The panel will provide advice to the U.S. organizations concerned on unresolved complaints from individuals about the handling of personal information that has been transferred from the EU under the Privacy Shield. This advice will be designed to ensure that the Privacy Shield Principles are being correctly applied and will include any remedies for the individual(s) concerned that the DPAs consider appropriate.

3. The panel will provide such advice in response to referrals from the organizations concerned and/or to complaints received directly from individuals against organizations which have committed to cooperate with DPAs for Privacy Shield purposes, while encouraging and if necessary helping such individuals in the first instance to use the in-house complaint handling arrangements that the organization may offer.

4. Advice will be issued only after both sides in a dispute have had a reasonable opportunity to comment and to provide any evidence they wish. The panel will seek to deliver advice as quickly as this requirement for due process allows. As a

general rule, the panel will aim to provide advice within 60 days after receiving a complaint or referral and more quickly where possible.

5. The panel will make public the results of its consideration of complaints submitted to it, if it sees fit.

6. The delivery of advice through the panel will not give rise to any liability for the panel or for individual DPAs.

ii. As noted above, organizations choosing this option for dispute resolution must undertake to comply with the advice of the DPAs. If an organization fails to comply within 25 days of the delivery of the advice and has offered no satisfactory explanation for the delay, the panel will give notice of its intention either to refer the matter to the Federal Trade Commission, the Department of Transportation, or other U.S. federal or state body with statutory powers to take enforcement action in cases of deception or misrepresentation, or to conclude that the agreement to cooperate has been seriously breached and must therefore be considered null and void. In the latter case, the panel will inform the Department of Commerce so that the Privacy Shield List can be duly amended. Any failure to fulfill the undertaking to cooperate with the DPAs, as well as failures to comply with the Privacy Shield Principles, will be actionable as a deceptive practice under Section 5 of the FTC Act or other similar statute.

d. An organization that wishes its Privacy Shield benefits to cover human resources data transferred from the EU in the context of the employment relationship must commit to cooperate with the DPAs with regard to such data (*see* Supplemental Principle on Human Resources Data).

e. Organizations choosing this option will be required to pay an annual fee which will be designed to cover the operating costs of the panel, and they may additionally be asked to meet any necessary translation expenses arising out of the panel's consideration of referrals or complaints against them. The annual fee will not exceed USD 500 and will be less for smaller companies.

6. Self-Certification

a. Privacy Shield benefits are assured from the date on which the Department has placed the organization's self-certification submission on the Privacy Shield List after having determined that the submission is complete.

b. To self-certify for the Privacy Shield, an organization must provide to the Department a self-certification submission, signed by a corporate officer on behalf of the organization that is joining the Privacy Shield, that contains at least the following information:

i. name of organization, mailing address, e-mail address, telephone, and fax numbers;

ii. description of the activities of the organization with respect to personal information received from the EU; and

iii. description of the organization's privacy policy for such personal information, including:

1. if the organization has a public website, the relevant web address where the privacy policy is available, or if the organization does not have a public website, where the privacy policy is available for viewing by the public;

2. its effective date of implementation;

3. a contact office for the handling of complaints, access requests, and any other issues arising under the Privacy Shield;

4. the specific statutory body that has jurisdiction to hear any claims against the organization regarding possible unfair or deceptive practices and violations of laws or regulations governing privacy (and that is listed in the Principles or a future annex to the Principles);

5. name of any privacy program in which the organization is a member;

6. method of verification (*e.g.*, in-house, third party) (*see* Supplemental Principle on Verification; and

7. the independent recourse mechanism that is available to investigate unresolved complaints.

c. Where the organization wishes its Privacy Shield benefits to cover human resources information transferred from the EU for use in the context of the employment relationship, it may do so where a statutory body listed in the Principles or a future annex to the Principles has jurisdiction to hear claims against the organization arising out of the processing of human resources information. In addition, the organization must indicate this in its self-certification submission and declare its commitment to cooperate with the EU authority or authorities concerned in conformity with the Supplemental Principles on Human Resources Data and the Role of the Data Protection Authorities as applicable and that it will comply with the advice given by such authorities. The organization must also provide the Department with a copy of its human resources privacy policy and provide information where the privacy policy is available for viewing by its affected employees.

d. The Department will maintain the Privacy Shield List of organizations that file completed self-certification submissions, thereby assuring the

availability of Privacy Shield benefits, and will update such list on the basis of annual self-recertification submissions and notifications received pursuant to the Supplemental Principle on Dispute Resolution and Enforcement. Such self-certification submissions must be provided not less than annually; otherwise the organization will be removed from the Privacy Shield List and Privacy Shield benefits will no longer be assured. Both the Privacy Shield List and the self-certification submissions by the organizations will be made publicly available. All organizations that are placed on the Privacy Shield List by the Department must also state in their relevant published privacy policy statements that they adhere to the Privacy Shield Principles. If available online, an organization's privacy policy must include a hyperlink to the Department's Privacy Shield website and a hyperlink to the website or complaint submission form of the independent recourse mechanism that is available to investigate unresolved complaints.

e. The Privacy Principles apply immediately upon certification. Recognizing that the Principles will impact commercial relationships with third parties, organizations that certify to the Privacy Shield Framework in the first two months following the Framework's effective date shall bring existing commercial relationships with third parties into conformity with the Accountability for Onward Transfer Principle as soon as possible, and in any event no later than nine months from the date upon which they certify to the Privacy Shield. During that interim period, where organizations transfer data to a third party, they shall (i) apply the Notice and Choice Principles, and (ii) where personal data is transferred to a third party acting as an agent, ascertain that the agent is obligated to provide at least the same level of protection as is required by the Principles.

f. An organization must subject to the Privacy Shield Principles all personal data received from the EU in reliance upon the Privacy Shield. The undertaking to adhere to the Privacy Shield Principles is not time-limited in respect of personal data received during the period in which the organization enjoys the benefits of the Privacy Shield. Its undertaking means that it will continue to apply the Principles to such data for as long as the organization stores, uses or discloses them, even if it subsequently leaves the Privacy Shield for any reason. An organization that withdraws from the Privacy Shield but wants to retain such data must affirm to the Department on an annual basis its commitment to continue to apply the Principles or provide "adequate" protection for the information by another authorized means (for example, using a contract that fully reflects the requirements of the relevant standard contractual clauses adopted by the European Commission); otherwise, the organization must return or delete the information. An organization that withdraws from the Privacy Shield must remove from any relevant privacy policy any references to the Privacy Shield that imply that the organization continues to actively participate in the Privacy Shield and is entitled to its benefits.

g. An organization that will cease to exist as a separate legal entity as a result of a merger or a takeover must notify the Department of this in advance. The notification should also indicate whether the acquiring entity or the entity resulting from the merger will (i) continue to be bound by the Privacy Shield Principles by the operation of law governing the takeover or merger or (ii) elect to self-certify its adherence to the Privacy Shield Principles or put in place other safeguards, such as a written agreement that will ensure adherence to the Privacy Shield Principles. Where neither (i) nor (ii) applies, any personal data that has been acquired under the Privacy Shield must be promptly deleted.

h. When an organization leaves the Privacy Shield for any reason, it must remove all statements implying that the organization continues to participate in the Privacy Shield or is entitled to the benefits of the Privacy Shield. The EU-U.S. Privacy Shield certification mark, if used, must also be removed. Any misrepresentation to the general public concerning an organization's adherence to the Privacy Shield Principles may be actionable by the FTC or other relevant government body. Misrepresentations to the Department may be actionable under the False Statements Act (18 U.S.C. § 1001).

7. Verification

a. Organizations must provide follow up procedures for verifying that the attestations and assertions they make about their Privacy Shield privacy practices are true and those privacy practices have been implemented as represented and in accordance with the Privacy Shield Principles.

b. To meet the verification requirements of the Recourse, Enforcement and Liability Principle, an organization must verify such attestations and assertions either through self-assessment or outside compliance reviews.

c. Under the self-assessment approach, such verification must indicate that an organization's published privacy policy regarding personal information received from the EU is accurate, comprehensive, prominently displayed, completely implemented and accessible. It must also indicate that its privacy policy conforms to the Privacy Shield Principles; that individuals are informed of any in-house arrangements for handling complaints and of the independent mechanisms through which they may pursue complaints; that it has in place procedures for training employees in its implementation, and disciplining them for failure to follow it; and that it has in place internal procedures for periodically conducting objective reviews of compliance with the above. A statement verifying the self-assessment must be signed by a corporate officer or other authorized representative of the organization at least once a year and made available upon request by individuals or in the context of an investigation or a complaint about non-compliance.

d. Where the organization has chosen outside compliance review, such a review must demonstrate that its privacy policy regarding personal

information received from the EU conforms to the Privacy Shield Principles, that it is being complied with, and that individuals are informed of the mechanisms through which they may pursue complaints. The methods of review may include, without limitation, auditing, random reviews, use of "decoys", or use of technology tools as appropriate. A statement verifying that an outside compliance review has been successfully completed must be signed either by the reviewer or by the corporate officer or other authorized representative of the organization at least once a year and made available upon request by individuals or in the context of an investigation or a complaint about compliance.

e. Organizations must retain their records on the implementation of their Privacy Shield privacy practices and make them available upon request in the context of an investigation or a complaint about non-compliance to the independent body responsible for investigating complaints or to the agency with unfair and deceptive practices jurisdiction. Organizations must also respond promptly to inquiries and other requests for information from the Department relating to the organization's adherence to the Principles.

8. Access

a. <u>The Access Principle in Practice</u>

i. Under the Privacy Shield Principles, the right of access is fundamental to privacy protection. In particular, it allows individuals to verify the accuracy of information held about them. The Access Principle means that individuals have the right to:

1. obtain from an organization confirmation of whether or not the organization is processing personal data relating to them;[4]

2. have communicated to them such data so that they could verify its accuracy and the lawfulness of the processing; and

3. have the data corrected, amended or deleted where it is inaccurate or processed in violation of the Principles.

ii. Individuals do not have to justify requests for access to their personal data. In responding to individuals' access requests, organizations should first be guided by the concern(s) that led to the requests in the first place. For example, if an access request is vague or broad in scope, an organization may engage the individual in a dialogue so as to better understand the motivation for the request and to locate responsive information. The organization might

[4] The organization should answer requests from an individual concerning the purposes of the processing, the categories of personal data concerned, and the recipients or categories of recipients to whom the personal data is disclosed.

inquire about which part(s) of the organization the individual interacted with or about the nature of the information or its use that is the subject of the access request.

iii. Consistent with the fundamental nature of access, organizations should always make good faith efforts to provide access. For example, where certain information needs to be protected and can be readily separated from other personal information subject to an access request, the organization should redact the protected information and make available the other information. If an organization determines that access should be restricted in any particular instance, it should provide the individual requesting access with an explanation of why it has made that determination and a contact point for any further inquiries.

b. Burden or Expense of Providing Access

i. The right of access to personal data may be restricted in exceptional circumstances where the legitimate rights of persons other than the individual would be violated or where the burden or expense of providing access would be disproportionate to the risks to the individual's privacy in the case in question. Expense and burden are important factors and should be taken into account but they are not controlling factors in determining whether providing access is reasonable.

ii. For example, if the personal information is used for decisions that will significantly affect the individual (*e.g.*, the denial or grant of important benefits, such as insurance, a mortgage, or a job), then consistent with the other provisions of these Supplemental Principles, the organization would have to disclose that information even if it is relatively difficult or expensive to provide. If the personal information requested is not sensitive or not used for decisions that will significantly affect the individual, but is readily available and inexpensive to provide, an organization would have to provide access to such information.

c. Confidential Commercial Information

i. Confidential commercial information is information that an organization has taken steps to protect from disclosure, where disclosure would help a competitor in the market. Organizations may deny or limit access to the extent that granting full access would reveal its own confidential commercial information, such as marketing inferences or classifications generated by the organization, or the confidential commercial information of another that is subject to a contractual obligation of confidentiality.

ii. Where confidential commercial information can be readily separated from other personal information subject to an access request, the organization should redact the confidential commercial information and make available the non-confidential information.

d. Organization of Data Bases

i. Access can be provided in the form of disclosure of the relevant personal information by an organization to the individual and does not require access by the individual to an organization's data base.

ii. Access needs to be provided only to the extent that an organization stores the personal information. The Access Principle does not itself create any obligation to retain, maintain, reorganize, or restructure personal information files.

e. When Access May be Restricted

i. As organizations must always make good faith efforts to provide individuals with access to their personal data, the circumstances in which organizations may restrict such access are limited, and any reasons for restricting access must be specific. As under the Directive, an organization can restrict access to information to the extent that disclosure is likely to interfere with the safeguarding of important countervailing public interests, such as national security; defense; or public security. In addition, where personal information is processed solely for research or statistical purposes, access may be denied. Other reasons for denying or limiting access are:

1. interference with the execution or enforcement of the law or with private causes of action, including the prevention, investigation or detection of offenses or the right to a fair trial;

2. disclosure where the legitimate rights or important interests of others would be violated;

3. breaching a legal or other professional privilege or obligation;

4. prejudicing employee security investigations or grievance proceedings or in connection with employee succession planning and corporate re-organizations; or

5. prejudicing the confidentiality necessary in monitoring, inspection or regulatory functions connected with sound management, or in future or ongoing negotiations involving the organization.

ii. An organization which claims an exception has the burden of demonstrating its necessity, and the reasons for restricting access

and a contact point for further inquiries should be given to individuals.

f. Right to Obtain Confirmation and Charging a Fee to Cover the Costs for Providing Access

i. An individual has the right to obtain confirmation of whether or not this organization has personal data relating to him or her. An individual also has the right to have communicated to him or her personal data relating to him or her. An organization may charge a fee that is not excessive.

ii. Charging a fee may be justified, for example, where requests for access are manifestly excessive, in particular because of their repetitive character.

iii. Access may not be refused on cost grounds if the individual offers to pay the costs.

g. Repetitious or Vexatious Requests for Access

i. An organization may set reasonable limits on the number of times within a given period that access requests from a particular individual will be met. In setting such limitations, an organization should consider such factors as the frequency with which information is updated, the purpose for which the data are used, and the nature of the information.

h. Fraudulent Requests for Access

i. An organization is not required to provide access unless it is supplied with sufficient information to allow it to confirm the identity of the person making the request.

i. Timeframe for Responses

i. Organizations should respond to access requests within a reasonable time period, in a reasonable manner, and in a form that is readily intelligible to the individual. An organization that provides information to data subjects at regular intervals may satisfy an individual access request with its regular disclosure if it would not constitute an excessive delay.

9. Human Resources Data

a. Coverage by the Privacy Shield

i. Where an organization in the EU transfers personal information about its employees (past or present) collected in the context of the employment relationship, to a parent, affiliate, or unaffiliated service provider in the United States participating in the Privacy Shield, the transfer enjoys the benefits of the Privacy Shield. In

such cases, the collection of the information and its processing prior to transfer will have been subject to the national laws of the EU country where it was collected, and any conditions for or restrictions on its transfer according to those laws will have to be respected.

ii. The Privacy Shield Principles are relevant only when individually identified or identifiable records are transferred or accessed. Statistical reporting relying on aggregate employment data and containing no personal data or the use of anonymized data does not raise privacy concerns.

b. Application of the Notice and Choice Principles

i. A U.S. organization that has received employee information from the EU under the Privacy Shield may disclose it to third parties or use it for different purposes only in accordance with the Notice and Choice Principles. For example, where an organization intends to use personal information collected through the employment relationship for non-employment-related purposes, such as marketing communications, the U.S. organization must provide the affected individuals with the requisite choice before doing so, unless they have already authorized the use of the information for such purposes. Such use must not be incompatible with the purposes for which the personal information has been collected or subsequently authorised by the individual. Moreover, such choices must not be used to restrict employment opportunities or take any punitive action against such employees.

ii. It should be noted that certain generally applicable conditions for transfer from some EU Member States may preclude other uses of such information even after transfer outside the EU and such conditions will have to be respected.

iii. In addition, employers should make reasonable efforts to accommodate employee privacy preferences. This could include, for example, restricting access to the personal data, anonymizing certain data, or assigning codes or pseudonyms when the actual names are not required for the management purpose at hand.

iv. To the extent and for the period necessary to avoid prejudicing the ability of the organization in making promotions, appointments, or other similar employment decisions, an organization does not need to offer notice and choice.

c. Application of the Access Principle

i. The Supplemental Principle on Access provides guidance on reasons which may justify denying or limiting access on request in the human resources context. Of course, employers in the European Union must comply with local regulations and ensure that European

Union employees have access to such information as is required by law in their home countries, regardless of the location of data processing and storage. The Privacy Shield requires that an organization processing such data in the United States will cooperate in providing such access either directly or through the EU employer.

d. Enforcement

i. In so far as personal information is used only in the context of the employment relationship, primary responsibility for the data vis-à-vis the employee remains with the organization in the EU. It follows that, where European employees make complaints about violations of their data protection rights and are not satisfied with the results of internal review, complaint, and appeal procedures (or any applicable grievance procedures under a contract with a trade union), they should be directed to the state or national data protection or labor authority in the jurisdiction where the employees work. This includes cases where the alleged mishandling of their personal information is the responsibility of the U.S. organization that has received the information from the employer and thus involves an alleged breach of the Privacy Shield Principles. This will be the most efficient way to address the often overlapping rights and obligations imposed by local labor law and labor agreements as well as data protection law.

ii. A U.S. organization participating in the Privacy Shield that uses EU human resources data transferred from the European Union in the context of the employment relationship and that wishes such transfers to be covered by the Privacy Shield must therefore commit to cooperate in investigations by and to comply with the advice of competent EU authorities in such cases.

e. Application of the Accountability for Onward Transfer Principle

i. For occasional employment-related operational needs of the Privacy Shield organization with respect to personal data transferred under the Privacy Shield, such as the booking of a flight, hotel room, or insurance coverage, transfers of personal data of a small number of employees can take place to controllers without application of the Access Principle or entering into a contract with the third-party controller, as otherwise required under the Accountability for Onward Transfer Principle, provided that the Privacy Shield organization has complied with the Notice and Choice Principles.

10. Obligatory Contracts for Onward Transfers

a. Data Processing Contracts

i. When personal data is transferred from the EU to the United States only for processing purposes, a contract will be required, regardless of participation by the processor in the Privacy Shield.

ii. Data controllers in the European Union are always required to enter into a contract when a transfer for mere processing is made, whether the processing operation is carried out inside or outside the EU, and whether or not the processor participates in the Privacy Shield. The purpose of the contract is to make sure that the processor:

1. acts only on instructions from the controller;

2. provides appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alternation, unauthorized disclosure or access, and understands whether onward transfer is allowed; and

3. taking into account the nature of the processing, assists the controller in responding to individuals exercising their rights under the Principles.

iii. Because adequate protection is provided by Privacy Shield participants, contracts with Privacy Shield participants for mere processing do not require prior authorization (or such authorization will be granted automatically by the EU Member States), as would be required for contracts with recipients not participating in the Privacy Shield or otherwise not providing adequate protection.

b. Transfers within a Controlled Group of Corporations or Entities

i. When personal information is transferred between two controllers within a controlled group of corporations or entities, a contract is not always required under the Accountability for Onward Transfer Principle. Data controllers within a controlled group of corporations or entities may base such transfers on other instruments, such as EU Binding Corporate Rules or other intra-group instruments (*e.g.*, compliance and control programs), ensuring the continuity of protection of personal information under the Principles. In case of such transfers, the Privacy Shield organization remains responsible for compliance with the Principles.

c. Transfers between Controllers

i. For transfers between controllers, the recipient controller need not be a Privacy Shield organization or have an independent recourse mechanism. The Privacy Shield organization must enter into a contract with the recipient third-party controller that provides for the same level of protection as is available under the Privacy Shield,

not including the requirement that the third party controller be a Privacy Shield organization or have an independent recourse mechanism, provided it makes available an equivalent mechanism.

11. Dispute Resolution and Enforcement

a. The Recourse, Enforcement and Liability Principle sets out the requirements for Privacy Shield enforcement. How to meet the requirements of point (a)(ii) of the Principle is set out in the Supplemental Principle on Verification. This Supplemental Principle addresses points (a)(i) and (a)(iii), both of which require independent recourse mechanisms. These mechanisms may take different forms, but they must meet the Recourse, Enforcement and Liability Principle's requirements. Organizations satisfy the requirements through the following: (i) compliance with private sector developed privacy programs that incorporate the Privacy Shield Principles into their rules and that include effective enforcement mechanisms of the type described in the Recourse, Enforcement and Liability Principle; (ii) compliance with legal or regulatory supervisory authorities that provide for handling of individual complaints and dispute resolution; or (iii) commitment to cooperate with data protection authorities located in the European Union or their authorized representatives.

b. This list is intended to be illustrative and not limiting. The private sector may design additional mechanisms to provide enforcement, so long as they meet the requirements of the Recourse, Enforcement and Liability Principle and the Supplemental Principles. Please note that the Recourse, Enforcement and Liability Principle's requirements are additional to the requirement that self-regulatory efforts must be enforceable under Section 5 of the Federal Trade Commission Act, which prohibits unfair and deceptive acts, or another law or regulation prohibiting such acts.

c. In order to help ensure compliance with their Privacy Shield commitments and to support the administration of the program, organizations, as well as their independent recourse mechanisms, must provide information relating to the Privacy Shield when requested by the Department. In addition, organizations must respond expeditiously to complaints regarding their compliance with the Principles referred through the Department by DPAs. The response should address whether the complaint has merit and, if so, how the organization will rectify the problem. The Department will protect the confidentiality of information it receives in accordance with U.S. law.

d. Recourse Mechanisms

i. Consumers should be encouraged to raise any complaints they may have with the relevant organization before proceeding to independent recourse mechanisms. Organizations must respond to a consumer within 45 days of receiving a complaint. Whether a recourse mechanism is independent is a factual question that can be

demonstrated notably by impartiality, transparent composition and financing, and a proven track record. As required by the Recourse, Enforcement and Liability Principle, the recourse available to individuals must be readily available and free of charge to individuals. Dispute resolution bodies should look into each complaint received from individuals unless they are obviously unfounded or frivolous. This does not preclude the establishment of eligibility requirements by the organization operating the recourse mechanism, but such requirements should be transparent and justified (for example, to exclude complaints that fall outside the scope of the program or are for consideration in another forum), and should not have the effect of undermining the commitment to look into legitimate complaints. In addition, recourse mechanisms should provide individuals with full and readily available information about how the dispute resolution procedure works when they file a complaint. Such information should include notice about the mechanism's privacy practices, in conformity with the Privacy Shield Principles. They should also cooperate in the development of tools such as standard complaint forms to facilitate the complaint resolution process.

ii. Independent recourse mechanisms must include on their public websites information regarding the Privacy Shield Principles and the services that they provide under the Privacy Shield. This information must include: (1) information on or a link to the Privacy Shield Principles' requirements for independent recourse mechanisms; (2) a link to the Department's Privacy Shield website; (3) an explanation that their dispute resolution services under the Privacy Shield are free of charge to individuals; (4) a description of how a Privacy Shield-related complaint can be filed; (5) the timeframe in which Privacy Shield-related complaints are processed; and (6) a description of the range of potential remedies.

iii. Independent recourse mechanisms must publish an annual report providing aggregate statistics regarding their dispute resolution services. The annual report must include: (1) the total number of Privacy Shield-related complaints received during the reporting year; (2) the types of complaints received; (3) dispute resolution quality measures, such as the length of time taken to process complaints; and (4) the outcomes of the complaints received, notably the number and types of remedies or sanctions imposed.

iv. As set forth in Annex I, an arbitration option is available to an individual to determine, for residual claims, whether a Privacy Shield organization has violated its obligations under the Principles as to that individual, and whether any such violation remains fully or partially unremedied. This option is available only for these purposes. This option is not available, for example, with respect to

the exceptions to the Principles[5] or with respect to an allegation about the adequacy of the Privacy Shield. Under this arbitration option, the Privacy Shield Panel (consisting of one or three arbitrators, as agreed by the parties) has the authority to impose individual-specific, non-monetary equitable relief (such as access, correction, deletion, or return of the individual's data in question) necessary to remedy the violation of the Principles only with respect to the individual. Individuals and Privacy Shield organizations will be able to seek judicial review and enforcement of the arbitral decisions pursuant to U.S. law under the Federal Arbitration Act.

e. Remedies and Sanctions

i. The result of any remedies provided by the dispute resolution body should be that the effects of non-compliance are reversed or corrected by the organization, insofar as feasible, and that future processing by the organization will be in conformity with the Principles and, where appropriate, that processing of the personal data of the individual who brought the complaint will cease. Sanctions need to be rigorous enough to ensure compliance by the organization with the Principles. A range of sanctions of varying degrees of severity will allow dispute resolution bodies to respond appropriately to varying degrees of non-compliance. Sanctions should include both publicity for findings of non-compliance and the requirement to delete data in certain circumstances.[6] Other sanctions could include suspension and removal of a seal, compensation for individuals for losses incurred as a result of non-compliance and injunctive awards. Private sector dispute resolution bodies and self-regulatory bodies must notify failures of Privacy Shield organizations to comply with their rulings to the governmental body with applicable jurisdiction or to the courts, as appropriate, and to notify the Department.

f. FTC Action

ii. The FTC has committed to reviewing on a priority basis referrals alleging non-compliance with the Principles received from: (i) privacy self-regulatory organizations and other independent dispute resolution bodies; (ii) EU Member States; and (iii) the Department, to determine whether Section 5 of the FTC Act prohibiting unfair or deceptive acts or practices in commerce has been violated. If the FTC concludes that it has reason to believe Section 5 has been

[5] Section I.5 of the Principles.

[6] Dispute resolution bodies have discretion about the circumstances in which they use these sanctions. The sensitivity of the data concerned is one factor to be taken into consideration in deciding whether deletion of data should be required, as is whether an organization has collected, used, or disclosed information in blatant contravention of the Privacy Shield Principles.

violated, it may resolve the matter by seeking an administrative cease and desist order prohibiting the challenged practices or by filing a complaint in a federal district court, which if successful could result in a federal court order to same effect. This includes false claims of adherence to the Privacy Shield Principles or participation in the Privacy Shield by organizations, which either are no longer on the Privacy Shield List or have never self-certified to the Department. The FTC may obtain civil penalties for violations of an administrative cease and desist order and may pursue civil or criminal contempt for violation of a federal court order. The FTC will notify the Department of any such actions it takes. The Department encourages other government bodies to notify it of the final disposition of any such referrals or other rulings determining adherence to the Privacy Shield Principles.

g. Persistent Failure to Comply

i. If an organization persistently fails to comply with the Principles, it is no longer entitled to benefit from the Privacy Shield. Organizations that have persistently failed to comply with the Principles will be removed from the Privacy Shield List by the Department and must return or delete the personal information they received under the Privacy Shield.

ii. Persistent failure to comply arises where an organization that has self-certified to the Department refuses to comply with a final determination by any privacy self-regulatory, independent dispute resolution, or government body, or where such a body determines that an organization frequently fails to comply with the Principles to the point where its claim to comply is no longer credible. In these cases, the organization must promptly notify the Department of such facts. Failure to do so may be actionable under the False Statements Act (18 U.S.C. § 1001). An organization's withdrawal from a private-sector privacy self-regulatory program or independent dispute resolution mechanism does not relieve it of its obligation to comply with the Principles and would constitute a persistent failure to comply.

iii. The Department will remove an organization from the Privacy Shield List in response to any notification it receives of persistent failure to comply, whether it is received from the organization itself, from a privacy self-regulatory body or another independent dispute resolution body, or from a government body, but only after first providing 30 days' notice and an opportunity to respond to the organization that has failed to comply. Accordingly, the Privacy Shield List maintained by the Department will make clear which organizations are assured and which organizations are no longer assured of Privacy Shield benefits.

iv. An organization applying to participate in a self-regulatory body for the purposes of requalifying for the Privacy Shield must provide that body with full information about its prior participation in the Privacy Shield.

12. Choice – Timing of Opt Out

a. Generally, the purpose of the Choice Principle is to ensure that personal information is used and disclosed in ways that are consistent with the individual's expectations and choices. Accordingly, an individual should be able to exercise "opt out" choice of having personal information used for direct marketing at any time subject to reasonable limits established by the organization, such as giving the organization time to make the opt out effective. An organization may also require sufficient information to confirm the identity of the individual requesting the "opt out." In the United States, individuals may be able to exercise this option through the use of a central "opt out" program such as the Direct Marketing Association's Mail Preference Service. Organizations that participate in the Direct Marketing Association's Mail Preference Service should promote its availability to consumers who do not wish to receive commercial information. In any event, an individual should be given a readily available and affordable mechanism to exercise this option.

b. Similarly, an organization may use information for certain direct marketing purposes when it is impracticable to provide the individual with an opportunity to opt out before using the information, if the organization promptly gives the individual such opportunity at the same time (and upon request at any time) to decline (at no cost to the individual) to receive any further direct marketing communications and the organization complies with the individual's wishes.

13. Travel Information

a. Airline passenger reservation and other travel information, such as frequent flyer or hotel reservation information and special handling needs, such as meals to meet religious requirements or physical assistance, may be transferred to organizations located outside the EU in several different circumstances. Under Article 26 of the Directive, personal data may be transferred "to a third country which does not ensure an adequate level of protection within the meaning of Article 25(2)" on the condition that it (i) is necessary to provide the services requested by the consumer or to fulfill the terms of an agreement, such as a "frequent flyer" agreement; or (ii) has been unambiguously consented to by the consumer. U.S. organizations subscribing to the Privacy Shield provide adequate protection for personal data and may therefore receive data transfers from the EU without meeting these conditions or other conditions set out in Article 26 of the Directive. Since the Privacy Shield includes specific rules for sensitive information, such information (which may need to be collected, for example, in

connection with customers' needs for physical assistance) may be included in transfers to Privacy Shield participants. In all cases, however, the organization transferring the information has to respect the law in the EU Member State in which it is operating, which may inter alia impose special conditions for the handling of sensitive data.

14. Pharmaceutical and Medical Products

a. Application of EU Member State Laws or the Privacy Shield Principles

i. EU Member State law applies to the collection of the personal data and to any processing that takes place prior to the transfer to the United States. The Privacy Shield Principles apply to the data once they have been transferred to the United States. Data used for pharmaceutical research and other purposes should be anonymized when appropriate.

b. Future Scientific Research

i. Personal data developed in specific medical or pharmaceutical research studies often play a valuable role in future scientific research. Where personal data collected for one research study are transferred to a U.S. organization in the Privacy Shield, the organization may use the data for a new scientific research activity if appropriate notice and choice have been provided in the first instance. Such notice should provide information about any future specific uses of the data, such as periodic follow-up, related studies, or marketing.

ii. It is understood that not all future uses of the data can be specified, since a new research use could arise from new insights on the original data, new medical discoveries and advances, and public health and regulatory developments. Where appropriate, the notice should therefore include an explanation that personal data may be used in future medical and pharmaceutical research activities that are unanticipated. If the use is not consistent with the general research purpose(s) for which the personal data were originally collected, or to which the individual has consented subsequently, new consent must be obtained.

c. Withdrawal from a Clinical Trial

i. Participants may decide or be asked to withdraw from a clinical trial at any time. Any personal data collected previous to withdrawal may still be processed along with other data collected as part of the clinical trial, however, if this was made clear to the participant in the notice at the time he or she agreed to participate.

d. Transfers for Regulatory and Supervision Purposes

i. Pharmaceutical and medical device companies are allowed to provide personal data from clinical trials conducted in the EU to regulators in the United States for regulatory and supervision purposes. Similar transfers are allowed to parties other than regulators, such as company locations and other researchers, consistent with the Principles of Notice and Choice.

e. "Blinded" Studies

i. To ensure objectivity in many clinical trials, participants, and often investigators as well, cannot be given access to information about which treatment each participant may be receiving. Doing so would jeopardize the validity of the research study and results. Participants in such clinical trials (referred to as "blinded" studies) do not have to be provided access to the data on their treatment during the trial if this restriction has been explained when the participant entered the trial and the disclosure of such information would jeopardize the integrity of the research effort.

ii. Agreement to participate in the trial under these conditions is a reasonable forgoing of the right of access. Following the conclusion of the trial and analysis of the results, participants should have access to their data if they request it. They should seek it primarily from the physician or other health care provider from whom they received treatment within the clinical trial, or secondarily from the sponsoring organization.

f. Product Safety and Efficacy Monitoring

i. A pharmaceutical or medical device company does not have to apply the Privacy Shield Principles with respect to the Notice, Choice, Accountability for Onward Transfer, and Access Principles in its product safety and efficacy monitoring activities, including the reporting of adverse events and the tracking of patients/subjects using certain medicines or medical devices, to the extent that adherence to the Principles interferes with compliance with regulatory requirements. This is true both with respect to reports by, for example, health care providers to pharmaceutical and medical device companies, and with respect to reports by pharmaceutical and medical device companies to government agencies like the Food and Drug Administration.

g. Key-coded Data

i. Invariably, research data are uniquely key-coded at their origin by the principal investigator so as not to reveal the identity of individual data subjects. Pharmaceutical companies sponsoring such research do not receive the key. The unique key code is held only by the researcher, so that he or she can identify the research subject under special circumstances (*e.g.*, if follow-up medical attention is

required). A transfer from the EU to the United States of data coded in this way would not constitute a transfer of personal data that would be subject to the Privacy Shield Principles.

15. Public Record and Publicly Available Information

a. An organization must apply the Privacy Shield Principles of Security, Data Integrity and Purpose Limitation, and Recourse, Enforcement and Liability to personal data from publicly available sources. These Principles shall apply also to personal data collected from public records, *i.e.*, those records kept by government agencies or entities at any level that are open to consultation by the public in general.

b. It is not necessary to apply the Notice, Choice, or Accountability for Onward Transfer Principles to public record information, as long as it is not combined with non-public record information, and any conditions for consultation established by the relevant jurisdiction are respected. Also, it is generally not necessary to apply the Notice, Choice, or Accountability for Onward Transfer Principles to publicly available information unless the European transferor indicates that such information is subject to restrictions that require application of those Principles by the organization for the uses it intends. Organizations will have no liability for how such information is used by those obtaining such information from published materials.

c. Where an organization is found to have intentionally made personal information public in contravention of the Principles so that it or others may benefit from these exceptions, it will cease to qualify for the benefits of the Privacy Shield.

d. It is not necessary to apply the Access Principle to public record information as long as it is not combined with other personal information (apart from small amounts used to index or organize the public record information); however, any conditions for consultation established by the relevant jurisdiction are to be respected. In contrast, where public record information is combined with other non-public record information (other than as specifically noted above), an organization must provide access to all such information, assuming it is not subject to other permitted exceptions.

e. As with public record information, it is not necessary to provide access to information that is already publicly available to the public at large, as long as it is not combined with non-publicly available information. Organizations that are in the business of selling publicly available information may charge the organization's customary fee in responding to requests for access. Alternatively, individuals may seek access to their information from the organization that originally compiled the data.

16. Access Requests by Public Authorities

a. In order to provide transparency in respect of lawful requests by public authorities to access personal information, Privacy Shield organizations may voluntarily issue periodic transparency reports on the number of requests for personal information they receive by public authorities for law enforcement or national security reasons, to the extent such disclosures are permissible under applicable law.

b. The information provided by the Privacy Shield organizations in these reports together with information that has been released by the intelligence community, along with other information, can be used to inform the annual joint review of the functioning of the Privacy Shield in accordance with the Principles.

c. Absence of notice in accordance with point (a)(xii) of the Notice Principle shall not prevent or impair an organization's ability to respond to any lawful request.

ANNEX I:
Arbitral Model

ANNEX I

This Annex I provides the terms under which Privacy Shield organizations are obligated to arbitrate claims, pursuant to the Recourse, Enforcement and Liability Principle. The binding arbitration option described below applies to certain "residual" claims as to data covered by the EU-U.S. Privacy Shield. The purpose of this option is to provide a prompt, independent, and fair mechanism, at the option of individuals, for resolution of claimed violations of the Principles not resolved by any of the other Privacy Shield mechanisms, if any.

A. Scope

This arbitration option is available to an individual to determine, for residual claims, whether a Privacy Shield organization has violated its obligations under the Principles as to that individual, and whether any such violation remains fully or partially unremedied. This option is available only for these purposes. This option is not available, for example, with respect to the exceptions to the Principles[1] or with respect to an allegation about the adequacy of the Privacy Shield.

B. Available Remedies

Under this arbitration option, the Privacy Shield Panel (consisting of one or three arbitrators, as agreed by the parties) has the authority to impose individual-specific, non-monetary equitable relief (such as access, correction, deletion, or return of the individual's data in question) necessary to remedy the violation of the Principles only with respect to the individual. These are the only powers of the arbitration panel with respect to remedies. In considering remedies, the arbitration panel is required to consider other remedies that already have been imposed by other mechanisms under the Privacy Shield. No damages, costs, fees, or other remedies are available. Each party bears its own attorney's fees.

C. Pre-Arbitration Requirements

An individual who decides to invoke this arbitration option must take the following steps prior to initiating an arbitration claim: (1) raise the claimed violation directly with the organization and afford the organization an opportunity to resolve the issue within the timeframe set forth in Section III.11(d)(i) of the Principles; (2) make use of the independent recourse mechanism under the Principles, which is at no cost to the individual; and (3) raise the issue through their Data Protection Authority to the Department of Commerce and afford the Department of Commerce an opportunity to use best efforts to resolve the issue within the timeframes set forth in the Letter from the International Trade Administration of the Department of Commerce, at no cost to the individual.

This arbitration option may not be invoked if the individual's same claimed violation of the Principles (1) has previously been subject to binding arbitration; (2) was the subject of a final judgment entered in a court action to which the individual was a party; or (3) was previously settled by the parties. In addition, this option may not be invoked if an EU Data Protection

[1] Section I.5 of the Principles.

Authority (1) has authority under Sections III.5 or III.9 of the Principles; or (2) has the authority to resolve the claimed violation directly with the organization. A DPA's authority to resolve the same claim against an EU data controller does not alone preclude invocation of this arbitration option against a different legal entity not bound by the DPA authority.

D. Binding Nature of Decisions

An individual's decision to invoke this binding arbitration option is entirely voluntary. Arbitral decisions will be binding on all parties to the arbitration. Once invoked, the individual forgoes the option to seek relief for the same claimed violation in another forum, except that if non-monetary equitable relief does not fully remedy the claimed violation, the individual's invocation of arbitration will not preclude a claim for damages that is otherwise available in the courts.

E. Review and Enforcement

Individuals and Privacy Shield organizations will be able to seek judicial review and enforcement of the arbitral decisions pursuant to U.S. law under the Federal Arbitration Act.[2] Any such cases must be brought in the federal district court whose territorial coverage includes the primary place of business of the Privacy Shield organization.

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[2]Chapter 2 of the Federal Arbitration Act ("FAA") provides that "[a]n arbitration agreement or arbitral award arising out of a legal relationship, whether contractual or not, which is considered as commercial, including a transaction, contract, or agreement described in [section 2 of the FAA], falls under the Convention [on the Recognition and Enforcement of Foreign Arbitral Awards of June 10, 1958, 21 U.S.T. 2519, T.I.A.S. No. 6997 ("New York Convention")]." 9 U.S.C. § 202. The FAA further provides that "[a]n agreement or award arising out of such a relationship which is entirely between citizens of the United States shall be deemed not to fall under the [New York] Convention unless that relationship involves property located abroad, envisages performance or enforcement abroad, or has some other reasonable relation with one or more foreign states." *Id.* Under Chapter 2, "any party to the arbitration may apply to any court having jurisdiction under this chapter for an order confirming the award as against any other party to the arbitration. The court shall confirm the award unless it finds one of the grounds for refusal or deferral of recognition or enforcement of the award specified in the said [New York] Convention." *Id.* § 207. Chapter 2 further provides that "[t]he district courts of the United States . . . shall have original jurisdiction over . . . an action or proceeding [under the New York Convention], regardless of the amount in controversy." *Id.* § 203.

Chapter 2 also provides that "Chapter 1 applies to actions and proceedings brought under this chapter to the extent that chapter is not in conflict with this chapter or the [New York] Convention as ratified by the United States." *Id.* § 208. Chapter 1, in turn, provides that "[a] written provision in . . . a contract evidencing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract or transaction, or the refusal to perform the whole or any part thereof, or an agreement in writing to submit to arbitration an existing controversy arising out of such a contract, transaction, or refusal, shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract." *Id.* § 2. Chapter 1 further provides that "any party to the arbitration may apply to the court so specified for an order confirming the award, and thereupon the court must grant such an order unless the award is vacated, modified, or corrected as prescribed in sections 10 and 11 of [the FAA]." *Id.* § 9.

This arbitration option is intended to resolve individual disputes, and arbitral decisions are not intended to function as persuasive or binding precedent in matters involving other parties, including in future arbitrations or in EU or U.S. courts, or FTC proceedings.

F. The Arbitration Panel

The parties will select the arbitrators from the list of arbitrators discussed below.

Consistent with applicable law, the U.S. Department of Commerce and the European Commission will develop a list of at least 20 arbitrators, chosen on the basis of independence, integrity, and expertise. The following shall apply in connection with this process:

Arbitrators:

(1) will remain on the list for a period of 3 years, absent exceptional circumstances or for cause, renewable for one additional period of 3 years;
(2) shall not be subject to any instructions from, or be affiliated with, either party, or any Privacy Shield organization, or the U.S., EU, or any EU Member State or any other governmental authority, public authority, or enforcement authority; and
(3) must be admitted to practice law in the U.S. and be experts in U.S. privacy law, with expertise in EU data protection law.

G. Arbitration Procedures

Consistent with applicable law, within 6 months from the adoption of the adequacy decision, the Department of Commerce and the European Commission will agree to adopt an existing, well-established set of U.S. arbitral procedures (such as AAA or JAMS) to govern proceedings before the Privacy Shield Panel, subject to each of the following considerations:

1. An individual may initiate binding arbitration, subject to the pre-arbitration requirements provision above, by delivering a "Notice" to the organization. The Notice shall contain a summary of steps taken under Paragraph C to resolve the claim, a description of the alleged violation, and, at the choice of the individual, any supporting documents and materials and/or a discussion of law relating to the alleged claim.
2. Procedures will be developed to ensure that an individual's same claimed violation does not receive duplicative remedies or procedures.
3. FTC action may proceed in parallel with arbitration.
4. No representative of the U.S., EU, or any EU Member State or any other governmental authority, public authority, or enforcement authority may participate in these arbitrations, provided, that at the request of an EU individual, EU DPAs may provide assistance in the preparation only of the Notice but EU DPAs may not have access to discovery or any other materials related to these arbitrations.
5. The location of the arbitration will be the United States, and the individual may choose video or telephone participation, which will be provided at no cost to the individual. In-person participation will not be required.

6. The language of the arbitration will be English unless otherwise agreed by the parties. Upon a reasoned request, and taking into account whether the individual is represented by an attorney, interpretation at the arbitral hearing as well as translation of arbitral materials will be provided at no cost to the individual, unless the panel finds that, under the circumstances of the specific arbitration, this would lead to unjustified or disproportionate costs.
7. Materials submitted to arbitrators will be treated confidentially and will only be used in connection with the arbitration.
8. Individual-specific discovery may be permitted if necessary, and such discovery will be treated confidentially by the parties and will only be used in connection with the arbitration.
9. Arbitrations should be completed within 90 days of the delivery of the Notice to the organization at issue, unless otherwise agreed to by the parties.

H. Costs

Arbitrators should take reasonable steps to minimize the costs or fees of the arbitrations.

Subject to applicable law, the Department of Commerce will facilitate the establishment of a fund, into which Privacy Shield organizations will be required to pay an annual contribution, based in part on the size of the organization, which will cover the arbitral cost, including arbitrator fees, up to maximum amounts ("caps"), in consultation with the European Commission. The fund will be managed by a third party, which will report regularly on the operations of the fund. At the annual review, the Department of Commerce and European Commission will review the operation of the fund, including the need to adjust the amount of the contributions or of the caps, and will consider, among other things, the number of arbitrations and the costs and timing of the arbitrations, with the mutual understanding that there will be no excessive financial burden imposed on Privacy Shield organizations. Attorney's fees are not covered by this provision or any fund under this provision.

Concurring Statement

SEPARATE STATEMENT OF COMMISSIONER NOAH JOSHUA PHILLIPS

Despite representing that it would not share its users' health details with anyone, Flo Health, Inc. ("Flo") allegedly did so. As charged in the complaint, Flo coded app events, a mechanism by which app developers use third-party analytics to track how users use their apps, with words like "Pregnancy", and then shared them with analytics divisions of third parties including Facebook and Google.[1] I support this complaint and consent, which sends an important message about the care that app developers must take to level with users about how they share user data.

I write to respond to the vision my colleagues articulate about when the Commission should use consumer notice in our data security and privacy enforcement program.

The order that we place on the public record for comment requires Flo to seek deletion of data it improperly shared with third parties; obtain users' affirmative express consent before sharing their health information with third parties; report to the Commission future unauthorized disclosures; obtain an outside assessment of its privacy practices; and provide the following notice to consumers:

> Between June 1, 2016 and February 23, 2019, the company that makes the Flo Period & Ovulation Tracker app sent an identifying number related to you and information about your period and pregnancy to companies that help us measure and analyze trends, usage, and activities on the app, including the analytics divisions of Facebook, Flurry, Fabric, and Google. No information was shared with the social media divisions of these companies. We did not share your name, address, or birthday with anyone at any time.[2]

In championing the consumer notice remedy in their concurring statement, Commissioners Chopra and Slaughter propose that the Commission no longer assess each case on its particular merits when determining when to order consumer notice.[3] Rather, they assert that "the Commission should presumptively seek notice provisions in privacy and data security matters, especially in matters that do not include redress for victims."[4] I disagree with that approach.

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1 The Complaint does not challenge the use of third-party analytics services, upon which developers routinely rely. Because Flo Health coded events with names like "R_Pregnancy_Week_Chosen", rather than something generic like "Event 1", the events conveyed health information. The Wall Street Journal reported this conveyance on February 22, 2019, and the next day Flo Health ceased its conduct.

2 Consent, Exhibit A.

3 Commissioners Chopra and Slaughter also assert that the "plain language" of the Health Breach Notification Rule covers Flo. I disagree. We have never applied the Rule to a health app such as Flo in the past, in part because the language of the Rule is not so plain. And I do not support announcing such a novel interpretation of the Rule here, in the context of an enforcement action. *See* Joint Statement of Comm'r Chopra and Comm'r Slaughter, *In re Flo Health*, File No. 1923133 (Jan. 13, 2021).

4 *Id*.

Concurring Statement

The Commission has used notice requirements to prevent ongoing harm to consumers and to enable them to remediate the effects of harm suffered. To that end, the Commission has required consumer notice in cases where:

- consumers' health or safety is at risk;[5]
- consumers are subject to recurring charges that they may be unaware of;[6]
- consumers have a financial or legal interest that needs to be protected;[7]
- notice is necessary to prevent the ongoing dissemination of deceptive information;[8] or
- consumers on their own would not have been able to discover or determine the illegal behavior and would not know to take remedial action.[9]

Using these guidelines, the Commission has found consumer notice appropriate in some privacy and data security cases as well, such as when there was a need to inform consumers about ongoing data collection and sharing[10] or to correct a deceptive data breach notification.[11] On the data security front, where it can be critical that consumers know that sensitive information has been breached or exposed, a panoply of state breach notification laws require notice to consumers.

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5 For example, in *Daniel Chapter One*, No. 9329 (Jan. 25, 2010) https://www ftc.gov/enforcement/cases-proceedings/082-3085/daniel-chapter-one, the final order required the respondent to notify consumers that the company's cancer treatment claims regarding its dietary supplements were deceptive, and the supplements could actually interfere with cancer treatment.

6 For example, in the stipulated final order in *FTC v. Lumos Labs, Inc.*, No. 3:16-cv-0001, at 12-13, 22-23 (C.D. Cal. Jan. 8, 2016), the required notices described the FTC's allegations and explained how to cancel service.

7 In *FTC v. American Financial Benefits Center*, No. 4:18-cv-00806 (N.D. Cal. Feb. 7, 2018), consumers were notified that their recurring payments to the company were not being used to pay off their student loans.

8 In *FTC v. Applied Food Sciences, Inc.*, No. 1:14-cv-00851 at 12, 21 (W.D. Tex. Sept. 10, 2014), a wholesaler of dietary supplement ingredients distributed misleading information to supplement makers, touting the results of a clinical study that the FTC's investigation had shown to be botched. The company was required to notify all supplement makers who had received the misleading information that the FTC did not find the study credible.

9 For example, in *Oracle Corp.*, No. C-4571 (Mar. 29, 2016), https://www ftc.gov/enforcement/cases-proceedings/132-3115/oracle-corporation-matter, the settlement required Oracle to notify consumers about certain data security risks and explain how to protect their personal information by deleting older versions of Java.

10 *Unrollme Inc.*, No. C-4692 (Dec. 17, 2019), https://www.ftc.gov/enforcement/cases-proceedings/172-3139/unrollme-inc-matter.

11 *Unrollme Inc.*, No. C-4692 (Dec. 17, 2019), https://www.ftc.gov/enforcement/cases-proceedings/172-3139/unrollme-inc-matter.

When warranted, notice to consumers can be an important tool. But neither the Commission, nor any of the 50 states with data breach notification laws, have taken the position of requiring consumer notice for the mere sake of the notice itself. Commissioners Chopra and Slaughter stress that notice is warranted especially where redress is not paid to consumers. How consumer notice substitutes for redress, an equitable mechanism to return to consumers what they have lost, is not clear. Nor is it clear what, if anything, limits this approach to notice to data security and privacy cases. To the extent notice is intended as a penalty, I disagree. My view is that we should target notice as a means to help consumers take action to protect themselves. Contacting consumers when there is no remedial action that they can take runs the risk of undermining consumer trust and needlessly overwhelming consumers.[12]

12 I am also concerned about the possibility of notice fatigue. For example, in the context of security warnings on mobile devices, there is evidence of a decreased neurological response after repeated exposure to warnings. *See, e.g.*, Anthony Vance et al., *Tuning Out Security Warnings: A Longitudinal Examination of Habituation Through fMRI, Eye Tracking, and Field Experiments*, 42 MIS Quarterly, No. 2, June 2018, at 1, https://misq.org/skin/frontend/default/misq/pdf/appendices/2018/V42I1Appendices/14124_RA_VanceJenkins.pdf.

JOINT STATEMENT OF COMMISSIONER ROHIT CHOPRA AND COMMISSIONER REBECCA KELLY SLAUGHTER CONCURRING IN PART, DISSENTING IN PART

Today, the FTC is ordering Flo Health, Inc. ("Flo") to notify consumers that it has been charged with sharing consumers' menstruation and fertility information without their consent. This proposed settlement is a change for the FTC, which has never before ordered notice of a privacy action. We commend the agency's staff for securing this relief and for addressing Flo's concerning practices.

While we are pleased to see this change, we are disappointed that the Commission is not using all of its tools to hold accountable those who abuse and misuse personal data. We believe that Flo's conduct violated the Health Breach Notification Rule, yet the Commission's proposed complaint fails to include this allegation. The rule helps ensure that consumers are informed when their data is misused, and firms like Flo should not be ignoring it.

Importance of Notice

Flo Health is the developer of a popular mobile app that collects menstruation and fertility information from millions of users worldwide. As detailed in the Commission's complaint, Flo promised these users that it would not disclose their sensitive information to third parties, but did so anyway – sharing it with Facebook, Google, and others.[1] This alleged conduct broke user trust, and it broke the law.

In addition to requiring Flo to improve its privacy practices, the FTC's proposed order directs Flo to notify its users of this serious breach. Notice confers a number of benefits in cases like this one. Consumers deserve to know when a company made false privacy promises, so they can modify their usage or switch services. Notice also informs how consumers review a service, and whether they will recommend it to others. Finally, notice accords consumers the dignity of knowing what happened. For all these reasons, the Commission should presumptively seek notice provisions in privacy and data security matters, especially in matters that do not include redress for victims.[2]

1 Compl., In the Matter of Flo Health, Inc., Docket No. 1923133, ¶¶ 13-24.

2 In a separate statement, Commissioner Phillips argues that notice should be limited to circumstances under which it can "help consumers take action to protect themselves." *See* Separate Statement of Commissioner Noah Joshua Phillips In the Matter of Flo Health, Inc. Comm'n File No. 1923133 at 2 (Jan. 13, 2021). In our view, the notice requirement here squarely meets that test, as consumers can switch to more privacy-protecting services or adjust their data-sharing behavior with companies that act unlawfully. Commissioner Phillips further suggests that notice is no substitute for redress. We agree. But when redress is not ordered, notice at least ensures consumers are aware of the FTC's action, which might otherwise be achieved through a redress check. Finally, Commissioner Phillips argues that consumers may not read all notices. This is a valid concern, and notice is no substitute for other remedies, such as admissions of liability or substantive limits on the collection, use, and abuse of personal data.

Health Breach Notification Rule

The Commission must also ensure it is vigorously enforcing the laws on the books. Congress has entrusted the FTC with promulgating and enforcing the Health Breach Notification Rule, one of only a handful of federal privacy laws protecting consumers. The rule requires vendors of unsecured health information, including mobile health apps, to notify users and the FTC if there has been an unauthorized disclosure. Although the FTC has advised mobile health apps to examine their obligations under the rule,[3] including through the use of an interactive tool,[4] the FTC has never brought an action to enforce it.[5]

In our view, the FTC should have charged Flo with violating the Health Breach Notification Rule. Under the rule, Flo was obligated to notify its users after it allegedly shared their health information with Facebook, Google, and others without their authorization.[6] Flo did not do so, making the company liable under the rule.[7]

The Health Breach Notification Rule was first issued more than a decade ago, but the explosion in connected health apps make its requirements more important than ever. While we

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3 *Mobile Health App Developers: FTC Best Practices*, FED. TRADE COMM'N, https://www ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices (last visited on Jul. 31, 2020).

4 *Mobile Health Apps Interactive Tool*, FED. TRADE COMM'N, https://www ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool (last visited on Jul. 31, 2020).

5 Commissioner Phillips suggests that enforcing the rule against Flo would be "novel." Phillips Statement, s*upra* note 2, at 1. But, this could be said of any enforcement action in this context, since the Commission has never enforced the Health Breach Notification Rule. If there is concern that Flo did not know it was violating the rule, that would be relevant to the question of whether Flo is liable for civil penalties. *See* 15 U.S.C. § 45(m)(1)(A). Flo's lack of knowledge about the rule's requirements would not be relevant to the question of whether the Commission could charge Flo with a violation.

6 *See* Compl., *supra* note 1, ¶¶ 18-24. The FTC's Health Breach Notification Rule covers (a) health care providers that (b) store unsecured, personally identifiable health information that (c) can be drawn from multiple sources, and the rule is triggered when such entities experience a "breach of security." *See* 16 C.F.R. § 318. Under the definitions

cross-referenced by the Rule, Flo – which markets itself as a "health assistant" – is a "health care provider," in that it "furnish[es] health care services and supplies." *See* 16 C.F.R. § 318.2(e); 42 U.S.C. § 1320d(6), d(3). Additionally, Flo stores personally identifiable health information that is not secured according to an HHS-approved method, and that can be drawn from multiple source. *See* 16 C.F.R. § 318.2(i); *Fitness Trackers and Apps*, FLO HEALTH, https://flo health/faq/fitness-trackers-and-apps (last visited on Jan. 6, 2020) (instructing users on how to sync Flo with other apps). When Flo, according to the complaint, disclosed sensitive health information without users' authorization, this was a "breach of security" under the rule 16 C.F.R. § 318.2(a) (defining "breach of security" as "acquisition of [PHR identifiable health information] without the authorization of the individual.")

7 *See* 16 C.F.R. § 318.7 (stating that a violation of the rule constitutes a violation of a trade regulation rule). Notably, California's recent action against a similar fertility-tracking app charged with similar privacy violations included a $250,000 civil penalty. Press Release, Cal. Att'y Gen., Attorney General Becerra Announces Landmark Settlement Against Glow, Inc. – Fertility App Risked Exposing Millions of Women's Personal and Medical Information (Sep. 17, 2020), https://oag.ca.gov/news/press-releases/attorney-general-becerra-announces-landmark-settlement-against-glow-inc-%E2%80%93.

would prefer to see substantive limits on firms' ability to collect and monetize our personal information, the rule at least ensures that services like Flo need to come clean when they experience privacy or security breaches. Over time, this may induce firms to take greater care in collecting and monetizing our most sensitive information.

Conclusion

We are pleased to see a notice provision in today's proposed order, but there is much more the FTC can do to protect consumers' data, and hold accountable those who abuse it. Where Congress has given us rulemaking authority, we should use it.[8] And where we have rules already on the books, we should enforce them. Here, the Health Breach Notification Rule will have its intended effect only if the FTC is willing to enforce it.

We believe enforcing the rule was warranted here, and we respectfully dissent from the

Commission's failure to do so. Particularly as we seek more authority from Congress in the privacy space, it is critical we demonstrate we are prepared to use the authorities we already have.

8 We have previously articulated opportunities to make use of our existing authorities when it comes to data protection. *See* Statement of Commissioner Rohit Chopra Regarding the Report to Congress on the FTC's Use of Its Authorities to Protect Consumer Privacy and Security, Comm'n File P065404 (June 18, 2020), https://www.ftc.gov/public-statements/2020/06/statement-commissioner-rohit-chopra-regarding-report-congress-ftcs-use-its; Remarks of Commissioner Rebecca Kelly Slaughter at Silicon Flatirons, The Near Future of U.S. Privacy Law, University of Colorado Law School (Sep. 6, 2019), https://www.ftc.gov/system/files/documents/public_statements/1543396/slaughter_silicon_flatirons_remarks_9-6-19.pdf.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (the "Commission") has accepted, subject to final approval, an agreement containing a consent order from Flo Health, Inc. ("Respondent" or "Flo Health").

The proposed consent order ("Proposed Order") has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement, along with any comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the Proposed Order.

This matter involves Flo Health, a technology start-up that develops and distributes a mobile application called the Flo Period & Ovulation Tracker ("App"), which collects and stores menstruation and fertility information about millions of users worldwide. Respondent has been a participant in the EU-U.S. Privacy Shield ("Privacy Shield") and the U.S.-Swiss Privacy Shield framework since August 12, 2018.

The Commission's proposed complaint alleges that Flo Health deceived consumers, in violation of Section 5(a) of the Federal Trade Commission Act, in seven ways:

- First, the complaint alleges that Flo Health represented that it would not disclose "information regarding … marked cycles, pregnancy, symptoms, notes …" to any third parties, or disclose "any data related to health" to particular third parties. In fact, Flo Health disclosed custom app events—records of individual users' interactions with various features of the App, which conveyed identifying information about App users' menstrual cycles, fertility, and pregnancies—to various third-party marketing and analytics firms.

- Second, the complaint alleges that Flo Health represented that it would *only* disclose device identifiers or personal data "like" device identifiers to certain third parties. In fact, in addition to disclosing device and advertising identifiers, Flo Health also disclosed custom app events conveying health information to those parties.

- Third, the complaint alleges that Flo Health represented that third parties would not use Flo App users' personal information "for any purpose except to provide services in connection with the App." In fact, Flo Health agreed to terms with multiple third parties that permitted these third parties to use Flo App users' personal health information for the third parties' own purposes, including for advertising and product improvement. Indeed, from June 2016 to February 2019, one of the third parties (Facebook, Inc.) used Flo App users' personal health information for its own purposes, including its own research and product development.

- Counts IV through VII allege misrepresentations of compliance with the Privacy Shield Principles of Notice (Count IV), Choice (Count V), Accountability for Onward Transfers (Count VI), and Purpose Limitation (Count VII). Count IV alleges that Flo Health represented compliance with the Privacy Shield frameworks, when in fact it did not give Flo App users notice about to whom their data would be disclosed and for what purposes. Count V alleges that Flo Health disclosed this information without providing Flo App users with choice with respect to these disclosures or the purposes for which the data could be processed (e.g., Facebook's advertising). Count VI alleges that Flo Health failed to limit by contract the third parties' use of users' health data or require by contract the third parties' compliance with the Privacy Shield principles. And Count VII alleges that Flo Health processed users' health data in a manner incompatible with the purposes for which it had been collected because Flo disclosed the data to third parties under contracts permitting them to use the data for their own purposes.

The Proposed Order contains injunctive provisions addressing the alleged deceptive conduct. Part I prohibits Flo Health from making false or deceptive statements regarding: (1) the purposes for which Flo Health or any entity to whom it discloses Covered Information (i.e., personal information, including identifiable health information) collects, maintains, uses, or discloses such information; (2) the extent to which consumers may exercise control over Flo Health's access, collection, maintenance, use, disclosure, or deletion of Covered Information; (3) the extent to which Flo Health complies with any privacy, security, or compliance program, including the Privacy Shield; and (4) the extent to which Flo Health collects, maintains, uses, discloses, deletes, or permits or denies access to any Covered Information, or the extent to which Flo Health protects the availability, confidentiality, or integrity of Covered Information.

Part II of the Proposed Order requires Flo Health to ask any "Third Party" (i.e., any party other than Flo Health, its service providers, or subcontractors) that has received "Health Information" about "Covered App Users" to destroy such information.

Part III of the Proposed Order requires that Flo provide notice to users and the public that it shared certain information about users' periods and pregnancies with the data analytics divisions (but not the social media divisions) of a number of third parties, including Facebook, Flurry, Fabric, and Google.

Part IV of the Proposed Order requires that, before disclosing any consumer's health information to a third party, Flo Health must provide notice and obtain express affirmative consent, including informing the user of the categories of information to be disclosed, the identities of the third parties, and how the information will be used.

Part V of the Proposed Order requires an outside "Compliance Review," conducted within 180 days after entry of the Proposed Order, to verify any attestations and assertions Flo Health made pursuant to the EU-U.S. Privacy Shield or the U.S.-Swiss Privacy Shield framework.

Part VI of the Proposed Order requires Flo Health to cooperate with the Compliance Reviewer and Part VII requires that a senior manager of Flo Health certify Flo Health's compliance with the Proposed Order.

Part VIII of the Proposed Order requires notification of the Commission following any "Covered Incident," which includes any incident in which Flo Health disclosed individually identifiable Health Information from or about a consumer to a third party without first receiving the consumer's affirmative express consent.

Parts IX through XII of the Proposed Order are reporting and compliance provisions, which include recordkeeping requirements and provisions requiring Flo Health to provide information or documents necessary for the Commission to monitor compliance with the Proposed Order. Part XIII states that the Proposed Order will remain in effect for twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the Proposed Order. It is not intended to constitute an official interpretation of the complaint or Proposed Order, or to modify in any way the Proposed Order's terms.

Complaint

IN THE MATTER OF

KUSHLY INDUSTRIES LLC
AND
CODY ALT

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTIONS 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4749; File No. 202 3111
Complaint, June 29, 2021– Decision, June 29, 2021

This consent order addresses Kushly Industries LLC's advertising of products containing cannabidiol. The complaint alleges that Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by disseminating false and unsubstantiated advertisements that claimed that: (1) CBD Products effectively treat, mitigate, or cure diseases or health conditions including: sleep disorders, including insomnia and narcolepsy; psychiatric disorders, including depression, bipolar disorder, post-traumatic stress disorder, psychosis, and anorexia nervosa; cancer; multiple sclerosis; Parkinson's disease; hypertension; Alzheimer's disease; acne, psoriasis, eczema; arthritis; muscle spasms; pain resulting from endometriosis; and dysmenorrhea; and (2) studies or scientific research prove that CBD Products effectively treat, mitigate, or cure multiple sclerosis, general anxiety disorder, post-traumatic stress disorder, panic disorder, obsessive-compulsive disorder and social anxiety disorder, depression, cancer, sleep disorders, hypertension, Parkinson's disease, Alzheimer's disease, acne, psoriasis, and eczema, and improve sleep. The consent order prohibits Respondents from making any representation about the efficacy of any covered product, including that such product effectively treats, mitigates, or cures diseases or health conditions including: sleep disorders, including insomnia and narcolepsy; headaches; psychiatric disorders, including depression, bipolar disorder, general anxiety disorder, panic disorder, obsessive-compulsive disorder and social anxiety disorder; post-traumatic stress disorder, psychosis, and anorexia nervosa; cancer; multiple sclerosis; chronic drowsiness; Parkinson's disease; hypertension; Alzheimer's disease; acne, psoriasis, eczema; arthritis; muscle spasms; pain resulting from endometriosis; and dysmenorrhea, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

Participants

For the *Commission*: *Luis Gallegos* and *Reid Tepfer.*

For the *Respondents*: *David Rossiter Callaway, Goodwin Procter LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Kushly Industries LLC, a limited liability company, and Cody Alt, individually and as an officer of Kushly Industries LLC (collectively, "Respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Kushly Industries LLC ("Kushly") is an Arizona limited liability company with its principal office or place of business at East Rancho Vista Drive, #3014, Scottsdale, Arizona 85251.

2. Respondent Cody Alt ("Alt") is the owner, chief executive officer, and manager of Kushly. Individually or in concert with others, he controls or has had the authority to control, or participates in the acts and practices alleged in this Complaint. His principal office or place of business is the same as Kushly.

3. The acts and practices of Respondents alleged in this Complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Respondents' Marketing of CBD Products

4. Cannabidiol ("CBD") is a non-psychoactive cannabinoid that naturally occurs in, and can be extracted from, the hemp plant, *cannabis sativa*. Respondents have labeled, advertised, promoted, offered for sale, and sold products containing CBD ("CBD Products") that are intended for human use. These CBD Products are "food" and/or "drugs," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

5. Respondents sell various CBD Products, including but not limited to tinctures, gummies, softgel capsules, skincare products, toothpicks, bath salts, and topical ointments. Consumers can purchase Kushly brand CBD Products from Respondents by ordering them through Respondents' website at Kushly.com.

6. Respondents promote CBD Products through a variety of means, including through their website, Kushly.com, and through social media platforms including, but not limited to, Twitter, Instagram, Snapchat, TikTok, and Facebook.

7. Respondent Alt directly participates in the promotion and advertising of Kushly's CBD Products and has often been featured and quoted in press articles about Kushly, its products, and the CBD industry.

8. Respondents have disseminated or have caused to be disseminated advertisements, blog and social media posts, and other promotional materials for CBD Products. These advertisements, posts, and materials have included the following statements:

a. Excerpt from "CBD Lotions – Do They Really Work?" Kushly (Kushly.com), posted Mar. 24, 2020, https://Kushly.com/blogs/news/cdb-lotion:

> [CBD] also affects the brain positively, allowing for the minimization of symptoms related to anxiety, depression, and other mental disorders. CBD has also shown some promise with regards to the treatment of seizures as well as neurological problems such as Parkinson's or Alzheimer's disease….

b. Excerpt from "Cannabis Health Benefits For Women: How Cannabis Can Help Maintain Women's Health," Kushly (Kushly.com), posted Dec. 1, 2019, https://Kushly.com/blogs/news/cannabis-health-benefits-for-women:

> The THC content of cannabis helps to minimize the endometriosis pain as it activates the production of dopamine in the body, but CBD has also been hailed as a valuable substance for treating endometriosis with some experts suggesting applying CBD topicals directly to the pain site to help soothe discomforts and aches.

c. Excerpt from "CBD Oil and Wellness: How Does It Work?" Kushly, (Kushly.com), posted Nov. 29, 2019, Kushly.com/blogs/news/cbd-and-wellness-how-does-it-work:

> [T]he active compound, cannabidiol or CBD is getting all the spotlight with its healing potential in treating conditions like eczema, arthritis, some forms of cancers, muscle and joint pains and even Alzheimer's disease….
>
> Going back to CBD, a lot of studies confirmed that this compound could be used to treat body conditions relating to the endocrine system. Cannabidiol helps you sleep better, ease tensed muscles and painful joints, it equally makes your eczema symptoms vanish without too much effort….
>
> Another good news is that CBD oil can aid in these situations by potentially relieving the pain experienced by women.
>
> When rubbed to the affected areas, a person may instantly feel relieved. The compound is absorbed by the body and it works in the endocrine system. Furthermore, CBD oil contains essential fatty acids that balance out hormones. Due to these, acne can be reduced. Headaches associated with hormonal change and lack of sleep can be relieved using CBD oil.

d. Excerpt from "Eat Away Chronic Pain: Best CBD-Infused Edibles to Try," Kushly, (Kushly.com), posted Nov. 28, 2019, Kushly.com/blogs/news/eat-away-chronic-pain-best-cbd-infused-edibles-to-try:

> In fact, many scientists and doctors have stated that CBD can help people with various diseases. Some of these medical conditions include:
>
> - Chronic pain
> - Skin diseases
> - Anxiety and depression
> - Diabetes
> - Insomnia and other sleep disorders
> - Multiple sclerosis…
> - Alzheimer's disease
> - Parkinson's disease
> - Certain types of cancer…

e. Excerpt from "Best CBD Oils to Put You to Sleep in Minutes," Kushly (Kushly.com), posted Oct. 4, 2019, Kushly.com/blogs/news/best-cbd-oils-to-put-you-to-sleep-in-minutes:

> Thanks to the discovery and promotion of CBD hemp oil and other products from medical cannabis, millions of sleep-deprived Americans now have help for this insomnia as well as daytime sleepiness or fatigue, restless leg syndrome, and sleep apnea.

f. Excerpt from "Get to Know: CBD, Its Products, and Applications," Kushly (Kushly.com), posted Oct. 1, 2019, Kushly.com/blogs/news/get-to-know-cbd-its-products-and-applications:

> Here are some science-backed health benefits of CBD: …
>
> - Reduction of Anxiety and Depression…
>
> Some studies showed the potential of CBD hemp oil to treat both mental disorders. Many patients prefer this treatment over the use of pharmaceutical drugs, which can result in various side effects such as insomnia, headache, and agitation.
>
> - Capacity to Heal and Protect the Nervous System
>
> CBD's capability to influence the ECS has also an additional benefit, it can treat neurological disorders such as . . . multiple sclerosis.

- Improvement of Heart Health

  A body of research has linked CBD to the improvement in heart function and blood circulation. Experts attribute it to the substance's antioxidant and stress-reducing properties. Moreover, CBD has the capacity to lower blood pressure….

- Treat Acne and Other Skin Diseases

  Being an anti-inflammatory substance, CBD is being used to treat acne, psoriasis, and other skin irritations.

g. Excerpt from "CBD Oil as Aid to Medicine: How Does It Work?" Kushly (Kushly.com), posted Sept. 27, 2019, Kushly.com/blogs/news/cbd-oil-as-aid-to-medicine-how-does-it-work:

> How is CBD oil aid [sic] to Medicine?...
>
> Aside from helping to alleviate the side-effects of some cancer treatments, CBD oil is also showing potential in preventing the development of cancer itself and the spread of tumors.

h. Excerpt from "Medical Marijuana," Kushly (Kushly.com), Sept. 20, 2019, Kushly.com/blogs/news/how-the-human-body-reacts-to-medical-marijuana:

> Furthermore, WHO listed a host of issues that CBD has the potential to alleviate or treat:…
>
> - Anxiety and Depression
>
> Some studies have shown the potential of cannabis to treat both anxiety and depression based illnesses. Many patients prefer to use CBD hemp oil over pharmaceutical drugs. They believe that CBD oil is safer and that pharmaceutical drugs have side effects like insomnia, headache, and agitation….
>
> - Cancer Symptoms…
>
> The substance also has powerful anti-cancer properties.

i. Excerpt from "This Is Not a Drill: Reasons to Add Cannabis to Your Wellness Routine," Kushly, (Kushly.com), posted Sept. 15, 2019,

Kushly.com/blogs/news/reasons-to-add-cannabis-to-your-wellness-routine:

> How can CBD improve your Wellbeing?
>
> Here are some of the fantastic benefits cannabidiol can provide for your wellness routine:…
>
> - Promotes Cardiovascular Health…
>
> Researchers found that CBD can help alleviate high blood pressure and Scientists [sic] have pointed out the substance's capacity to reduce stress and anxiety and for lowering blood pressure. Cannabidiol's antioxidant properties can also improve heart function and blood circulation….
>
> - Treats Acne and Other Skin Diseases
>
> …CBD oil is also known for its anti-inflammatory properties and ability to reduce sebum production, which can help to soothe and reduce soreness and skin irritation caused by acne, psoriasis and other skin conditions while keeping the skin nourished and moisturized. CBD oil can also treat eczema by stimulating abnormal cell death….
>
> - Gives Nightly Quality Sleep
>
> To sufferers of insomnia and other sleep disorders, CBD can be a welcome relief. Cannabidiol can be a natural and safe remedy for insomnia.

j. Excerpt from "Beat Workplace Stress With CBD: Your Guide to Productivity and Ease," Kushly (Kushly.com), posted Aug. 27, 2019, Kushly.com/blogs/news/beat-workplace-stress-with-cbd-your-guide-to-productivity-and-ease:

> Apart from chronic pain, one of the primary reasons users take CBD is to reduce anxiety. Studies have shown CBD hemp oil to be a potent treatment to different types of anxiety disorders, such as generalized anxiety disorder and PTSD….
>
> Researchers found that people who take CBD to address their ADHD improved their attentiveness and concentration….

k. Excerpt from "Can CBD Help in Treating Mental Illnesses?" Kushly (Kushly.com), posted Aug. 13, 2019, Kushly.com/blogs/news/can-cbd-help-in-treating-mental-illnesses:

> Why CBD is a great Treatment for Mental Illnesses…
>
> Here are some effects that make cannabidiol a viable addition to mental illness treatments:…
>
> Depression and manic depression (also called bipolar disorder) are some of the most known mental disorders….
>
> Perhaps one of the most important traits of CBD is its regulatory effects. In skincare, this substance is known to regulate sebum production to avoid oily skin and also jumpstarts oil production to combat dry skin. The same characteristic is observed in regulating mood disorders. It has shown potential in treating depression by giving uplifting effects, while it can address manic episodes by regulating serotonin.
>
> Aids Sleep
>
> Patients suffering from PTSD are known to relive the experience, leading to difficulty falling or staying asleep….
>
> Just like for depression and bipolarism, its mood-enhancing effects makes it feasible for treating mood related manifestations of PTSD and other similar conditions.
>
> Enhances Appetite
>
> Conditions such as anorexia nervosa is [sic] a type of eating disorder. It is characterized by the irrational fear of gaining weight, which leads patients to lose interest in food. It also leads to loss of appetite. Some risk factors include depression, anxiety disorder, and weight consciousness.
>
> Anorexia is one of the qualifying medical conditions for medical marijuana for a good reason. Doctors have classified CBD as an effective aid to medical treatments. Aside from being able to treat depression, this compound can increase the appetite of the patient, allowing them to reach a healthier weight.

l. Excerpt from "CBD and Psychotherapy: The Role of Cannabis In Mental Health," Kushly (Kushly.com), July 24, 2019, Kushly.com/blogs/news/cbd-and-psychotherapy-the-role-of-cannabis-in-mental-health; captured 5/4/20:

> CBD Benefits Backed with Science…
>
> Prevent Nerve-Related Diseases…
>
> A more significant finding from a 2008 study showed that cannabidiol helped create new nerve cells in aging brains. As the brain ages, the production of new neurons slows down, which causes degenerative diseases. Therefore, new cells need to be created continuously and CBD can take part in this process. In addition to this, CBD also helps prevent nerve-related illnesses including neuropathy and Alzheimer's disease.
>
> Reduce Anxiety
>
> According to a 2012 research, a number of respondents shown reduce anxiety symptoms after taking cannabidiol….
>
> Effective for Depression
>
> Clinical depression is a serious mental condition that is characterized by persistent sadness, sudden loss of appetite and suicidal thoughts….
>
> Intake of CBD is proven to stabilize a person's mood by enhancing serotonergic and glutamate signaling of the brain. Regular intake showed the effectiveness of the compound in making respondents feel better and stress-free.

m. Excerpt from "Narcolepsy and the Healing Power of CBD Cannabis Oil," Kushly (Kushly.com), posted July 10, 2019, Kushly.com/blogs/news/narcolepsy-and-the-healing-power-of-cbd-cannabis-oil:

> Narcolepsy and the Healing Power of CBD Cannabis Oil…
>
> **Cannabis oil seems to be the answer…**
>
> Any person who consumes small doses of CBD will experience a higher state of alertness which is exactly what someone with narcolepsy will require. It will be important for people with this condition to ensure that they take only enough to provide them with the necessary benefits. It has been seen in studies that CBD can help to significantly improve the consistency of sleeping cycles. This results in a situation where a person is able to feel alert for many hours each day.

n. Excerpt from KushlyBrand, posted Mar. 31, 2020, "Hemp Lotion and It's Benefits," www.facebook.com/notes/kushlybrands/hemp-lotion-and-its-benefits/646013019278539/?_tn_=HH-R:

> The entire medical community is trying to invest more resources into investigating the effects of CBD, and science has shown that CBD does have anti-inflammatory properties. Here are the top benefits of CBD, as suggested by the users.
>
> - Acne
> - Anorexia
> - Anxiety
> - Chronic pain
> - Depression…
> - Arthritis
> - Seizures…
> - High blood pressure
> - Insomnia
> - Muscle spasms
> - Parkinson's disease

o. Excerpt from "6 Reasons Why CBD Cannabidiol Can Help Children with Anxiety," Kushly (Kushly.com), posted July 14, 2019, https://Kushly.com/blogs/news/6-reasons-why-cbd-cannabidiol-can-help-children-with-anxiety; captured 10/22/20:

> **CBD Cannabidiol Treats Anxiety**
>
> Among its many health benefits, CBD also treats mental health problems [hyperlink to: kushly.com/blogs/news/can-cbd-treat-children-with-adhd-and-concentration-problems] such as anxiety. That is why, in the last ten years, many people have turned to CBD for the relief of anxiety. This has been supported by research such as the review that was published in the *Neurotherapeutics* that reported that CBD can effectively reduce anxiety in people with general anxiety disorder, post-traumatic stress disorder, panic disorder, obsessive-compulsive disorder and social anxiety disorder. (1). ***So far, CBD has not shown any adverse effects when used for these problems and the researchers have called for CBD to be studied further as a potential treatment method for anxiety….***

p. Excerpt from "Daily Dose of CBD," Kushly (Kushly.com), posted May 26, 2019, Kushly.com/blogs/news/daily-dose-of-cbd:

> **How CBD Affects the Brain**
>
> - **Protects and Rejuvenates Nerves…**
>
> The discovery of cannabis' power to prevent brain degeneration is perhaps one of the most important breakthroughs in modern medicine. At a time when Alzheimer's disease, dementia, Parkinson's disease, and other neurological diseases affect millions of people, the discovery of cannabis as an effective medicine is a watershed moment in brain research and treatment. This substance is one of the few that has the power to reduce brain damage caused by many factors. It protects the brain from stress caused by traumatic blows, lack of oxygen supply, as well as autoimmune and genetic disorders….
>
> - **Relieves Anxiety and Depression…**
>
> Modern brain-scanning machines, such as fMRI, have found that people with chronic anxiety and depression have a smaller hippocampus, the part of the brain linked to long-

term memory, spatial navigation and spatial memory, and behavioral inhibition. Because of CBD's ability to regenerate neurons in this area, the behavior and moods of the anxious and depressed can be modified. With a larger hippocampus, they can now better manage their behavior in the face of stress and other emotional trauma.

Count I
False or Unsubstantiated Efficacy Claims Regarding CBD

9. In connection with the advertising, promotion, offering for sale, sale, or labeling of CBD Products, Respondents have represented, directly or indirectly, expressly or by implication, that CBD Products effectively treat, mitigate, or cure diseases or health conditions including: sleep disorders, including insomnia and narcolepsy; psychiatric disorders, including depression, bipolar disorder, post-traumatic stress disorder, psychosis, and anorexia nervosa; cancer; multiple sclerosis; Parkinson's disease; hypertension; Alzheimer's disease; acne, psoriasis, eczema; arthritis; muscle spasms; pain resulting from endometriosis; and dysmenorrhea.

10. The representations set forth in Paragraph 9 are false or misleading, or were not substantiated at the time the representations were made.

Count II
False Establishment Claims Regarding CBD Products

11. In connection with the advertising, promotion, offering for sale, sale, or labeling of CBD Products, Respondents have represented, directly or indirectly, expressly or by implication, that studies or scientific research prove that CBD Products effectively treat, mitigate, or cure multiple sclerosis, general anxiety disorder, post-traumatic stress disorder, panic disorder, obsessive-compulsive disorder and social anxiety disorder, depression, cancer, sleep disorders, hypertension, Parkinson's disease, Alzheimer's disease, acne, psoriasis, and eczema, and improve sleep.

12. In fact, studies or scientific research do not prove that CBD Products effectively treat, mitigate, or cure chronic pain, multiple sclerosis, general anxiety disorder, post-traumatic stress disorder, panic disorder, obsessive-compulsive disorder and social anxiety disorder, depression, cancer, sleep disorders, hypertension, Parkinson's disease, Alzheimer's disease, acne, psoriasis, and eczema, or improve sleep. Therefore, the representations set forth in Paragraph 11 are false or misleading.

Violations of Sections 5 and 12

13. The acts and practices of Respondents as alleged in this Complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this 29th day of June, 2021, has issued this Complaint against Respondents.

By the Commission.

DECISION

The Federal Trade Commission ("Commission") initiated an investigation of certain acts and practices of the Respondents named in the caption. The Commission's Bureau of Consumer Protection ("BCP") prepared and furnished to Respondents a draft Complaint. BCP proposed to present the draft Complaint to the Commission for its consideration. If issued by the Commission, the draft Complaint would charge the Respondents with violations of the Federal Trade Commission Act.

Respondents and BCP thereafter executed an Agreement Containing Consent Order ("Consent Agreement"). The Consent Agreement includes: 1) statements by Respondents that they neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Decision and Order, and that only for purposes of this action, they admit the facts necessary to establish jurisdiction; and 2) waivers and other provisions as required by the Commission's Rules.

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the Federal Trade Commission Act, and that a Complaint should issue stating its charges in that respect. The Commission accepted the executed Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments. The Commission duly considered any comments received from interested persons pursuant to Section 2.34 of its Rules, 16 C.F.R. § 2.34. Now, in further conformity with the procedure prescribed in Rule 2.34, the Commission issues its Complaint, makes the following Findings, and issues the following Order:

Findings

1. The Respondents are:

    a. Respondent Kushly Industries LLC ("Kushly") is an Arizona limited liability company with its principal office or place of business at East Rancho Vista Drive, #3014, Scottsdale, Arizona 85251.

    b. Respondent Cody Alt ("Alt") is the owner, chief executive officer, and manager of Kushly. Individually or in concert with others, he controls or had the authority to control, or participated in the acts and practices

alleged in this complaint. His principal office or residence is the same as Kushly.

2. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

Definitions

For purposes of this Order, the following definitions apply:

A. "CBD Product" means any Drug, Food, or Dietary Supplement containing cannabidiol.

B. "CBG Product" means any Drug, Food, or Dietary Supplement containing cannabigerol.

C. "Covered Product" means any Drug, Food, or Dietary Supplement, including but not limited to CBD Products or CBG Products.

D. "Dietary Supplement" means: (a) any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or (b) any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional Food or as a sole item of a meal or the diet.

E. "Drug" means: (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (c) articles (other than Food) intended to affect the structure or any function of the body of humans or other animals; and (d) articles intended for use as a component of any article specified in (a), (b), or (c); but does not include devices or their components, parts, or accessories.

F. "Essentially Equivalent Product" means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; provided that the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts in the field indicates that the amount and

combination of additional ingredients is unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

G. "Food" means: (a) any article used for food or drink for humans or other animals; (b) chewing gum; and (c) any article used for components of any such article.

H. "Respondents" means the Corporate Respondent and the Individual Respondent, individually, collectively, or in any combination.

1. "Corporate Respondent" means Kushly Industries LLC, a limited liability company, and its successors and assigns.

2. "Individual Respondent" means Cody Alt.

Provisions

I. Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation

IT IS ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the labeling, advertising, promotion, offering for sale, or sale of any Covered Product, must not make, or assist others in making, expressly or by implication, any representation that such Covered Product effectively treats, mitigates, or cures diseases or health conditions including: sleep disorders, including insomnia and narcolepsy; headaches; psychiatric disorders, including depression, bipolar disorder, general anxiety disorder, panic disorder, obsessive-compulsive disorder and social anxiety disorder; post-traumatic stress disorder, psychosis, and anorexia nervosa; cancer; multiple sclerosis; chronic drowsiness; Parkinson's disease; hypertension; Alzheimer's disease; acne, psoriasis, eczema; arthritis; muscle spasms; pain resulting from endometriosis; and dysmenorrhea, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of this Provision, "competent and reliable scientific evidence" must consist of human clinical testing of the Covered Product, or of an Essentially Equivalent Product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Provision entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this

Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

II. Prohibited Representations: Other Health-Related Claims

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the labeling, advertising, promotion, offering for sale, or sale of any Covered Product must not make, or assist others in making, any representation, other than representations covered under the Provision of this Order entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, expressly or by implication, about the health benefits, performance, or efficacy, safety, or side effects of such Covered Product, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Provision of this Order titled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission. Persons covered by this section will have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

III. Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by this Order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, *however*, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by (1) any Respondent; (2) any Respondent's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Respondent; (4) any person or entity affiliated with or acting on behalf of any Respondent; (5) any supplier of any ingredient contained in the product at issue to any of the foregoing or to the product's manufacturer; or (6) the supplier or manufacturer of such product.

For purposes of this Provision, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondents, Respondents must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Respondents' size and complexity, the nature and scope of Respondents' activities, and the sensitivity of the personal information collected from or about the participants.

IV. Prohibited Misrepresentations Regarding Tests, Studies, or Other Research

IT IS FURTHER ORDERED that Respondents, Respondents' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the labeling, advertising, promotion, offering for sale, or sale of any product must not misrepresent, in any manner, expressly or by implication:

A. that any Covered Product is clinically proven to:

1. treat, alleviate, or cure chronic pain, multiple sclerosis, anxiety, depression, cancer, sleep disorders, hypertension, Parkinson's disease, Alzheimer's disease, acne, psoriasis, and eczema,

B. that the performance or benefits of a Covered Product are scientifically or clinically proven or otherwise established; or

C. the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

V. FDA Approved Claims

IT IS FURTHER ORDERED that nothing in this Order prohibits Respondents, or Respondents' officers, agents, employees, and attorneys, or all other persons in active concert or participation with any of them, from:

A. For any drug, making a representation that is approved in labeling for such drug under any tentative final or final monograph promulgated by the Food and Drug Administration ("FDA"), or under any new drug application approved by the FDA; and

B. For any product, making a representation that is specifically authorized in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990 or authorized under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

VI. Monetary Relief

IT IS FURTHER ORDERED that:

A. Respondents must pay to the Commission $30,583.14, which Respondents stipulate their undersigned counsel holds in escrow for no purpose other than payment to the Commission.

B. Such payment must be made within 5 days of the effective date of this Order by electronic fund transfer in accordance with instructions that will be provided by a representative of the Commission.

VII. Additional Monetary Provisions

IT IS FURTHER ORDERED that:

A. Respondents relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission to enforce its rights to any payment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by or on behalf of the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other relief (including consumer information remedies) as it determines to be reasonably related to Respondents' practices alleged in the Complaint. Any money not used is to be deposited to the U.S. Treasury. Respondents have no right to challenge any activities pursuant to this Provision.

E. In the event of default on any obligation to make payment under this Order, interest, computed as if pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment. In the event such default continues for 10 days beyond the date that payment is due, the entire amount will immediately become due and payable.

F. Each day of nonpayment is a violation through continuing failure to obey or neglect to obey a final order of the Commission and thus will be deemed a separate offense and violation for which a civil penalty shall accrue.

G. Respondents acknowledge that their Taxpayer Identification Numbers (Social Security or Employer Identification Numbers), which Respondents have previously submitted to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. § 7701.

VIII. Customer Information

IT IS FURTHER ORDERED that Respondents must directly or indirectly provide sufficient customer information to enable the Commission to efficiently administer consumer redress to all purchasers of Kushly Industries LLC's CBD Products who made purchases from May 26, 2019 through August 27, 2020. If a representative of the Commission requests in writing any information related to redress, Respondents must provide it, in the form prescribed by the Commission representative, within 14 days.

IX. Notices to Customers

IT IS FURTHER ORDERED that Respondents must notify customers as follows:

A. Respondents must identify all consumers who purchased Kushly Industries LLC's CBD Products from May 26, 2019 through August 27, 2020 ("eligible customers").

1. Such eligible customers, and their contact information, must be identified to the extent such information is in Respondents' possession, custody or control, including from third parties such as resellers;

2. Eligible customers include those identified at any time, including after Respondents' execution of the Agreement through one year after the issuance date of the Order.

B. Respondents must notify all identified eligible customers by mailing each a notice:

1. The letter must be in the form shown in Attachment A.

2. The envelope containing the letter must be in the form shown in Attachment B.

3. The mailing of the notification letter must not include any other enclosures.

4. The mailing must be sent by first-class mail, postage prepaid, address correction service requested with forwarding and return postage guaranteed. For any mailings returned as undeliverable, Respondents must use standard address search methodologies such as re-checking Respondents' records and the Postal Service's National Change of Address database and re-mailing to the corrected address within 8 days.

C. Respondents must notify all eligible customers within 180 days after the issuance date of this Order and any eligible customers identified thereafter within 30 days of their identification.

D. Respondents must provide a website notice on their website kushly.com and all social media accounts, including Facebook, Instagram, YouTube, TikTok, Pinterest, LinkedIn, Tumblr, SoundCloud, MySpace, and Twitter. Such notice must link to a copy of the Order along with the telephone number and email addresss dedicated to responding to inquiries about redress. Respondents must respond promptly and accurately to such inquiries, including: 1) whether the consumer is an eligible customer; 2) and if so, the redress required by the Order and steps taken for that customer. The notice must be posted not later than 3 days

after the effective date of the Order and for at least 1 year after the redress period ends.

E. Respondents must report on their notification program under penalty of perjury:

1. Respondents must submit a report at the conclusion of the program summarizing their compliance to date, including the total number of eligible customers identified and notified.

2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Respondents must submit it within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

X. Notice to Wholesalers, Affiliates, and Other Distributors

IT IS FURTHER ORDERED that within 30 days of the effective date of this Order, Respondents must notify all affiliates or other resellers who either (1) purchased CBD Products from Respondents or (2) sold, distributed, or promoted CBD Products on behalf of Respondents by sending each by first-class mail, postage paid and return receipt requested, or by courier service with signature proof of delivery, the notification letter attached as Attachment A. Respondents must include a copy of this Order, but no other document or enclosure.

XI. Acknowledgments of the Order

IT IS FURTHER ORDERED that Respondents obtain acknowledgments of receipt of this Order:

A. Each Respondent, within 10 days after the effective date of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 5 years after the issuance date of this Order, the Individual Respondent for any business that such Respondent, individually or collectively with Corporate Respondent, is the majority owner or controls directly or indirectly, and the Corporate Respondent, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for labeling, advertising, marketing, promotion, offering for sale, or sale of CBD or CBG Products and all agents and representatives who participate in labeling, advertising, marketing, promotion, offering for sale, or sale of CBD or CBG Products; and (3) any business entity resulting from any change in structure as set forth in the Provision titled Compliance Reports and Notices. Delivery must occur within 10 days after the

effective date of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Respondent delivered a copy of this Order, that Respondent must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

XII. Compliance Reports and Notices

IT IS FURTHER ORDERED that Respondents make timely submissions to the Commission:

A. One year after the issuance date of this Order, each Respondent must submit a compliance report, sworn under penalty of perjury, in which:

1. Each Respondent must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission, may use to communicate with Respondent; (b) identify all of that Respondent's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of Corporate Respondent (which the Individual Respondent must describe if he knows or should know due to his own involvement); (d) describe in detail whether and how that Respondent is in compliance with each Provision of this Order, including a discussion of all of the changes the Respondent made to comply with the Order; and (e) provide a copy of each Acknowledgment of the Order obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, the Individual Respondent must: (a) identify all his telephone numbers and all his physical, postal, email and Internet addresses, including all residences; (b) identify all his business activities, including any business for which such Respondent performs services whether as an employee or otherwise and any entity in which such Respondent has any ownership interest; and (c) describe in detail such Respondent's involvement in each such business activity, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 10 years after the issuance date of this Order, each Respondent must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Respondent must submit notice of any change in: (a) any designated point of contact; or (b) the structure of the Corporate Respondent or any

entity that Respondent has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, the Individual Respondent must submit notice of any change in: (a) name, including alias or fictitious name, or residence address; or (b) title or role in any business activity, including (i) any business for which such Respondent performs services whether as an employee or otherwise and (ii) any entity in which such Respondent has any ownership interest and over which Respondents have direct or indirect control. For each such business activity, also identify its name, physical address, and any Internet address.

C. Each Respondent must submit notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Respondent within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: In re Kushly Industries LLC.

XIII. Recordkeeping

IT IS FURTHER ORDERED that Respondents must create certain records for 10 years after the issuance date of the Order and retain each such record for 5 years. Specifically, Corporate Respondent and the Individual Respondent for any business that such Respondent, individually or collectively with any other Respondent, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. accounting records showing the revenues from all goods or services sold, the costs incurred in generating those revenues, and resulting net profit or loss;

B. personnel records showing, for each person providing services in relation to any aspect of the Order, whether as an employee or otherwise, that person's: name;

addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. copies or records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. a copy of each unique advertisement or other marketing material making a representation subject to this Order.

E. for 5 years from the date of the last dissemination of any representation covered by this Order:

1. all materials that were relied upon in making the representation; and

2. all tests, studies, analysis, demonstrations, other research or other evidence in Respondent's possession, custody, or control that contradicts, qualifies, or otherwise calls into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations;

F. for 5 years from the date received, copies of all subpoenas and other communications with law enforcement, if such communication relate to Respondents' compliance with this Order;

G. for 5 years from the date created or received, all records, whether prepared by or on behalf of Respondents, that demonstrate non-compliance OR tend to show any lack of compliance by Respondents with this Order; and

H. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission.

XIV. Compliance Monitoring

IT IS FURTHER ORDERED that, for the purpose of monitoring Respondents' compliance with this Order:

A. Within 10 days of receipt of a written request from a representative of the Commission, each Respondent must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury, and produce records for inspection and copying.

B. For matters concerning this Order, representatives of the Commission are authorized to communicate directly with each Respondent. Respondents must permit representatives of the Commission to interview anyone affiliated with any

Respondent who has agreed to such an interview. The interviewee may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Respondents or any individual or entity affiliated with Respondents, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49 and 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning the Individual Respondent, pursuant to Section 604(2) of the Fair Credit Reporting Act, 15 U.S.C. § 1681b(a)(2).

XV. Order Effective Dates

IT IS FURTHER ORDERED that this Order is final and effective upon the date of its publication on the Commission's website (ftc.gov) as a final order. This Order will terminate 20 years from the date of its issuance (which date may be stated at the end of this Order, near the Commission's seal), or 20 years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying settlement) in federal court alleging any violation of this Order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

A. Any Provision in this Order that terminates in less than 20 years;

B. This Order's application to any Respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this Provision.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Provision as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

ATTACHMENT A TO THE ORDER

CLAIMS ABOUT PRODUCTS CONTAINING CBD
In the Matter of Kushly Industries et al.

<Date>

Subject: Kushly Industries LLC d/b/a Kushly CBD Products

<Name of customer>

<mailing address of customer
including zip code>

Dear <Name of customer>:

Our records show that you bought CBD products from Kushly between May 26, 2019 and August 27, 2020. The Federal Trade Commission (FTC) sued us for deceptive or false advertising of those products.

- The FTC says **we do not have scientific evidence** that our CBD products can treat or cure diseases and health conditions including
    - sleep disorders like insomnia and narcolepsy;
    - psychiatric disorders like depression, bipolar disorder, post-traumatic stress disorder, psychosis, and anorexia nervosa;
    - diseases and conditions like cancer, multiple sclerosis, Parkinson's disease, Alzheimer's disease, and hypertension;
    - skin conditions like acne, psoriasis, and eczema; and
    - pain associated with arthritis, endometriosis, and menstruation (dysmenorrhea).
- The FTC says **we do not have scientific evidence** that our CBD products can help muscles heal fast.
- The FTC says studies **do not prove** that our CBD products treat or cure any of the diseases and health conditions listed above.

As part of a settlement with the FTC, we agreed not to make those misleading claims in the future.

What you should know about CBD products

CBD products could be dangerous if you take them with other medicines or at a high dose. They also could interfere with other medications you're taking or treatments you're getting. Talk to your doctor before you use CBD products. Learn more at ftc.gov/miraclehealth.

Sincerely,
[signature]

Cody Alt
CEO
Kushly Industries LLC

ATTACHMENT B TO THE ORDER – ENVELOPE TEMPLATE

The envelope for the notification letter must be in the following form, with the underlined text completed as directed:

[*Identify Respondent*
Street Address
City, State and Zip Code]

FORWARDING AND RETURN POSTAGE GUARANTEED ADDRESS CORRECTION SERVICE REQUESTED

[name and
mailing address of customer,
including zip code]

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an agreement containing a consent order from Kushly Industries LLC and Cody Alt, individually and as an officer of Kushly Industries LLC ("Respondents"). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received, and will

decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

This matter involves the Respondents' advertising of products containing cannabidiol ("CBD Products"). The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements that claimed that: (1) CBD Products effectively treat, mitigate, or cure diseases or health conditions including: sleep disorders, including insomnia and narcolepsy; psychiatric disorders, including depression, bipolar disorder, post-traumatic stress disorder, psychosis, and anorexia nervosa; cancer; multiple sclerosis; Parkinson's disease; hypertension; Alzheimer's disease; acne, psoriasis, eczema; arthritis; muscle spasms; pain resulting from endometriosis; and dysmenorrhea; and (2) studies or scientific research prove that CBD Products effectively treat, mitigate, or cure multiple sclerosis, general anxiety disorder, post-traumatic stress disorder, panic disorder, obsessive-compulsive disorder and social anxiety disorder, depression, cancer, sleep disorders, hypertension, Parkinson's disease, Alzheimer's disease, acne, psoriasis, and eczema, and improve sleep.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food Respondents sell or market, including CBD Products.

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product effectively treats, mitigates, or cures diseases or health conditions including: sleep disorders, including insomnia and narcolepsy; headaches; psychiatric disorders, including depression, bipolar disorder, general anxiety disorder, panic disorder, obsessive-compulsive disorder and social anxiety disorder; post-traumatic stress disorder, psychosis, and anorexia nervosa; cancer; multiple sclerosis; chronic drowsiness; Parkinson's disease; hypertension; Alzheimer's disease; acne, psoriasis, eczema; arthritis; muscle spasms; pain resulting from endometriosis; and dysmenorrhea, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety or side effects of any covered product, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the

relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, "competent and reliable scientific evidence" means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III requires that, with regard to any human clinical test or study ("test") upon which Respondents rely to substantiate any claim covered by the order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits Respondents from misrepresenting: (1) that any covered product is clinically proven to treat, alleviate, or cure chronic pain, multiple sclerosis, anxiety, depression, cancer, sleep disorders, hypertension, Parkinson's disease, Alzheimer's disease, acne, psoriasis, and eczema; (2) that the performance or benefits of a covered product are scientifically or clinically proven or otherwise established; or (3) the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

Part V provides Respondents a safe harbor for making claims approved by the Food and Drug Administration.

Parts VI and **VII** require Respondents to pay to the Commission $30,583.14 and describes the procedures and legal rights related to that payment.

Part VIII, **IX**, and **X** requires Respondents to provide customer information to the Commission and to provide notice of the order to customers, affiliates, and other resellers.

Part XI requires Respondents to submit an acknowledgement of receipt of the order, and for the individual Respondent to serve the order on certain individuals, including all officers or directors of any business the individual Respondent controls and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which a Respondent has delivered a copy of the order.

Part XII requires Respondents to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations.

Part XIII contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance with the order.

Part XIV contains other requirements related to the Commission's monitoring of Respondents' order compliance.

Part XV provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

INTERLOCUTORY, MODIFYING, VACATING, AND MISCELLANEOUS ORDERS

IN THE MATTER OF

LOUISIANA REAL ESTATE APPRAISERS BOARD

Docket No. 9374. Order, February 12, 2021

Order granting Complaint Counsel's motion to lift the stay imposed on this proceeding and order that the evidentiary hearing commence ten weeks after issuance of the order lifting the stay.

ORDER LIFTING STAY AND RESUMING ADMINISTRATIVE PROCEEDINGS

Complaint Counsel have moved that the Commission lift a stay that it has imposed on this proceeding and order that the evidentiary hearing commence ten weeks after issuance of the order lifting the stay. Complaint Counsel's Motion to Lift the Stay and Set Hearing Date (Dec. 18, 2020), *supplemented by* Supplement to Complaint Counsel's Motion to Lift the Stay and Set Hearing Date (Jan. 19, 2021). Respondent Louisiana Real Estate Appraisers Board ("Respondent" or "the Board") does not oppose the lifting of the stay, but argues that in light of concerns raised by the COVID-19 pandemic, the evidentiary hearing should commence no sooner than August 16, 2021. Respondent Louisiana Real Estate Appraisers Board's Opposition in Part to Complaint Counsel's Motion to Lift the Stay and Set Hearing Date (Dec. 28, 2020) ("Response").[1] As explained below, we have determined to grant Complaint Counsel's motion.

Background

On April 11, 2019, the Board filed a complaint with the United States District Court for the Middle District of Louisiana, seeking, *inter alia*, a declaration that the Commission had violated the Administrative Procedure Act in issuing an Opinion and Order[2] denying Respondent's motion to dismiss the complaint in this proceeding and dismissing Respondent's third and ninth affirmative defenses. The Board asked the court to hold unlawful and set aside the Commission's April 10, 2018 Order and to order the Commission to dismiss its administrative complaint. On July 29, 2019, the District Court issued an order staying all pending activity in this administrative proceeding.[3] In recognition of the District Court's action,

1 Respondent, however, repeatedly suggests that a later trial date may ultimately prove necessary. Response at 3 n.3, 10. According to Respondent, "no in-person administrative proceeding should take place until all participants, including the Administrative Law Judge, witnesses, counsel, and staff, are vaccinated against COVID-19." *Id.* at 10.

2 *La. Real Estate Appraisers Bd.*, Docket No. 9374, Opinion and Order of the Commission (Apr. 10, 2018), https://www.ftc.gov/system/files/documents/cases/d09374_opinion_and_order_of_the_commission_04102018_redacted_public_version.pdf.

3 *La. Real Estate Appraisers Bd. v. United States FTC*, 2019 WL 3412162 (M.D. La. July 29, 2019).

the Commission subsequently issued its own order staying the proceeding pending further judicial action and a further order from the Commission.[4]

The Commission appealed the action of the District Court. On October 2, 2020, the United States Court of Appeals for the Fifth Circuit vacated the District Court's stay order and remanded to the District Court with instructions to dismiss the Board's lawsuit for lack of jurisdiction.[5] The appellate court subsequently rejected the Board's petitions for panel rehearing and for rehearing *en banc*, as well as the Board's motion to stay issuance of the appellate court's mandate. A request for the Supreme Court to stay the Commission's proceeding pending Supreme Court review also has been denied. The Fifth Circuit's mandate has issued. Consequently, only the Commission's own August 5, 2019 stay currently bars resumption of this administrative proceeding. Complaint Counsel's Motion asks us to lift that stay.

Analysis

Respondent does not oppose lifting the stay. Response at 1. Although Respondent has now petitioned the Supreme Court to review the Fifth Circuit's order lifting the judicial stay, Petition for a Writ of Certiorari, *La. Real Estate Appraisers Bd. v. United States FTC*, No. 20-1018 (Jan. 22, 2021), 2021 WL 307477, Commission rules provide that the "pendency of a collateral federal court action that relates to the administrative adjudication shall not stay the proceeding: (i) [u]nless a court of competent jurisdiction, or the Commission for good cause, so directs . . . ." Commission Rule of Practice 3.41(f)(1), 16 C.F.R. § 3.41(f)(1). Under the circumstances presented, continuing a stay of this proceeding would conflict with the public interest in expeditiously resolving the Commission's complaints, *see* 16 C.F.R. § 3.1, and promptly providing guidance to Respondent and to third parties in similar circumstances. And if the allegations in the Complaint are established, a continued stay could undermine the public interest in maintaining competition.[6] For these reasons, the Commission does not find good cause to continue to stay this proceeding.

Respondent argues that beginning the evidentiary hearing in a time frame consistent with Complaint Counsel's request would be "unsafe for all participants and prejudicial to [Respondent's] ability to effectively prepare and present its case." Response at 1. We share Respondent's concern for the health of participants and support staff involved with our adjudicative proceedings. Indeed, our initial response to the COVID-19 pandemic was to issue a series of short stays of ongoing adjudicative proceedings.[7] As circumstances that called for these

4 *La. Real Estate Appraisers Bd.*, Docket No. 9374, Order Staying Administrative Proceeding, (Aug. 5, 2019), https://www.ftc.gov/system/files/documents/cases/d9374_lreab_commission_order-august_5-2019.pdf.

5 *La. Real Estate Appraisers Bd. v. United States FTC*, 976 F.3d 597 (2020).

6 Respondent's assurance that it will not enforce the rule that is the source of dispute until this proceeding is resolved, Response at 3, 9, does not preclude the possibility of competitive harm from the ongoing effects of Respondent's known regulatory policies.

7 *See, e.g.*, *Altria Group, Inc.*, Docket No. 9393, Order Regarding Scheduling in Light of Public Health Emergency (Apr. 3, 2020), https://www ftc.gov/system/files/documents/cases/d09393orderstayinghearing.pdf; *Altria Group, Inc.*, Docket No. 9393, Second Order Regarding Scheduling in Light of Public Health Emergency (Apr. 13, 2020),

stays continued, we realized we must move forward with the business of the agency. We allowed our last health-related stays to lapse after July 6, 2020. In consultation with the Office of the Secretary and the Chief Administrative Law Judge, we have been thinking carefully about how to conduct evidentiary hearings via video conferencing. And we now find ourselves positioned to move forward with virtual trials in a way that is in the interest of the health and safety of the litigants and consistent with due process.

Respondent has suggested no reason why safety concerns would arise if the hearing were conducted by video conferencing and trial preparations were accomplished via video and/or telephone. Rather, Respondent has questioned the effectiveness and fairness of such mechanisms. Respondent has asserted that unless it can prepare its witnesses "in person" it will be unable to "fairly and fully present witness testimony," *id.* at 2; *see also id.* at 5, but it has not demonstrated that witness preparation could not be accomplished by telephone and/or video mechanisms. Indeed, such means are not unknown even in non-pandemic times when a witness faces travel difficulties or schedule conflicts. Respondent's counsel have also suggested that consultation with their client "in real time" might be necessary for effective cross-examination, *id.*at 2, 5, but they have not shown why this could not be accomplished electronically, with flexible trial administration. Respondent's additional basis for requiring an in-person trial – that this proceeding is likely to involve some questions of fact, resulting in need to assess witness credibility, *id.* at 3-4 – does not distinguish this proceeding from other cases in which courts have found that they could adequately assess witness credibility, discussed below, or from trial practice in general.[8]

Respondent cites three instances where individual courts have delayed trials because of health concerns, *id.* at 7, but numerous courts have been conducting virtual trials during the pandemic,[9] and administrative agencies have similarly had experience with utilizing video conferencing for their hearings.[10] In particular, courts and agencies have found that current

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https://www.ftc.gov/system/files/documents/cases/d09393_commission_order_ext_staypublic_0.pdf; *Altria Group, Inc.*, Docket No. 9393, Third Order Regarding Scheduling in Light of Public Health Emergency (June 3, 2020), https://www.ftc.gov/system/files/documents/cases/d09393_commission_third_order_regarding_scheduling_in_light_of_public_health_emergency.pdf. As noted above, this proceeding had already been stayed for other reasons.

8 Matters that do not involve disputed issues of material fact may be resolved by summary judgment or summary decision, without need for a trial. Fed. R. Civ. P. 56; 16 C.F.R. § 3.24.

9 *See, e.g.*, *Liu v. State Farm Mut. Auto Ins. Co.*, No. 2:18-1862-BJR, 2020 U.S. Dist. LEXIS 237718 at *2, 9 (W.D. Wa. Dec. 17, 2020) (ordering that multi-day jury trial take place via video conference due to COVID-19); *Flores v. Town of Islip*, No. 2:18cv3549, 2020 WL 5211052 (E.D.N.Y. Sept. 1, 2020) (ordering multi-day bench trial of Voting Rights Act case via video conference); *Vitamins Online, Inc. v. HeartWise, Inc.*, No. 2:13-cv-00982-DAK, 2020 WL 3452872 (D. Utah Jun. 24, 2020) (ordering bench trial of Lanham Act case via video conference; trial took fifteen days); *Financial Guaranty Ins. Co. v. Putnam Advisory Co.*, No. 12-cv-7372 (LJL), 2020 WL 3428136 (S.D.N.Y. Jun. 23, 2020) (with parties' consent, court found that COVID-19 constituted compelling circumstances for trial via video conference; trial took twelve days); *Centripetal Networks, Inc. v. Cisco Systems, Inc.*, No. 2:18cv94, 2020 WL 3411385 (E.D. Va. Apr. 23, 2020) (ordering that bench trial take place via video conference in a complex patent case; trial took 22 days).

Interlocutory Orders, Etc,

video conference technology, properly used, can meet the requirements of fairness and due process for a trial or hearing. For example:

- The district court in *Liu v. State Farm* found good cause to conduct a jury trial via simultaneous video transmission due to COVID-19. 2020 U.S. Dist. LEXIS 237718 at 5-7. Simultaneous video transmission would meet the requirement of Federal Rule of Civil Procedure 43(a) that the trial be conducted in "open court" because "near instantaneous transmission of testimony with no discernable difference between it and 'live' testimony [would] allow[] a juror to judge credibility unimpeded." *See also Warner v. Cate*, No. 1:12-cv-1146-LJO-MJS, 2015 U.S. Dist. LEXIS 102043 (E.D. Ca. Aug. 4, 2015) at *3 ("Because a witness testifying by video is observed directly with little, if any, delay in transmission, … courts have found that video testimony can sufficiently enable cross-examination and credibility determinations, as well as preserve the overall integrity of the proceedings.")

- The district court in *Gould Elecs. v. Livingston Cty. Rd. Comm'n,* 470 F.Supp.3d 735, 741 (E.D. Mich. 2020), observed that during the current pandemic "videoconference technology has been implemented successfully to conduct bench trials in cases involving varying degrees of complexity." Finding that it was not currently safe to conduct a trial in a courtroom, and that it was unclear when it would become so, the court ordered a video conference trial, specifically rejecting one party's claim that such a trial would violate due process. *Id.* at 742. Simultaneous video transmission would allow the court and counsel to view a witness live, "along with his hesitation, his doubts, his variations of language, his confidence or precipitancy, and his calmness or consideration." *Id.* at 743, quoting *In re RFC & ResCap Liquidating Trust Action,* 444 F. Supp. 3d 967, 970 (D. Minn. 2020).

- In *MPLX Ozark Pipe Line LLC*, 171 FERC ¶ 63018, 2020 WL 2119359 (May 4, 2020), FERC's Chief Administrative Law Judge ordered a virtual hearing. The ALJ observed that judges had successfully conducted various types of conferences and oral arguments via video conference, including one with over a hundred participants, and that any unique concerns regarding preparation of particular witnesses for the hearing could be raised before the ALJ. 171 FERC at ¶ 66141. *See also William Beaumont Hosp. &Mich. Nurses Ass'n,* 370 NLRB No. 9, 2020 WL 4754961 (Aug. 13, 2020) (respondent failed to show that a hearing held by video conference would deny it due process).

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10 *See* Admin. Conf. of the U.S., *Best Practices for Using Video Teleconferencing for Hearings* (Dec. 5, 2014), https://www.acus.gov/recommendation/best-practices-using-video-teleconferencing-hearings; Admin. Conf. of the U.S., *Agency Use of Video Hearings: Best Practices and Possibilities For Expansion* (Jun. 17, 2011), https://www.acus.gov/recommendation/agency-use-video-hearings-best-practices-and-possibilities-expansion.

Reviewing these precedents, we conclude that the Administrative Law Judge can conduct an adjudication via video conferencing consistent with due process and fundamental fairness. Given the challenges of the COVID-19 pandemic, including its continued spread and the uncertain duration of its status as a public health crisis, we have determined that the Commission should utilize the available technology in preference to subjecting this case to further delay. Consequently, inclusion in this Order of provisions specifying that the trial be conducted via video conferencing appropriately addresses Respondent's objections to the hearing date and enables the Commission to move forward with the business of the agency.

Accordingly,

IT IS HEREBY ORDERED that

(1) Complaint Counsel's Motion to Lift the Stay and Set Hearing Date is **GRANTED**;

(2) the stay of this proceeding imposed by the Commission's order of August 5, 2019, is lifted;

(3) the evidentiary hearing in this proceeding before the Chief Administrative Law Judge of the Federal Trade Commission is rescheduled to commence on April 20, 2021, at 10:00 a.m.;

(4) the Chief Administrative Law Judge shall establish a revised prehearing schedule that will permit the evidentiary hearing to commence on the date set by the Commission;

(5) the evidentiary hearing in this proceeding will take place virtually via live web streaming; and

(6) public access to the evidentiary hearing in this proceeding, to the extent permitted by any *in camera* orders, shall be allowed only via telephone or live web streaming, in either instance, only for monitoring purposes.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

PEPSICO, INC.

Docket No. C-4301. Order, February 18, 2021

Letter Order approving respondent's motion to extend the term of the Monitor's agreement for an additional two years.

LETTER APPROVING THE THIRD AMENDMENT TO THE MONITOR'S AGREEMENT

Megan H. Hurley, Esq.
Senior Vice President and General Counsel
PepsiCo Beverages North America

Eric A. Croson
Ann Arbor, Michigan 48108

Re: *In the Matter of PepsiCo, Inc.*, Docket No. C-4301

Dear Ms. Hurley and Mr. Croson:

This letter serves to approve the Third Amendment to the Monitor's agreement submitted to the Commission on January 14, 2021. The Amendment extends the term of the Monitor's agreement for an additional two years.

By direction of the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

ALTRIA GROUP, INC.,
AND
JUUL LABS, INC.

Docket No. 9393. Order, February 22, 2021

Order denying respondent's motion for a further, 90-day continuance, citing continuing health concerns engendered by the pandemic.

ORDER GRANTING CONTINUANCE

This proceeding involves the Commission's challenge to a series of agreements, along with the resulting partial purchase transaction, between Altria Group, Inc. ("Altria") and Juul Labs, Inc. ("JLI"), collectively "Respondents." Through those agreements and the transaction, Altria allegedly ceased to compete in the United States market for closed-system electronic cigarettes in return for a substantial ownership interest in JLI. Following a series of continuances ordered by the Commission in recognition of the dangers posed by the COVID-19 pandemic, the evidentiary hearing in this proceeding is scheduled to begin on April 13, 2021.[1]

Respondents have now moved for a further, 90-day continuance, citing continuing health concerns engendered by the pandemic. Motion to Reschedule the Evidentiary Hearing Due to the Ongoing Pandemic (Jan. 15, 2021) ("Respondents' Motion" or "Respondents' Motion to Reschedule the Evidentiary Hearing"). Complaint Counsel oppose Respondents' Motion.

The FTC's Rules of Practice authorize the Commission to order a later hearing date in an adjudicative proceeding "upon a showing of good cause." 16 C.F.R. § 3.41(b); *see also* 16 C.F.R. § 3.21(c)(1). As discussed below, we conclude that the evidentiary hearing in this proceeding may be safely and fairly conducted electronically, without posing health risks or prejudicing any party. However, due to conflicts posed to the current hearing schedule by the timing of another evidentiary hearing, scheduled to commence on April 20, 2021, we have determined that there is good cause to defer commencement of the evidentiary hearing in this proceeding until June 2, 2021.

Respondents argue that retaining the April 13 date and holding an in-person hearing "would create a non-trivial risk of COVID-19 infection for the Chief ALJ, the witnesses, Complaint Counsel, Respondents' counsel, and their support teams—many of whom are unlikely to be vaccinated by April." Respondents' Motion at 2. We share Respondent's concern for the health of participants and support staff involved with our adjudicative proceedings. Indeed, our initial response to the COVID-19 pandemic was to issue a series of short stays of this and other

1 *Altria Group, Inc.*, Docket No. 9393, Third Order regarding Scheduling in Light of Public Health Emergency (June 3, 2020), https://www.ftc.gov/system/files/documents/cases/d09393_commission_third_order_regarding_scheduling_in_light_of_public_health_emergency.pdf ("Third Stay Order").

pending adjudicative proceedings.[2] As circumstances that called for these stays continued, we realized we must move forward with the business of the agency. We allowed our last health-related stays to lapse after July 6, 2020. In consultation with the Office of the Secretary and the Chief Administrative Law Judge, we have been thinking carefully about how to conduct evidentiary hearings via video conferencing. And we now find ourselves positioned to move forward with virtual trials in a way that is in the interest of the health and safety of the litigants and consistent with due process.

Respondents have suggested no reason why safety concerns would arise if the hearing were conducted by video conferencing and trial preparations were accomplished via video and/or telephone. Instead, Respondents have questioned the effectiveness and fairness of such mechanisms. Thus, Respondents have asserted that "a virtual hearing is no substitute for an in-person trial," and "even if the hearing could be conducted remotely, the reality is that the trial team's *preparations* before and during the hearing could not be." *Id.* at 7. Although Respondents have identified a number of trial, trial-supportive, and pretrial activities that they would prefer to conduct in person, *id.* at 2, 4, 6-8, Respondents have not demonstrated that virtual alternatives would not suffice. Indeed, numerous courts and agencies have been turning to virtual trials as the best mechanism for dealing with the pandemic.[3] Respondents stress that credibility determinations may play an important role in the evidentiary hearing, *id.* at 2, 7-8, but they have not shown that credibility cannot be adequately assessed through video conferencing. A number of courts have found that video conference technology, properly used, can meet the requirements of fairness and due process. For example:

- The district court in *Liu v. State Farm* found good cause to conduct a jury trial via simultaneous video transmission due to COVID-19. 2020 WL 8465987. Simultaneous video transmission would meet the requirement of Federal Rule of Civil Procedure 43(a) that the trial be conducted in "open court" because "near

2 *See, e.g.*, *Altria Group, Inc.*, Docket No. 9393, Order Regarding Scheduling in Light of Public Health Emergency (Apr. 3, 2020), https://www ftc.gov/system/files/documents/cases/d09393orderstayinghearing.pdf; *Altria Group, Inc.*, Docket No. 9393, Second Order Regarding Scheduling in Light of Public Health Emergency (Apr. 13, 2020), https://www.ftc.gov/system/files/documents/cases/d09393_commission_order_ext_staypublic_0.pdf; *Altria Group, Inc.*, Docket No. 9393, Third Stay Order.

3 *See, e.g.*, *Liu v. State Farm Mut. Auto Ins. Co.*, No. 2:18-1862-BJR, 2020 WL 8465987 (W.D. Wa. Dec. 17, 2020) (ordering that multi-day jury trial take place via video conference due to COVID-19); *Flores v. Town of Islip*, No. 2:18cv3549, 2020 WL 5211052 (E.D.N.Y. Sept. 1, 2020) (ordering multi-day bench trial of Voting Rights Act case via video conference); *Vitamins Online, Inc. v. HeartWise, Inc.*, No. 2:13-cv-00982-DAK, 2020 WL 3452872 (D. Utah Jun. 24, 2020) (ordering bench trial of Lanham Act case via video conference; trial took fifteen days); *Financial Guaranty Ins. Co. v. Putnam Advisory Co.*, No. 12-cv-7372 (LJL), 2020 WL 3428136 (S.D.N.Y. Jun. 23, 2020) (with parties' consent, court found that COVID-19 constituted compelling circumstances for trial via video conference; trial took twelve days); *Centripetal Networks, Inc. v. Cisco Systems, Inc.*, No. 2:18cv94, 2020 WL 3411385 (E.D. Va. Apr. 23, 2020) (ordering that bench trial take place via video conference in a complex patent case; trial took 22 days). In *MPLX Ozark Pipe Line LLC*, 171 FERC ¶ 63018, 2020 WL 2119359 (May 4, 2020), FERC's Chief Administrative Law Judge ordered a virtual hearing, observing that any unique concerns regarding preparation of particular witnesses for the hearing could be raised before the ALJ. 171 FERC at ¶ 66141. *See also William Beaumont Hosp. & Mich. Nurses Ass'n,* 370 NLRB No. 9, 2020 WL 4754961 (Aug. 13, 2020) (respondent failed to show that a hearing held by video conference would deny it due process).

instantaneous transmission of testimony with no discernable difference between it and 'live' testimony [would] allow[] a juror to judge credibility unimpeded." *Id.* at *2.

- The district court in *Gould Elecs. v. Livingston Cty. Rd. Comm'n,* 470 F. Supp. 3d 735, 741 (E.D. Mich. 2020), observed that during the current pandemic "videoconference technology has been implemented successfully to conduct bench trials in cases involving varying degrees of complexity." Finding that it was not currently safe to conduct a trial in a courtroom, and that it was unclear when it would become so, the court ordered a video conference trial, specifically rejecting one party's claim that such a trial would violate due process. *Id.* at 742. Simultaneous video transmission would allow the court and counsel to view a witness live, "along with his hesitation, his doubts, his variations of language, his confidence or precipitancy, and his calmness or consideration." *Id.* at 743, quoting *In re RFC & ResCap Liquidating Trust Action,* 444 F. Supp. 3d 967, 970 (D. Minn. 2020).

- In *Warner v. Cate,* No. 1:12-cv-1146-LJO-MJS, WL 4645019 (E.D. Ca. Aug. 4, 2015) at *3, the court explained that "[b]ecause a witness testifying by video is observed directly with little, if any, delay in transmission, … courts have found that video testimony can sufficiently enable cross-examination and credibility determinations, as well as preserve the overall integrity of the proceedings."[4]

Finally, Respondents argue that delaying the evidentiary hearing by 90 days would not harm the public interest. Respondents' Motion at 8. The Commission's scheduling determinations reflect its commitment to conduct its adjudications expeditiously, to the extent practicable and consistent with the requirements of law. *See* 16 C.F.R. § 3.1. Prompt resolution of adjudicative proceedings speeds resolution of the particular disputes at issue and provides timely guidance to others facing similar issues. And if the allegations in the Complaint are established, an unwarranted delay of the hearing could undermine the public interest in maintaining competition. Respondents argue that any benefit from the Complaint's proposed remedy would take years to materialize. Respondents' Motion at 8-9. That, of course, is no basis for adding an unnecessary increment to the time before competitive benefits result.

We conclude that the Chief Administrative Law Judge can conduct an adjudication via video conferencing consistent with due process and fundamental fairness and that the pandemic-related arguments advanced in Respondents' Motion do not constitute good cause for further

4 Respondents also suggest—without actually asserting—that the FTC Act prohibits virtual trials. Respondents' Motion at 7 ("The FTC Act contemplates in-person trials."). Respondents point to Section 5(b) of that statute, 15 U.S.C. § 45(b) (as well as identical language in Section 11(b) of the Clayton Act, 16 U.S.C. § 21(b)), which provides for issuance of a Commission complaint "containing a notice of a hearing upon a day and at a place therein fixed at least thirty days after the service of said complaint" and gives the respondent "the right to appear at the place and time so fixed." Obviously, the chosen language does not—and in 1914 could not—advert to video conferencing, but the statute is satisfied by determinations fixing a hearing to be conducted virtually and providing for Respondents to appear electronically.

delay. Given the challenges of the COVID-19 pandemic, including its continued spread and the uncertain duration of its status as a public health crisis, we have determined that the Commission should utilize the available technology in preference to subjecting this case to unnecessary delay. Consequently, inclusion in this Order of provisions specifying that the trial be conducted via video conferencing appropriately addresses Respondents' objections to the hearing date and enables the Commission to move forward with the business of the agency.

Nonetheless, a more modest continuance than requested by Respondents has become necessary. The federal courts have recently lifted a long-running stay in another FTC adjudicative proceeding, and the evidentiary hearing in that matter has been scheduled to commence on April 20, 2021.[5] To avoid conflict between the two hearings, we have determined to defer commencement of the evidentiary hearing in this proceeding until June 2, 2021. This should allow both evidentiary hearings to proceed without overlapping.

Accordingly,

IT IS HEREBY ORDERED that

(1) Respondents' Motion to Reschedule the Evidentiary Hearing is **GRANTED IN PART**;

(2) the evidentiary hearing in this proceeding before the Chief Administrative Law Judge of the Federal Trade Commission is rescheduled to commence on June 2, 2021, at 10:00 a.m.;

(3) the Chief Administrative Law Judge shall establish a revised prehearing schedule that will permit the evidentiary hearing to commence on the date set by the Commission;

(4) the evidentiary hearing in this proceeding will take place virtually via live web streaming; and

(5) public access to the evidentiary hearing in this proceeding, to the extent permitted by any *in camera* orders, shall be allowed only via telephone or live web streaming, in either instance, only for monitoring purposes.

By the Commission.

5 *La. Real Estate Appraisers Bd.*, Docket No. 9374, Order Lifting Stay and Resuming Administrative Proceedings (Feb. 12, 2021).

Interlocutory Orders, Etc.

IN THE MATTER OF

TRAFFIC JAM EVENTS, LLC,
AND
DAVID J. JEANSONNE II

Docket No. 9395. Order, March 1, 2021

Order extending the withdrawal of this matter from adjudication for the purpose of considering a Consent Proposal.

ORDER EXTENDING WITHDRAWAL OF MATTER FROM ADJUDICATION UNTIL APRIL 5, 2021

On December 28, 2020, the Commission issued an Order withdrawing this matter from adjudication for the purpose of considering a Consent Proposal. Pursuant to that Order, this matter is scheduled to revert to Part 3 adjudicative status on Monday, March 1, 2021. To facilitate further consideration of the Consent Proposal, the Commission has decided to extend the withdrawal of this matter from adjudication.

Accordingly,

IT IS ORDERED THAT, pursuant to 3.25(c) of the Commission Rules of Practice, 16 C.F.R. § 3.25(b)(2015), this matter will remain withdrawn from adjudication through April 2, 2021, after which it will return to adjudicative status.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

TRAFFIC JAM EVENTS, LLC,
AND
DAVID J. JEANSONNE II

Docket No. 9395. Order, April 2, 2021

Order to extend the withdrawal of this matter from adjudication to facilitate further consideration of the consent proposal.

ORDER EXTENDING WITHDRAWAL OF MATTER FROM ADJUDICATION UNTIL MAY 3, 2021

On December 28, 2020, the Commission issued an Order withdrawing this matter from adjudication for the purpose of considering a consent proposal. Pursuant to that Order, this matter is scheduled to revert to Part 3 adjudicative status at on Monday, April 5, 2021. To facilitate further consideration of the consent proposal, the Commission has decided to extend the withdrawal of this matter from adjudication.

Accordingly,

IT IS ORDERED THAT, pursuant to 3.25(c) of the Commission Rules of Practice, 16 C.F.R. § 3.25(b) (2015), this matter will remain withdrawn from adjudication through May 3, 2021, after which it will return to adjudicative status.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

LOUISIANA REAL ESTATE APPRAISERS BOARD

Docket No. 9374. Order, April 14, 2021

Order granting Complaint Counsel and Respondent's joint motion to withdraw this matter from adjudication to enable the Commission to consider a proposed Consent Agreement.

ORDER WITHDRAWING MATTER FROM ADJUDICATION FOR THE PURPOSE OF CONSIDERING A PROPOSED CONSENT AGREEMENT

Complaint Counsel and Respondent having jointly moved that this matter be withdrawn from adjudication to enable the Commission to consider a proposed Consent Agreement; and

Complaint Counsel and Respondent, having submitted a proposed Consent Agreement containing a proposed Decision and Order, executed by Respondent and by Complaint Counsel and approved by the Acting Director of the Bureau of Competition that, if accepted by the Commission, would resolve this matter in its entirety;

IT IS ORDERED, pursuant to Rule 3.25(c) of the Commission Rules of Practice, 16 C.F.R. § 3.25(c), that this matter in its entirety be, and it hereby is, withdrawn from adjudication until Monday, June 21, 2021, and that all proceedings before the Administrative Law Judge are hereby stayed pending determination by the Commission with respect to the proposed Consent Agreement, pursuant to Rule 3.25(f), 16 C.F.R. § 3.25(f); and

IT IS FURTHER ORDERED, pursuant to Rule 3.25(b) of the Commission Rules of Practice, 16 C.F.R. § 3.25(b), that the proposed Consent Agreement shall not be placed on the public record unless and until it is accepted by the Commission.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

TRAFFIC JAM EVENTS, LLC,
AND
DAVID J. JEANSONNE II

Docket No. 9395. Order, May 3, 2021

Order returning this matter to adjudication because further consideration of the consent proposal is no longer in the public interest.

ORDER RETURNING THE MATTER TO ADJUDICATION AND SETTING A NEW EVIDENTIARY HEARING DATE

On December 28, 2020, the Commission issued an order withdrawing this matter from adjudication for purposes of considering a consent proposal. Pursuant to that Order, the Commission stayed all proceedings before the Administrative Law Judge in this matter pending a determination by the Commission with respect to the consent proposal.[1] The Commission has twice extended the withdrawal of this matter from adjudication;[2] absent further extension, this matter is scheduled to revert to adjudicative status on May 4, 2021.

Once a matter has been withdrawn from adjudication, the Commission "may accept a proposed consent agreement, reject it and return the matter or affected portions thereof to adjudication for further proceedings, or take such other action as it may deem appropriate." 16 C.F.R. § 3.25(f). Further consideration of the consent proposal is no longer in the public interest. Therefore, the Commission has determined to return this matter to adjudication. Accordingly,

IT IS HEREBY ORDERED that this matter be returned to adjudicative status and the stay in these proceedings be lifted; and

IT IS FURTHER ORDERED that the evidentiary hearing in this matter before the Administrative Law Judge of the Federal Trade Commission be rescheduled to commence on September 14, 2021, at 10:00 a.m.; and

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1 *Traffic Jam Events, LLC*, No. 9395, Order Withdrawing Matter from Adjudication for the Purpose of Considering a Proposed Consent Agreement (Dec. 28, 2020), https://www ftc.gov/system/files/documents/cases/d09395_commission_order_withdrawing_matter_from_adjudication_pursuant_to_commission_rule_3.25cpublic.pdf.

2 *Traffic Jam Events, LLC*, No. 9395, Order Extending Withdrawal of This Matter Until April 5, 2021 (Mar. 1, 2021), https://www.ftc.gov/system/files/documents/cases/d09395_commission_order_extending_withdrawalpublic.pdf; *Traffic Jam Events, LLC*, No. 9395, Order Extending Withdrawal of This Matter Until May 3, 2021 (Apr. 2, 2021), https://www.ftc.gov/system/files/documents/cases/d09395trafficjamorderextendwithdrawalmay3_002.pdf.

IT IS FURTHER ORDERED that the Administrative Law Judge establish a revised prehearing schedule that will permit the evidentiary hearing to commence on the date set by the Commission.

By the Commission.

Interlocutory Orders, Etc,

IN THE MATTER OF

HEALTH RESEARCH LABORATORIES, LLC, WHOLE BODY SUPPLEMENTS, LLC, AND KRAMER DUHON

Docket No. 9397. Order, May 14, 2021

Order granting in part and denying in part Respondents' motion to enter a new scheduling Order or, in the alternative, to transfer the case to the Commission.

ORDER FOR FURTHER PROCEEDINGS BEFORE THE COMMISSION

On April 20, 2021, the Administrative Law Judge (ALJ) granted Respondents' motion to transfer this matter to the Commission for further proceedings pursuant to Commission Rule 3.12(b)(2), 16 C.F.R. § 3.12(b)(2). Order Granting In Part and Denying In Part Respondents' Motion to Enter New Scheduling Order or, in the Alternative, to Transfer Case to the Commission (Apr. 20, 2021) ("April 20 Order").[1]

Rule 3.12(b)(2) provides that a respondent who elects not to contest the allegations of fact in the complaint can, as Respondents did here, file an answer admitting all of the material allegations to be true. Such an answer constitutes a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, provides a record basis for the Commission to issue a final decision. Rule 3.12(b)(2). A Rule 3.12(b)(2) answer does not, however, necessarily terminate all proceedings in the case. For example, the respondent can -- and in this case, did -- reserve its rights to submit proposed findings of fact and conclusions of law. *Id.* Respondents' Answer also asserts a legal defense that challenges the constitutionality of the FTC's administrative process and of some elements of the FTC's structure.

Respondents argued to the ALJ that the case is now "ripe for a decision" without further discovery on the basis of a "record" consisting of the Complaint and Respondents' Answer. Respondents' Expedited Motion to Enter New Scheduling Order or, in the Alternative, Transfer Case to the Commission at 1-2 (Mar. 31, 2021). Similarly, Respondents have now argued that "the Commission is required to issue its final decision based solely on the facts alleged in the complaint." Response to Motion to Withdraw Expedited Motion to Reschedule Hearing Date and Request for Schedule at 2 (Apr. 26, 2021). Respondents have also filed Respondents'

1 Transfer to the Commission moots a motion filed by Complaint Counsel to reschedule the evidentiary hearing. Expedited Motion to Reschedule Evidentiary Hearing Date (Mar. 30, 2021) ("Motion to Reschedule"). Complaint Counsel have subsequently filed a Motion to Withdraw Complaint Counsel's Expedited Motion to Reschedule Evidentiary Hearing Date and Request for Schedule (Apr. 26, 2021). Withdrawal of the Motion to Reconsider is granted; this Order sets out our determinations regarding scheduling. Respondents have moved for an extension of time to respond to the Motion to Reschedule. Respondents' Motion to Extend Time to Respond to Complaint Counsel's Motion to Reschedule the Evidentiary Hearing Date (Apr. 16, 2021). Respondents' motion for an extension is denied as moot.

Stipulation as to "Fencing-In" Relief (Apr. 13, 2021) ("Respondents' Stipulation"), in which Respondents "stipulate and agree that the Initial Decision of the ALJ can include whatever 'fencing-in' relief is permitted by statute and requested in the Complaint."[2] Respondents do not make clear what implications they attach to the stated limitation to fencing-in relief "permitted by statute"[3] and do not specify whether they will accept and agree to the specific items of relief identified in the Notice of Contemplated Relief that was attached to the Complaint.

Complaint Counsel, for their part, asserted before the ALJ that discovery was required on the issue of remedy notwithstanding the Rule 3.12(b)(2) Answer. *See, e.g.*, Complaint Counsel's Second Motion to Compel Respondents to Supplement Interrogatory Responses at 1-2 (Mar. 24, 2021[]). As the ALJ recognized, there is nothing in Rule 3.12(b)(2) that prevents Complaint Counsel from pursuing discovery on issues that remain in dispute after a Rule 3.12(b)(2) answer. Order Granting Respondents' Motion for Leave to Amend Answer at 5 (Mar. 10, 2021). The issues in dispute and corresponding discovery needs, however, appear to remain in flux, with the recent filing of Respondents' Stipulation and, perhaps, with Respondents' recent provision of supplemental interrogatory responses. *See* Respondents' Expedited Motion to Partially Reconsider May [sic] 6, 2021 Order Granting Complaint Counsel's Motion to Compel and Statement of Impasse at 3 (Apr. 13, 2021). Consequently, as we structure the next steps in this proceeding, it is important that we understand what, if any factual issues remain to be resolved.

Under these circumstances, we have determined to ask the parties to identify any additional material facts that they intend to assert and to state whether those facts are in dispute. Based on the filings we are requesting, the Commission will determine the scope and manner of further proceedings. Future proceedings will include, but not necessarily be limited to, an opportunity for the parties to submit proposed findings of fact and conclusions of law and a proposed order, together with reasons therefor and briefs in support thereof, addressing the elements of liability, the appropriate remedy, and legal defenses. If substantial factual issues remain in dispute, we will consider remanding this proceeding to the ALJ for further fact-finding procedures. Accordingly,

IT IS HEREBY ORDERED that Complaint Counsel shall, within seven (7) days of the date of this Order, file with the Commission and serve upon Respondents a statement of the material facts that Complaint Counsel intend to assert, other than facts expressly alleged in the Complaint, and shall identify the decisional issue(s) to which each asserted fact relates.

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2 As the ALJ has noted, Rule 3.12(b)(2) contemplates a final decision by the Commission and does not provide for an Initial Decision by the ALJ. April 20 Order at 3 n.4, 4. Clarification regarding the application of Respondents' Stipulation to the Commission's final opinion and order would be desirable.

3 Elsewhere, Respondents state both that they "have no objection to a *blanket* prohibition on disseminating or causing to be disseminated ***any*** advertising or promotional materials for ***any*** supplements that makes ***any*** representations regarding health or disease," Respondents' Expedited Motion to Partially Reconsider May [sic] 6, 2021 Order Granting Complaint Counsel's Motion to Compel and Statement of Impasse at 7 (Apr. 13, 2021), (emphasis original), and that "[t]he *only* relief permitted by Section 5 of the FTC Act is an order requiring Respondents to cease and desist from the allegedly deceptive act or practice -- which is the dissemination of advertising and promotional materials regarding the four supplements." *Id.* at 5 (emphasis original).

IT IS FURTHER ORDERED that Respondents shall within seven (7) days of the date of service of Complaint Counsel's statement, file with the Commission and serve upon Complaint Counsel a Response to Complaint Counsel's statement. For each fact that Complaint Counsel have identified, Respondents shall state whether they dispute the asserted fact and shall explain the basis for any disputes identified. Such Response shall clarify whether Respondents' Stipulation applies to the Commission's final opinion and order and shall specify whether Respondents will accept and agree to the specific items of relief identified in the Notice of Contemplated Relief that was attached to the Complaint. Such Response shall also identify any additional material facts, other than those alleged in the Complaint or asserted by Complaint Counsel, that Respondents intend to assert and shall identify the decisional issue(s) to which each additional fact relates.

IT IS FURTHER ORDERED that within five (5) days of the date of service of Respondents' Response, Complaint Counsel may file with the Commission and serve upon Respondents a brief reply to any new matters raised in the Response. If Respondents have identified any additional facts that they intend to assert, Complaint Counsel, within five (5) days of the date of service of Respondents' Response, shall file with the Commission and serve upon Respondents a reply in which, for each fact that Respondents have identified, Complaint Counsel shall state whether they dispute the asserted fact and shall explain the basis for any disputes identified. And

IT IS FURTHER ORDERED that Complaint Counsel's Expedited Motion to Reschedule Evidentiary Hearing Date is **DEEMED WITHDRAWN**. Respondents' Motion to Extend Time to Respond to Complaint Counsel's Motion to Reschedule the Evidentiary Hearing Date is **DENIED**.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

HACKENSACK MERIDIAN HEALTH, INC.,
AND
ENGLEWOOD HEALTHCARE FOUNDATION

Docket No. 9399. Order, May 25, 2021

Order granting Complaint Counsel and Respondents' motion to postpone the commencement of the administrative hearing in this proceeding.

ORDER GRANTING CONTINUANCE

On May 20, 2021, Complaint Counsel and Respondents Hackensack Meridian Health, Inc. ("HMH") and Englewood Healthcare Foundation ("Englewood") moved to postpone by 30 days the commencement of the administrative hearing in this proceeding, currently scheduled to begin on June 15, 2021, and to stay all pre-hearing deadlines by corresponding 30-day periods. Joint Expedited Motion for a Continuance of Administrative Proceedings ("Joint Motion") at 1, 4.

This Joint Expedited Motion follows the Commission's issuance on December 3, 2020, of an administrative complaint challenging a proposed transaction whereby HMH would acquire Englewood ("the Proposed Transaction"). The Commission at that time also filed a complaint in the U.S. District Court for the District of New Jersey seeking a preliminary injunction barring the Proposed Transaction until completion of the administrative proceeding. The preliminary injunction hearing concluded on May 18, 2021, and closing arguments are scheduled for June 2, 2021. The parties anticipate a decision in the federal district court action within the next several months. *Id.* at 2. The parties state that "[i]t is highly likely that [the preliminary injunction] ruling will cause these administrative proceedings to be suspended or rendered moot." *Id.* at 4.

The parties argue that granting the requested continuance and extending pre-hearing deadlines would protect the parties and third parties and their witnesses from unnecessary burdens and expense, without prejudicing the Commission. *Id.* at 1-4. They explain that third parties will need to review voluminous documents, submit line-by-line proposed redactions of confidential information, and prepare legal memoranda requesting *in camera* treatment of those materials. *Id.* at 3. Furthermore, all parties will have to bear the expense of preparing for a full trial, including document and data review and motion practice. *Id.* And party and third-party witnesses face the burden and disruption of preparing to testify and testifying. *Id.* According to the parties, these witnesses include operators of hospitals and clinicians, whose burdens are of particular concern during a time of global pandemic. *Id.* at 2.

Commission Rule 3.41(f) provides, in relevant part, that a pending "collateral federal court action that relates to the administrative adjudication shall not stay the proceeding [u]nless a court of competent jurisdiction, or the Commission for good cause, so directs." 16 C.F.R. § 3.41(f). This rule reflects the Commission's commitment to move forward as expeditiously as possible with its administrative hearings. *See, e.g.*, 16 C.F.R. §§ 3.1, 3.11(b)(4), 3.41(b).

Yet, as we have explained in the past, the public interest is not ideally served if litigants and third parties bear expenditures that later prove unnecessary. *See, e.g., In re Sanford Health*, Docket No. 9376, 2017 WL 5845596, at *1 (F.T.C. Nov. 21, 2017). Commission Rule 3.41(b) authorizes the Commission to delay a hearing date, upon a showing of good cause. 16 C.F.R. § 3.41(b). Under the circumstances presented, we find that the requested continuance and the extension of pre-hearing deadlines are justified. Deferring the start of trial and extending pre-hearing deadlines by 30 days will provide additional time for resolution of the district court action, which could obviate the need for an administrative hearing, without unduly delaying the Commission proceeding. We have granted continuances under comparable circumstances in the past. *See, e.g., In re Thomas Jefferson Univ.*, Docket No. 9392, 2020 WL 7237952 (F.T.C. Nov. 6, 2020); *In re RAG-Stiftung*, Docket No. 9384, 2020 WL 91294 (F.T.C. Jan. 2, 2020); *In re Sanford Health*, Docket No. 9376, 2017 WL 6604532 (F.T.C. Dec. 21, 2017); *Sanford Health*, 2017 WL 5845596; *In re The Penn State Hershey Med. Ctr.*, Docket No. 9368, 2016 WL 3345405 (F.T.C. June 10, 2016); *In re Advocate Health Care Network*, Docket No. 9369, 2016 WL 3182774 (F.T.C. June 2, 2016). Accordingly,

IT IS HEREBY ORDERED that the Joint Expedited Motion for a Continuance of Administrative Proceedings is **GRANTED**; and

IT IS FURTHER ORDERED that the evidentiary hearing in this proceeding shall commence at 10:00 a.m. on July 15, 2021, and that, unless modified by the Chief Administrative Law Judge, all related pre-hearing deadlines shall be extended by 30 days.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

TRAFFIC JAM EVENTS, LLC,
AND
DAVID J. JEANSONNE II

Docket No. 9395. Order, June 9, 2021

Order granting Complaint Counsel's request for court enforcement of a subpoena to nonparty Platinum Plus Printing, LLC.

ORDER DIRECTING GENERAL COUNSEL TO ENFORCE NONPARTY SUBPOENA

On December 10, 2020, Complaint Counsel filed a motion requesting that the Chief Administrative Law Judge ("ALJ") certify to the Commission, pursuant to Commission Rule 3.38(c), 16 C.F.R. § 3.38(c), Complaint Counsel's request for court enforcement of a subpoena to nonparty Platinum Plus Printing, LLC ("PPP"). PPP opposed the motion, asserting that the subpoena was overbroad and sought information that was irrelevant or could be obtained from parties to the action. Following a period when this proceeding had been removed from adjudication, on May 13, 2021, the ALJ granted Complaint Counsel's motion, certifying their request for court enforcement of the subpoena and recommending that court enforcement be sought. Having reviewed the parties' respective filings and the ALJ's certification and recommendation, we direct the General Counsel to seek enforcement of the subpoena in federal district court.[1]

Respondents Traffic Jam Events, LLC and its owner, managing member, and president, David J. Jeansonne II, provide marketing services to auto dealerships nationwide. Complaint ¶¶ 2, 3; Answer ¶¶ 2, 3. As Respondents put it, Traffic Jam Events "is in the business of creating mailers on behalf of automotive dealerships to promote automotive sales." Answer at 1. The Commission's Complaint charges that Respondents violated the FTC Act by (1) providing false or misleading information about COVID-19 stimulus relief in connection with their marketing of motor vehicles and (2) falsely or misleadingly advertising that consumers had won a specific prize that could be collected by visiting a particular auto dealership, when consumers had not won the specific prize. Complaint ¶¶ 15-19. The Complaint also charges that Respondents failed to make certain disclosures required by the Truth in Lending Act and Regulation Z, 12 C.F.R. § 226.24(d). Complaint ¶¶ 20-23.

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1 We use the following abbreviations for citations to the pleadings:

Motion:	Complaint Counsel's Motion to Certify to the Commission a Request Seeking Court Enforcement of a Subpoena *Duces Tecum* Issued to Platinum Plus Printing, LLC (Dec. 10, 2020)
Widor Decl.:	Declaration of Thomas J. Widor attached to Motion
Opposition:	Platinum Plus Printing, LLC's Response to Complaint Counsel's Motion to Certify (Dec. 21, 2020)
ALJ Order:	Order Granting Motion for Certification to the Commission of Request for Court Enforcement of Nonparty Subpoena (May 13, 2021)

Complaint Counsel assert that nonparty PPP assisted Respondents in executing their deceptive advertising and marketing, including the dissemination of one of the COVID-19 mailers cited in the Complaint. Motion at 1. Complaint Counsel further assert that Respondents share numerous other connections to PPP, such as that Respondent Jeansonne is a manager of PPP; PPP's registered agent is a key employee of Respondent Traffic Jam Events; and PPP and Traffic Jam Events share a business address. Motion at 5; Widor Decl. ¶¶ 8-10. On September 10, 2020, Complaint Counsel served PPP with a subpoena *duces tecum* for the production of documents broadly regarding: PPP's corporate structure and relationship with Respondents, as well as any related agreements or payments (requests for production ("RFPs") 1-3); the creation, development, review, and dissemination of advertisements for Respondents (RFPs 4-6); communications relating to the Respondents and their customers, advertisements, and advertisement recipients (RFPs 7-9); complaints regarding Respondents or their advertising, and communications relating to the Federal Trade Commission (RFPs 10-11); and the identities of employees and others having responsibilities relating to advertisements in general and PPP's relationship with Respondents in particular (RFP 12). *See* Widor Decl. Ex. A.

PPP did not produce the requested documents, serve objections to the individual requests for production, or move to quash. *See* Widor Decl. ¶¶ 4, 23 & Ex. B. Instead, three days after the production deadline, on October 13, 2020, counsel for PPP sent a letter to Complaint Counsel listing a number of general objections to the subpoena. Widor Decl. Ex. B. Complaint Counsel and PPP's counsel met and conferred on October 27, 2020, at which time counsel for PPP indicated her client's willingness to produce documents on a rolling basis subject to some modifications. Widor Decl. Ex D. When PPP still did not produce documents, on November 6, 2020, Complaint Counsel moved the ALJ for an order compelling PPP's compliance under Commission Rule 3.38(a). *See* Widor Decl. Ex. C. The ALJ denied Complaint Counsel's motion on the ground that Rule 3.38(a) does not authorize him to compel nonparties to comply with subpoenas. *See In re Traffic Jam Events, LLC*, No. 9395, 2020 WL 6938319 (Nov. 20, 2020). Instead, enforcement of such subpoenas must be obtained in federal district court in accordance with Rule 3.38(c), which provides that "in instances where a nonparty fails to comply with a subpoena or order, [the ALJ] shall certify to the Commission a request that court enforcement of the subpoena or order be sought." *Id.* at *2; *see also* 15 U.S.C. § 49 ("[I]n case of disobedience to a subpoena the Commission may invoke the aid of any court of the United States in requiring the attendance and testimony of witnesses and the production of documentary evidence.").

Following the ALJ's decision, Complaint Counsel sought to enforce the subpoena by moving the ALJ for a certification under Rule 3.38(c). PPP opposed the Motion, asserting that the subpoena was overbroad and sought information that was irrelevant or could be obtained from Respondents. Opposition at 1-2. To support these objections, PPP invoked two provisions of our Rules—Rule 3.31(c)(1) and Rule 3.31(c)(2)(i), 16 C.F.R. §§ 3.31(c)(1) & 3.31(c)(2)(i). Opposition at 1. Rule 3.31(c)(1) allows parties to seek discovery "to the extent that it may be reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent." Rule 3.31(c)(2)(i) provides that the ALJ shall limit discovery to nonparties if he finds that it "is unreasonably cumulative or duplicative,

or is obtainable from some other source that is more convenient, less burdensome, or less expensive."[2]

Over these objections, the ALJ certified Complaint Counsel's request for enforcement of the subpoena and recommended that the Commission authorize enforcement in federal court. Emphasizing PPP's connections to the Respondents and its role in the distribution of the allegedly deceptive advertising, the ALJ found that the requested information was relevant within the meaning of Rule 3.31(c). *See* ALJ Order at 5. Further, the ALJ rejected the argument that PPP's business records would necessarily be duplicative of those of Respondents, given that one of the nonparty printers subpoenaed by Complaint Counsel reported that it dealt directly with PPP and not with Respondents. *Id*. Moreover, the ALJ found that there have been substantial difficulties in procuring documents from Respondents, and he consequently rejected PPP's assertion that the requested documents could be obtained from Respondents with greater convenience or less burden. *Id.* (citing *Tacita Fair v. Commun. Unlimited, Inc.*, 2019 U.S. Dist. LEXIS 7632, at *5 (E.D. Mo. Jan. 16, 2019)). The ALJ also determined that the subpoena was stated with reasonable particularity, as required by Rule 3.34, and that Respondent had failed to comply with the subpoena. ALJ Order at 5.

We agree with the ALJ's conclusions. The subpoena seeks documents that may be reasonably expected to yield information relevant to the allegations of the Complaint, to the proposed relief, or to the Respondents' defenses. For example, documents about PPP's creation of advertising materials for Respondents may be relevant to advertisement substantiation or to Respondents' knowledge and intent. Requests about PPP's communications with Respondents' clients or customers may lead to relevant information regarding the advertisements' materiality or Respondents' knowledge and intent, among other things. Requests concerning PPP's corporate structure, relationship with the Respondents, and payments between Respondents and PPP may be helpful to determining relevant actors' liability or drafting an appropriate remedy. Indeed, Complaint Counsel have identified potentially significant relationships between PPP and Respondents and are evaluating whether to seek leave to amend the Complaint to add PPP as a respondent based on evidence obtained since the Commission issued the Complaint. Complaint Counsel's Motion to Compel Platinum Plus Printing, LLC to Produce Materials Responsive to a Subpoena *Duces Tecum* at 1 n.1 (Nov. 6, 2020); *see also Auto-Owners Ins. Co. v. Se. Floating*

2 More specifically, PPP asserted that documents regarding its corporate structure (RFP 1), payments between PPP and Respondents (RFP 3), PPP's creation of advertising materials for Respondents (RFP 5), PPP's communications with Respondents' clients or customers (RFP 8), and PPP's communications related to the Federal Trade Commission (RFP 10) are irrelevant. Opposition at 2-6. PPP further asserted that documents regarding agreements and payments between PPP and Respondents (RFPs 2-3), PPP's creation, development, review, and dissemination of advertisements for Respondents, and communications related to such advertisements (RFPs 4-5, 9), dissemination schedules and recipients of advertisements (RFPs 6, 7), and communications between PPP and Respondents (RFP 8) could be more easily and conveniently obtained from Respondents. *Id.* at 3-5. With respect to RFP 12, which sought information about individuals with responsibilities related to Respondents, PPP asked to strike it as improper because it was really an interrogatory and interrogatories cannot be directed to nonparties. Opposition at 7 (citing 16 C.F.R. § 3.35). RFP 12, however, does not ask PPP to answer any questions but only to produce responsive documents to the extent they exist.

Docks, Inc., 231 F.R.D. 426, 430 (M.D. Fla. 2005) (allowing plaintiff to conduct discovery regarding nonparties' corporate structure, corporate governance, and relationship to defendants because it could show that nonparties were interrelated with defendants and should be added to the lawsuit as real parties in interest). Further, as the ALJ found, the discovery sought is not unreasonably cumulative or duplicative or obtainable from some other source that is more convenient, less burdensome, or less expensive.[3] We therefore find that the subpoena is proper, that PPP has failed to comply with the subpoena, and that PPP's objections do not provide a basis for its failure to comply. Accordingly,

IT IS ORDERED THAT the General Counsel take appropriate action to enforce in federal district court Complaint Counsel's subpoena *duces tecum* to Platinum Plus Printing, LLC.

By the Commission.

3 Complaint Counsel argue that PPP waived this argument because it did not raise it as an objection when its discovery response was due or in the meet-and-confer conference. Motion at 6. The ALJ declined to find the argument waived for purposes of the Motion because PPP did raise it in its response to Complaint Counsel's earlier motion to compel. ALJ Order at 5 n.4. We need not decide the issue of waiver of this or any other argument because we find that, even assuming the objections were timely and properly made, they do not support PPP's withholding of responsive documents.

Interlocutory Orders, Etc.

IN THE MATTER OF

HEALTH RESEARCH LABORATORIES, LLC, WHOLE BODY SUPPLEMENTS, LLC, AND KRAMER DUHON

Docket No. 9397. Order, June 15, 2021

Order denying Respondents' motion to strike Complaint Counsel's statements of the material facts and granting Complaint Counsel's motion to extend their time to reply to the Response to Statement of Additional Material Facts.

ORDER DENYING MOTION TO STRIKE COMPLAINT COUNSEL'S STATEMENT OF ADDITIONAL MATERIAL FACTS AND EXTENDING TIME FOR COMPLAINT COUNSEL'S REPLY

On May 14, 2021, the Commission issued an order directing the parties in this proceeding to file statements of the material facts that they intend to assert, other than facts expressly alleged in the Complaint. Order for Further Proceedings before the Commission (May 14, 2021). Complaint Counsel filed their statement on May 25, 2021, and Respondents have moved to strike that filing as untimely.[1] Complaint Counsel have filed a motion to extend their time to reply to the Response to Statement of Additional Material Facts until June 21, 2021.[2]

Complaint Counsel argue that their statement of facts was timely filed under the provisions of Commission Rule 4.3, 16 C.F.R. § 4.3, relating to timing. CC Motion at 3. Respondents have now stated that they do not oppose denial of their motion to strike.[3] We agree that, pursuant to Commission Rule 4.3(a), 16 C.F.R. § 4.3(a), Complaint Counsel's Statement of Additional Material Facts was timely filed on May 25, 2021, and deny the motion to strike.

Complaint Counsel state that an extension of time is needed to reply to new legal arguments raised by the Response to Statement of Additional Material Facts and to develop a proposal for structuring the remainder of this proceeding. CC Motion at 2. Respondents do not oppose extending time for the Reply until June 21. Response to Motion to Extend at 1. Although all parties will have an opportunity to brief issues relevant to liability, remedy, and defenses at a later date, we will not constrain Complaint Counsel from appropriately replying to issues raised in Respondents' filing and will extend the deadline until June 21. Accordingly,

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1 Respondents' Response to Complaint Counsel's Statement of Additional Material Facts at 5 (June 1, 2021) ("Response to Statement of Additional Material Facts").

2 Motion to Extend Date for Complaint Counsel's Reply to Respondents' Response to Complaint Counsel's Statement of Additional Material Facts and Opposition to Respondents' Motion to Strike (June 7, 2021) ("CC Motion").

3 Respondents' Response to Motion to Extend Date for Complaint Counsel's Reply to Respondents' Response to Complaint Counsel's Statement of Additional Material Facts and Opposition to Respondents' Motion to Strike at 1 (June 7, 2021) ("Response to Motion to Extend").

IT IS HEREBY ORDERED that Respondents' June 1, 2021 motion to strike Complaint Counsel's Statement of Additional Material Facts, is **DENIED**; and

IT IS FURTHER ORDERED that Complaint Counsel's Motion to Extend Date for Complaint Counsel's Reply is **GRANTED**, and the deadline for Complaint Counsel's Reply is extended to June 21, 2021.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

ALTRIA GROUP, INC.,
AND
JUUL LABS, INC.

Docket No. 9393. Order, June 17, 2021

Order continuing the evidentiary hearing to accommodate the June 18th federal holiday.

ORDER CONTINUING EVIDENTIARY HEARING

The next session of the evidentiary hearing in this proceeding is scheduled for June 18, 2021. Pursuant to legislation enacted today, June 17, June 18 will be observed as a federal holiday. That observance presents logistical difficulties for going forward with an evidentiary hearing session on June 18. Consequently, the evidentiary hearing must be stayed until Monday, June 21. Accordingly,

IT HEREBY ORDERED that the evidentiary hearing in this proceeding is stayed until June 21, 2021, and will resume at 9:45 a.m. on that date.

By the Commission.

RESPONSES TO PETITIONS TO QUASH OR LIMIT COMPULSORY PROCESS

GREAT OUTDOORS GROUP, LLC
D/B/A
GREAT AMERICAN OUTDOORS GROUP

FTC File No. 211 0059 – Decision, June 29, 2021

RESPONSE TO DUNHAM'S ATHLEISURE CORPORATION'S PETITION TO QUASH SPECIFICATIONS 2(A), (B), (E) AND (I) IN THE CIVIL INVESTIGATIVE DEMAND DATED MARCH 8, 2021.

By CHOPRA, Commissioner:

Dunham's Athleisure Corporation ("Dunham's") petitions the Commission to quash Specifications 2(a), (b), (e) and (i) in the Civil Investigative Demand ("CID") issued on March 8, 2021. The CID was issued in connection with the Commission's investigation into whether the proposed acquisition of Sportsman's Warehouse Holdings, Inc. ("Sportsman's") by Great Outdoors Group, LLC, d/b/a Great American Outdoors Group ("GAO"), if consummated, would violate Section 7 of the Clayton Act, 15 U.S.C. § 18, as amended or Section 5 of the Federal Trade Commission ("FTC Act"), 15 U.S.C. § 45, as amended, and whether the requirements of Section 7A of the Clayton Act, 15 U.S.C. § 18a, will be fulfilled regarding the transaction.

Dunham's argues that the four challenged subparts to Specification 2 should be quashed because: 1) compliance would impose an undue burden by requiring a laborious and costly review by senior managers and production in a format different from that stored ordinarily by the company; 2) the information sought is irrelevant to the Commission's investigation because Dunham's does not compete in the same product market nor serve the same customers as the merging firms; and 3) it has not received adequate assurances that proprietary and confidential business information it produces to the Commission will be protected from disclosure. We also consider whether Dunham's petition was filed timely.

For the reasons stated below, the Commission denies the petition as late filed. Even were it filed properly, the Commission would deny the petition on the merits.

I. Background

In December 2020, GAO entered into an agreement to acquire Sportman's, which if consummated would combine two large specialty outdoor sporting goods retailers. This petition arises out of the Commission's investigation to determine whether anticompetitive effects are likely to result from the proposed acquisition.

In order to investigate the proposed merger's competitive impact, on February 23, 2021, the Commission authorized staff to use compulsory process to obtain relevant information and

documents from the merging parties as well as from third parties who might possess such information.

Therefore, as authorized by the Commission's resolution and pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, on March 8, 2021, the Commission issued CIDs to third-party sporting goods retailers, including Dunham's. The CIDs consist of four specifications requesting information and documents to assist Commission staff assess the potential competitive effects of the proposed acquisition and the relevant product and geographic markets. Most relevant here, Specification 2 asks for certain financial information "by department or category" for each company store that sold "a relevant product" for each quarter since January 2015, including the "store number" (subpart a), "gross sales revenue" (subpart b), "Net Sales" (subpart e), and "gross margin" (subpart i). Pet. Exh. A at 1-2.[1]

The March 8 CID was served on Dunham's by overnight delivery service on March 11, 2021. The initial deadline for Dunham's to comply (the "return date") was April 7, 2021, and the deadline to file a petition to quash was March 31, 2021. *See* Pet. Exh. A at 1; 16 C.F.R. § 2.10(a)(1).[2]

After not hearing back from in-house counsel who had agreed to receive a courtesy copy of the CID, *see Email from Charles Dickinson to John Palmier* (dated March 9, 2021 at 2:42 PM); *Email from Charles Dickinson to John Palmier* (dated March 16, 2021 at 5:35 PM), on March 30, staff granted Dunham's recently-retained outside counsel a two-week extension until April 21 to comply with the CID. *See Email from Jonathan Emord to Charles Dickinson* (dated March 30, 2021 at 10:31 AM); *Email from Charles Dickinson to Jonathan Emord* (dated March 31, 2021 at 10:35 AM); *Email from Charles Dickinson to Jonathan Emord* (dated March 31, 2021 at 4:07 PM). On April 9, Dunham's produced a partial response to Specification 1, and reaffirmed its commitment to respond to the rest of the CID by April 21 after receiving staff assurances that information and materials obtained by the Commission as part of a nonpublic investigation receive statutory and regulatory protections from disclosure. *See Letter from Jonathan Emord to Charles Dickinson* (dated April 9, 2021); *Email from Peter Arhangelsky to Charles Dickinson* (dated April. 9, 2021 at 3:12 PM); *Email from Charles Dickinson to Peter Arhangelsky* (dated April. 9, 2021 at 5:59 PM).[3] On April 20, Dunham's requested and received

1 Specification 1 asks for a list of each company store that sold a relevant product since January 1, 2008. Specification 3 asks for all "online, catalog, and other non-brick-and-mortar sales" of relevant products since January 1, 2015. Specification 4 asks for a list of item codes for each relevant product currently sold by the company.

2 The CID stated the "[t]he Commission's Rules of Practice require that any petition to limit or quash this demand be filed within 20 days after service, or if the return date is less than 20 days after service, prior to the return date." Pet. Exh. A. at 1; *see* 16 C.F.R. § 2.10(a)(1). The April 7 return date was more than 20 days after the CID was served on March 11; therefore, the deadline to file a petition to quash was 20 days after service or March 31, 2021.

3 Commission staff told Dunham's that these protections include: 1) Section 21(f) of the FTC Act, 15 U.S.C. § 57b-2(f) (exempting information obtained by the Commission pursuant to subpoena, or voluntarily in lieu of subpoena, in a Commission investigation from disclosure under the Freedom of Information Act, 5 U.S.C. § 552); *see also* 16 C.F.R. §§ 4.10-4.11; 2) Section 6(f) of the FTC Act, 15 U.S.C. § 46(f) (restricting the Commission's authority to make public trade secrets or confidential commercial or financial information); s*ee also* 16 C.F.R. §

a second extension until April 27. *See Email from Peter Arhangelsky to Charles Dickinson* (dated April 20, 2021 at 12:10 PM); *Email from Charles Dickinson to Peter Arhangelsky* (dated April 20, 2021 at 6:46 PM).

Dunham's missed that deadline; instead, in a letter sent the following day, Dunham's agreed to produce information partially responsive to Specification 4, stated it had no information responsive to Specification 3, and (for the first time) objected to responding to Specification 2 based on undue burden, irrelevance, the risk that production would disclose confidential business information, and the purported availability of the requested information elsewhere. *See Email from Jonathan Emord to Charles Dickinson* (dated April 28, 2021 at 3:31 PM). Staff immediately sought to discuss Dunham's newly-raised concerns and provided a third extension until May 7 to facilitate that discussion. *See Email from Charles Dickinson to Jonathan Emord* (dated April 28, 2021 at 7:36 PM). Dunham's ignored that request after producing data in partial response to Specification 4. *See Email from Jonathan Emord to Charles Dickinson* (dated April 29, 2021 at 9:53 AM); *Email Charles Dickinson to Jonathan Emord* (dated May 5, 2021 at 1:36 PM); *Email from Peter Arhangelsky to Charles Dickinson* (dated May 6, 2021 at 1:47 PM).

On May 7, Commission staff notified Dunham's that it "is not currently in compliance" with the March 8 CID by the deadline that day in large part because Dunham's "has not produced any data or information in response to Specification 2." *See Email from Charles Dickinson to Peter Arhangelsky* (dated May 7, 2021 at 4:35 PM). Staff granted a fourth extension to May 12 solely to schedule a meet and confer "to come to an agreement on a schedule for compliance with the CID." *Id*. Dunham's agreed to meet on May 11. *See Email from Peter Arhangelsky to Charles Dickinson* (dated May 7, 2021 at 6:57 PM).

At the May 11 conference call, staff agreed to limit the number of Specification 2 subparts that Dunham's currently must respond to, Dunham's agreed to "provide a timetable for compliance by" May 14, and staff granted a fifth extension of the CID deadline to May 14 to facilitate that effort. *See Email from Charles Dickinson to Ryan Andrews, Peter Arhangelsky* (dated May 12, 2021 at 4:38 PM). Shortly afterwards, Dunham's asked for another extension until May 17 because a "key Dunham's employee" necessary to provide the compliance timetable was out of the office. *See Email from Jonathan Emord to Charles Dickinson* (dated May 12, 2021 at 6:27 PM). Staff granted this sixth extension request. *See Email from Charles Dickinson to Jonathan Emord* (dated May 13, 2021 at 8:20 PM). On May 17, Dunham's counsel requested another one-day extension because the employee still needed to contact others "to come up with a production estimate" and "to enable this assessment to be completed." *See Email from Jonathan Emord to Charles Dickinson* (dated May 17, 2021 at 2:37 PM). Instead of providing the requested compliance timetable, Dunham's filed its petition to quash later that day.

4.10(a)(2); and 3) Section 7A(h) of the Clayton Act, 15 U.S.C. § 18a(h) (providing confidential treatment of information submitted to the Commission).

II. Analysis

A. Dunham's Petition to Quash Was Untimely

We must first decide whether Dunham's filed its petition after the deadline to do so. We conclude that it did.

As explained above, because Dunham's was served with the Commission's CID on March 11, 2021, it was required to file a petition to quash by March 31, 2021. *See* n.2 *supra.* Dunham's did not file its petition to quash until May 17, 2021 – 47 days after its March 31 deadline – and therefore filed the petition late.

Dunham's claims that its motion was "filed within the time limit for response to the Bureau (under authority given by Bureau approved extensions)." Pet. at 1. But the only extensions granted here were extensions to the compliance deadline. Despite having asked for, and received, *six* extensions of the deadline to respond to the CID, Dunham's never requested (nor apparently even suggested a need for) an extension of the deadline in which to file a petition to quash. It thus never received such an extension. *See* 16 C.F.R. § 2.10(a)(5) (providing authority to certain Commission officials to grant extensions for petitions to quash). Dunham's also never moved for leave to late-file its petition after the March 31 deadline by providing a sufficient explanation for its tardiness. *See* 16 C.F.R. § 4.3(b) (Commission may consider a motion to extend made after the expiration date "where the untimely filing was the result of excusable neglect.").

Thus, we deny Dunham's petition because it was not filed timely.

B. Dunham's Petition Fails on the Merits: Burden, Relevance, and Confidentiality.

FTC compulsory process is proper "if the inquiry is within the authority of the agency, the demand is not too indefinite, and the information sought is reasonably relevant" to the investigation. *United States v. Morton Salt Co.,* 338 U.S. 632, 652 (1950). As explained above, Dunham's objects to responding to Specifications 2(a), (b), (e), and (i), which require the company to produce "gross sales revenue," "net sales" and "gross margin" from each of its 260 stores "by department or category" for each quarter from January 2015 to the present. *See* Pet. Exh. A at 1-2. Even if the petition were filed properly, we would deny it on the merits.

1. Burden

Dunham's claims that gathering the gross sales revenue, net sales, and gross margin data for each of its stores would be unduly burdensome and costly by requiring a laborious, disruptive, and lengthy review process that only senior managers could perform and the production of data in a format different than that ordinarily kept by the company. Pet. at 2-3; *see also* Pet. Exh. B. We are unpersuaded by this argument.

Responses to Petitions to Quash

As a threshold matter, we reject out of hand Dunham's complaint that responding to Specification 2(b), which requests the stores' gross sales revenue, imposes an undue burden. Staff does not currently seek this information and may never ask for it if staff is satisfied with Dunham's responses to the other three priority subparts of Specification 2.[4]

We further conclude that Dunham's has failed to show it incurs an undue burden by having to respond to just three (out of 14) key subparts to Specification 2: subparts (a), (e), and (i). Commission staff made several attempts to reasonably accommodate Dunham's concerns. Staff repeatedly offered to limit the scope of the CID to reduce Dunham's professed burden, by narrowing the number of Specifications and subparts in an effort to minimize any compliance burden on the company. Yet even the substantial reduction in the amount of store financial data requested of Dunham's has not induced the company to respond to its production obligations.

Dunham's complaint about having to divert some resources to review its corporate records is insufficient to show undue burden. "Some burden on subpoenaed parties is to be expected and is necessary in furtherance of the agency's legitimate inquiry and the public interest." *FTC v. Texaco, Inc*., 555 F.2d 862, 882 (D.C. Cir. 1977).[5] Indeed, "courts have refused to modify investigative subpoenas unless compliance threatens to unduly disrupt or seriously hinder normal operations of a business." *Id*. (citing cases). In order to substantiate its claim of undue burden, the party challenging administrative compulsory process must show that the cost is "unduly burdensome in the light of the company's normal operating costs." *See EEOC v. Md. Cup Corp.*, 785 F.2d 471, 479 (4th Cir. 1986). Courts routinely require the party claiming undue burden to "submit[] affidavits or offer[] evidence revealing the nature of the burden." *DIRECTV, Inc. v. Puccinelli*, 224 F.R.D. 677, 688–89 (D. Kan. 2004); *accord Huviron Co., Ltd*. v. *CCTVSTAR, Inc.*, No. 14-cv-01009, 2015 WL 12830387, at *1 (C.D. Cal. Sept. 16, 2015); *Heller v. City of Dallas*, 303 F.R.D. 466, 490 (N.D. Tex. 2014) (citing cases). Commission rules likewise require a petition to quash to set forth all objections to the CID, "including all appropriate . . . affidavits, and other supporting documentation." 16 C.F.R. § 2.10(a).

Dunham's has failed to substantiate its claim that requiring the review and production of store sales or margin data for a limited period of time would unduly disrupt its normal business operations. Instead, it relies solely on its counsel's argument unsupported by an affidavit or any documentary evidence. We cannot accept counsel's bald contention that Dunham's – a retailer with sufficient business acumen to operate 260 stores – operates without the ability to determine what its individual stores' sales, costs, or profits are. Because Dunham's failed to provide an affidavit from a manager or other knowledgeable personnel to explain what information is (and is not) available, the Commission is unable to verify its counsel's description of the burden. Commission staff's experience confirms that similarly situated retailers are able to produce

4 Because staff is not currently seeking a response to Specification 2(b), our order today does not require a response to that subpart of the specification.

5 Moreover, the Commission is not required to exhaust its efforts to gather responsive materials from the targets of an investigation before it may issue process to other parties that may have information relevant to its investigation. *See Gasoline Pricing Investig.*, 141 F.T.C. 498, 505, 2006 WL 6679070, *4 (2006).

comparable data by tracking sales and margins in a manner that allows them to respond to the CID.

We conclude that Dunham's has failed to show that responding to Specifications 2(a), (b), (e), and (i) would impose an undue burden.

2. Relevance

Dunham's also claims that the challenged Specification 2 subparts seek irrelevant information because the company does not compete in the same product market, or serve the same customers, as the merging parties. Pet. at 1-3. For example, Dunham's claims that, unlike the merging parties, it has no online sales and that its "markets are peculiarly local." Pet. at 1.

We find Dunham's conception of relevance to the Commission's investigation is unduly limited. Courts have long confirmed that an FTC investigation is lawful where the Commission seeks to learn whether there is *reason to believe* that the law has been violated and, if so, whether issuance of a complaint would be in the public interest. *See Texaco,* 555 F.2d at 872 (citing *Morton Salt Co.*, 338 U.S. at 642-43). The standard for the relevance of administrative compulsory process is, therefore, broader and "more relaxed" than would be in an adjudicatory discovery demand. *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1090 (D.C. Cir. 1992). Indeed, the Commission's compulsory process need not be limited to information necessary to prove a specific charge; it can demand any documents or information "relevant to the investigation—the boundary of which may be defined quite generally" by the Commission, *id*., which "can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not." *Texaco,* 555 F.2d at 872 (citing *Morton Salt*, 338 U.S. at 642-43). The requested information need only be "reasonably relevant" to the agency investigation and an agency explanation that the information is relevant will be upheld as long as it is not "obviously wrong." *Id*. at 876, 877 n.32. *See FTC v. Church & Dwight Co*., *Inc*., 747 F. Supp. 2d 3, 5–7 (D.D.C. 2010) (agency compulsory process upheld where agency's relevancy explanation was "not 'obviously wrong,'" because documents held by investigative target's foreign subsidiary could be "reasonably relevant" to investigation as to whether target had engaged in unfair competition by assessing factors that had led to a smaller foreign market share than that in the United States) (citing *Texaco,* 555 F.2d at 873, 877 n. 32), *aff'd*, 665 F.3d 1312 (D.C. Cir. 2011).

The challenged Specification 2 subparts easily meet those standards of relevance. Analyzing the store sales and margin data requested in the three key Specification 2 subparts will aid an analysis of the extent to which Dunham's poses a competitive constraint on the merging parties. Though Dunham's disputes that it competes with the merging parties, the CID properly seeks data that will allow Commission staff to undertake a rigorous analysis of this question. The requested information will also form a basis on which staff can define the relevant market or markets in which to assess the effects of the proposed acquisition and calculate market shares. These analyses, in turn, will inform the Commission of the ultimate issue of whether anticompetitive effects are likely to result from the proposed acquisition. The relevance of the requested information is clear.

3. Confidentiality

Dunham's also objects to the challenged Specification 2 subparts on the ground that responding to those inquiries may result in the disclosure of "the proprietary nature of [its] business model," which "would likely cause Dunham's to experience competitive injury." Pet. at 1-2. This claim too must be rejected.

As a general rule, the Commission is prohibited from disclosing any documents and information obtained through compulsory process, including proprietary business and sensitive customer information. *See* 15 U.S.C. §§ 46(f), 57b-2; 16 C.F.R. § 4.10(a). Thus, the mere fact that a subpoena or CID requires production of confidential or sensitive business information is no basis for noncompliance. *See FTC v. Dresser Industries, Inc.*, No. 77-44, 1977 WL 1394, at *5 (D.D.C. Apr. 26, 1977) (citing cases).

Courts have consistently held that these provisions provide adequate protection and that the Commission has a full right to access even the most highly sensitive or confidential business information including trade secrets. "Congress, in authorizing the Commission's investigatory power, did not condition the right to subpoena information on the sensitivity of the information sought. So long as the subpoena meets the requirements of the FTC Act, is properly authorized, and within the bounds of relevance and reasonableness, the confidential information is properly requested and must be complied with." *FTC v. Invention Submission Corp*., No. 89-272, 1991 WL 47104, at *4 (D.D.C. 1991), *aff'd*, 965 F.2d 1086, 1089 (D.C. Cir. 1992); *FTC v. Gibson Prod. of San Antonio, Inc.*, 569 F. 2d 900, 908 (5th Cir. 1978) (subpoenas at issue were not overly broad "simply because the requests may include confidential information."). The FTC need not make any special showing of relevance to obtain confidential material or trade secrets. *FTC v. Green*, 252 F. Supp. 153, 157 (S.D.N.Y. 1966).

Thus, the mere fact that Specifications 2(a), (e), and (i) might require the production of confidential or sensitive corporate information does not justify Dunham's refusal to comply.

III. CONCLUSION

For the foregoing reasons, **IT IS HEREBY ORDERED THAT** Dunham's Athleisure Corp.'s Petition to Quash Civil Investigative Demand be, and they hereby is, **DENIED**.

IT IS FURTHER ORDERED THAT Dunham's Athleisure Corp. shall comply in full with Specifications 2(a), (e), and (i) of the Commission's Civil Investigative Demand no later than July 14, 2021, or at such other date, time, and location as the Commission staff may determine.

By the Commission, Chair Khan not participating.

TABLE OF COMMODITIES
VOLUME 171

Page(s)

-- continued --