



UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION  
WASHINGTON, DC 20580

**Statement of Chairman Joseph J. Simons,  
Commissioner Noah Joshua Phillips, and Commissioner Christine S. Wilson Concerning  
the Proposed Acquisition of Allergan plc by AbbVie Inc.**

**May 5, 2020**

---

AbbVie Inc. (“AbbVie”), the seventh largest pharmaceutical company in the world by revenue, proposes to acquire Allergan plc (“Allergan”), the twentieth largest.<sup>1</sup> The parties’ portfolios are largely complementary, as AbbVie primarily develops and markets products in the immunology, oncology, and virology areas, while Allergan is focused on aesthetics and eye care. This transaction poses competitive concerns in three relevant markets: (1) drugs for the treatment of exocrine pancreatic insufficiency (“EPI”); (2) Interleukin-23 (“IL-23”) inhibitors for the treatment of moderate-to-severe Crohn’s disease; and (3) IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. In these areas, the parties are two of a limited number of firms with products on the market or in development.

The Commission has voted 3-2 to issue a complaint and accept a settlement resolving every substantial threat to competition uncovered by FTC staff and supported by the evidence, after a thorough investigation lasting ten months and involving more than forty interviews and the review of more than 430,000 documents. The proposed order remedies the competitive concerns by requiring the merging parties to divest Allergan’s EPI drugs Zenpep and Viokace to Nestlé, S.A. (“Nestlé”) and to transfer Allergan’s assets related to the IL-23 inhibitor brazikumab back to AstraZeneca plc (“AstraZeneca”), the drug’s original developer, by terminating the AstraZeneca license to Allergan. These divestitures fully remedy any potential loss of competition from the proposed transaction.

To challenge a merger successfully under the Clayton Act, the Commission must have proof that its likely effect is “substantially to lessen competition.” We cannot meet this burden of proof just by surmising there might be harm. Likewise, when the Commission pursues divestitures to replace competition otherwise lost by a merger, we also must rely on proof. For this reason, our decisions, as to the determination of harm and the quality of both divestitures, are based on what actual evidence shows, following an extensive investigation by the Commission staff.

Our colleagues Commissioners Chopra and Slaughter, who in the past have expressed<sup>2</sup> and today reiterate their general opposition to pharmaceutical mergers, have come to a different conclusion

---

<sup>1</sup> See RankingtheBrands.com, Top 50 Global Pharma Companies 2019, <https://www.rankingthebrands.com/The-Brand-Rankings.aspx?rankingID=370>.

<sup>2</sup> Dissenting Statement of Commissioner Rohit Chopra, *In the Matter of Bristol-Myers Squibb/Celgene* (Nov. 15, 2019), [https://www.ftc.gov/system/files/documents/public\\_statements/1554293/dissenting\\_statement\\_of\\_commissioner\\_ch](https://www.ftc.gov/system/files/documents/public_statements/1554293/dissenting_statement_of_commissioner_ch)

about the proposed settlement and have voted against accepting it. We respect their independent assessment of the proposed settlement. Differences of opinion facilitate healthy debate within the Commission. We value the exchange of ideas and policy perspectives, which enhances the Commission's ability to protect competition and consumers.

However, we disagree with Commissioner Chopra's characterization of the proposed settlement and of staff's investigation in this case. While we share his commitment to preserving competition in the pharmaceutical industry, we are concerned by his dissent's disregard for facts and law and its dismissal of the work of the dedicated and hardworking FTC staff. His dissent makes misleading claims about the staff's investigation, the state of competition in the pharmaceutical industry, and the Commission's enforcement record in this industry. It relies on false assertions, misapplication of law, and specious logic. It appears to have fully embraced the adage to "never let the truth get in the way of a good story" and engages in unbounded speculation, while criticizing forecasts based on rigorous investigation and grounded in evidence. Where facts conflict with theory, we follow the facts, even if they lead to an outcome we do not like.

In this statement, we attempt to set the record straight. We provide the perspective, context, logic, and facts missing from Commissioner Chopra's dissent. We also provide a response to the points raised in Commissioner Slaughter's dissent.

As occurs in every transaction, and despite the suboptimal working conditions created by the COVID-19 response, staff conducted a comprehensive and meticulous investigation of the proposed transaction and proposed divestiture buyers. As is typical, the identified competitive overlaps and required divestitures do not reflect the full scope of the Commission staff's investigation. Staff also investigated numerous other potential overlapping products and considered other possible effects that might result from the proposed combination of these companies. In addition, staff conducted extensive due diligence to evaluate the proposed divestiture buyers and the divestiture asset packages. Any assertion that the Commission did not consider every plausible theory or impact actionable under the antitrust laws is incorrect.

## **1. Divestiture of brazikumab to AstraZeneca**

The point of a structural remedy is to replace the competition threatened by the merger. In the case of brazikumab, the IL-23 inhibitor still under development, the question is whether AstraZeneca, the drug's original developer and one of the largest pharmaceutical companies in the world, suffices to replace Allergan, a company that licensed brazikumab from AstraZeneca in 2016, has not yet brought it to market, and is about half the size of AstraZeneca.

Commissioner Chopra's dissent argues that AstraZeneca lacks Allergan's incentives to bring brazikumab to market. The evidence in this matter supports the opposite conclusion. While the dissent characterizes the drug as "Allergan's" IL-23, AstraZeneca (in cooperation with Amgen,

---

[opra in the matter of bristol-myers-celgene 1910061.pdf](#) (hereinafter "Chopra Bristol-Meyers Dissent"); Dissenting Statement of Commissioner Rebecca Kelly Slaughter, *In the Matter of Bristol-Myers Squibb/Celgene* (Nov. 15, 2019), [https://www.ftc.gov/system/files/documents/public\\_statements/1554283/17\\_-\\_final\\_rks\\_bms-celgene\\_statement.pdf](https://www.ftc.gov/system/files/documents/public_statements/1554283/17_-_final_rks_bms-celgene_statement.pdf).

Inc.) developed the drug, and then licensed it to Allergan. The consent terminates that license and returns the product to AstraZeneca. The structure of the divestiture incentivizes AstraZeneca to continue to develop the drug and bring it to market. The role of a divestiture is to position the divestiture buyer, here the original drug developer, to move the drug forward in the same fashion as would have occurred absent the merger. No drug development is without risk and there is no guarantee today that Allergan will successfully commercialize this product. The Commission can, however, ensure that AstraZeneca has the appropriate incentives to push forward with development and bring the drug to market, in the same manner Allergan would have done absent the merger. We have required specific terms to accomplish this goal.

Under the terms of the settlement, the merged firm will fund up to an agreed amount: the *total* estimated cost expected to be incurred by AstraZeneca until completion of development for brazikumab in both Crohn's disease and ulcerative colitis indications, including the development of a companion diagnostic. The specified payments are contingent on AstraZeneca's continuing to develop brazikumab in each indication. That is, AstraZeneca gets paid to develop the drug, even before it profits from its sale. Furthermore, other than a pre-existing royalty payment to the inventor of brazikumab, AstraZeneca will own all rights to revenues generated by brazikumab.

Commissioner Chopra argues that the divestiture's structure weakens AstraZeneca's incentives to bring brazikumab to market because AstraZeneca will obtain the development rights without paying anything. That is a fallacy. AstraZeneca's incentive to develop brazikumab does not depend on how much AstraZeneca paid for those rights but how much money it can make going forward. What is more, consistent with divestitures the Commission has ordered in past pharmaceutical transactions, the settlement here affirmatively pays AstraZeneca to continue to develop brazikumab.

Commissioner Chopra's dissent criticizes staff for not doing a "rigorous analysis" of whether AstraZeneca "may find it worthwhile to prioritize" the development of brazikumab over other projects. This critique is without merit. A divestiture designed to restore competition does not require absolute certainty that AstraZeneca will develop brazikumab. There is always a risk that a product in development will fail, a reality that every pharmaceutical company faces daily. Instead, restoring competition requires that AstraZeneca's incentive for developing brazikumab be at least as strong as Allergan's. In fact, AstraZeneca has a *stronger* financial incentive to develop brazikumab than does Allergan because, under the proposed settlement, AstraZeneca will receive significant payments from Allergan that are contingent on AstraZeneca's continuing to develop the drug, and, other than a pre-existing royalty payment to the inventor of brazikumab, AstraZeneca will keep the profits for itself.

Commissioner Chopra's description of the arrangement as an "option" does nothing to support his point. What is more, the structure of the divestiture agreement is modeled on similar past arrangements, which have *succeeded* in bringing drugs to market. To resolve concerns following its investigation of Novartis's acquisition of GSK, the Commission required the divestiture of Braf-Mek Inhibitors to Array. Array was Novartis's development partner for the divested assets. As part of the divestiture, Novartis provided substantial financial support in the form of reimbursement to Array. At designated points for each trial, Novartis transitioned responsibility

and provided continuing financial support to Array for completing the trials. The clinical trial for Braf-Mek Inhibitors was a success and the drug is now on-market.

The dissent also argues that AstraZeneca is not an appropriate acquirer of Allergan’s brazikumab assets because, the dissent claims, AstraZeneca has demonstrated a lack of commitment to develop brazikumab. We have seen no evidence to support that assertion.<sup>3</sup> The only basis the dissent offers is the fact that AstraZeneca licensed the drug for development to Allergan in 2016. As a threshold matter, we reject the notions that any company that once licensed an interest in a developmental drug is inherently and forever a weaker competitor and that it must be excluded categorically from reentering the market through a government-compelled divestiture. Neither notion would make for sound policy. But leaving that policy issue aside, the point—again—is that the evidence about AstraZeneca’s plans for the products and the firm’s incentives to promote continued development uncovered by the investigation provide no basis for Commissioner Chopra’s claim.

AstraZeneca is one of the largest pharmaceutical companies in the world (approximately 50 percent larger than Allergan is today), with total revenues exceeding \$22 billion in 2018. It has a robust portfolio with many successful products, and identifies “Respiratory and Immunology” among its three focus areas in its public financial reporting.<sup>4</sup> While Commissioner Chopra makes much of AstraZeneca’s decision to sell off rights to various immunology drugs four to five years ago, AstraZeneca publicly told the market just last week that it had, consistent with plans announced last year, renamed the focus area to include immunology because of the significant number of immunology products in its pipeline.<sup>5</sup> That effort includes not just brazikumab, but also a number of other pipeline products.<sup>6</sup> Commissioner Chopra omits these facts. While the insinuation that AstraZeneca is not interested in immunology may suit his chosen narrative, it simply is not borne out by facts.

AstraZeneca’s history with brazikumab makes it a better candidate to be a divestiture buyer, not a worse one. AstraZeneca still employs the key team members, including the clinical lead, who were responsible for brazikumab during this earlier period of development. In sum, and contrary to our colleagues’ fears, AstraZeneca has ample resources, significant in-house expertise, and strong financial incentives to develop brazikumab.

---

<sup>3</sup> AstraZeneca’s business plans, documents and presentations do not indicate that AstraZeneca has any current or future plans to relicense or flip the divestiture assets. The basis for the dissent’s speculative concern is unclear.

<sup>4</sup> See AstraZeneca, First Quarter 2020 Results (Apr. 29, 2020) at pp. 8, 28, [https://www.astrazeneca.com/content/dam/az/PDF/2020/q1-2020/Q1\\_2020\\_results\\_presentation.pdf](https://www.astrazeneca.com/content/dam/az/PDF/2020/q1-2020/Q1_2020_results_presentation.pdf).

<sup>5</sup> See AstraZeneca Earnings Call Transcript (Apr. 29, 2020), <https://seekingalpha.com/symbol/AZN/earnings/transcripts>. AstraZeneca also announced an agreement with the University of Oxford for the global development and distribution of a potential COVID-19 vaccine. See AstraZeneca Press Release, *AstraZeneca and Oxford University announce landmark agreement for COVID-19 vaccine* (Apr. 30, 2020), <https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-and-oxford-university-announce-landmark-agreement-for-covid-19-vaccine.html>.

<sup>6</sup> AstraZeneca’s current Respiratory & Immunology pipeline lists 29 projects and includes Fasenra (on market for severe eosinophilic asthma, but being investigated for other indications), anifrolumab (in clinical development for lupus indications), and tezepulmab (in clinical development for atopic dermatitis and other indications). See AstraZeneca’s Respiratory & Immunology Pipeline, <https://www.astrazeneca.com/our-science/pipeline.html> (last visited May 5, 2020).

Commissioner Chopra's dissent raises concerns regarding the potential that the merged firm could use rebating practices to disadvantage AstraZeneca in bringing brazikumab to the market. In the context of a merger investigation, the role of a divestiture is to restore competition to the state that it would have been absent the merger, not to provide the divestiture buyer with advantages that Allergan would not have had. Commissioner Chopra's theory is that AbbVie could use bundled rebating practices involving its Humira and Skyrizi drugs to inhibit AstraZeneca, but we lack evidence, including from AstraZeneca, that these bundling practices threaten brazikumab's ability to compete in the market. Moreover, AstraZeneca is a sophisticated company and capable of its own strategic responses to defeat any such actions by AbbVie.

## 2. Nestlé as a Divestiture Buyer of Zenpep and Viokace Assets

Commissioner Chopra also takes issue with the divestiture buyer of the EPI drugs, arguing that Nestlé lacks experience in the pharmaceutical industry. Commissioner Chopra's concern appears to be based on the fact that Nestlé is a food and beverage company. According to Commissioner Chopra, "[i]t strains the bounds of credulity" that Nestlé, the "maker of KitKats and Tidy Cats ... whose core business is selling packaged consumer products like candy and cat litter" could be seen as "a formidable, committed competitor for a drug that patients with pancreatic cancer, cystic fibrosis, and other serious conditions depend on." This argument, while long on alliteration, is both wrong and misleading. A company can both sell consumer products and be a formidable competitor in the pharmaceutical industry. For example, Johnson & Johnson sells Band-Aids and baby powder and is, at the same time, a major player in pharmaceutical industry. Ironically, Nestlé seems to be exactly the type of buyer Commissioner Chopra has *encouraged* in previous dissenting statements, urging the Commission to consider divestitures to new innovators, not just established pharmaceutical companies.<sup>7</sup>

It is true that Nestlé is the world's largest food and beverage company, with tremendous financial resources and a substantial U.S. sales infrastructure. But—and contrary to Commissioner Chopra's assertions—Nestlé is no stranger to the healthcare space. Nestlé operates Nestlé Health Science ("NHSc"), an integrated multi-billion dollar health company that focuses on nutrition products, including medical nutrition products that physicians order or recommend for patients who have certain digestive health conditions. Many of these patients use Zenpep.

The claim that Nestlé lacks significant pharmaceutical experience is simply false. Nestlé has been involved in the pharmaceutical industry for over 40 years, in various iterations. From 1977 to 2010, Nestlé owned Alcon, one of the largest eye care pharmaceutical companies in the world. It bought the company in 1977 for \$280 million and, when it finally exited the company in 2010, Nestlé stated that it "realised in excess of USD 40 billion in cash" through its gradual divestment of the company.<sup>8</sup> Moreover, the dissent neglects to mention that Nestlé and L'Oreal began the Galderma joint venture in 1981, and that Nestlé's sale Galderma in 2019, for approximately \$10.1 billion, established the largest independent global dermatology company in the world, with

---

<sup>7</sup> See Chopra Bristol-Meyers Dissent, *supra* n.2 at n.4.

<sup>8</sup> Nestlé Press Release, *Nestlé to sell remaining Alcon shares to Novartis* (Jan. 4, 2010), <https://www.nestle.com/media/pressreleases/allpressreleases/alcon>.

approximately \$2.8 billion in revenue and approximately 5,000 employees.<sup>9</sup> The dissent also criticizes Nestlé for an alleged failure to bring products to market. Even assuming this criticism were accurate, this is the nature of pharmaceutical development. Not all projects succeed, and, in fact, most fail.<sup>10</sup>

Commissioner Chopra argues that, under Nestlé, Zenpep will not be able to compete against AbbVie’s EPI drug Creon and that Zenpep’s sales share will shrink. His dissent suggests that Zenpep will suffer the same fate as Pancreaze and Pertzye, two EPI drugs that “have less than 2% market share, even though they work just as well for most patients that use Creon and Zenpep.” He argues that Pancreaze and Pertzye have low shares of sales because these drugs have little “bargaining leverage” and that Zenpep under Nestlé will likewise have little “bargaining leverage.” This argument is without basis. Many factors account for differences in drugs’ sales shares of a therapeutic category, including a drug’s efficacy, patient experiences with the drug, and the order of introduction to market. His dissent claims that:

[REDACTED]

But this fails to explain why Nestlé could not follow the same strategy to maintain or even increase Zenpep’s share of EPI drug sales. Nestlé certainly has the resources to

[REDACTED]

Commissioner Chopra’s questioning of Nestlé’s ability to be a formidable competitor in pharmaceuticals also fails to acknowledge the significant pharmaceutical industry experience of Nestlé’s executives. In fact, Nestlé’s CEO, Mark Schneider, was previously the CEO of Fresenius Group, a global health care and pharmaceutical company. Nestlé’s Chief Financial Officer, François-Xavier Roger, worked at pharmaceutical companies Takeda and Sanofi-Aventis before joining Nestlé. More importantly, the dissent ignores the leadership of NHSc, the company that will actually sell the Zenpep product. NHSc executives have significant experience running U.S. and global pharmaceutical companies, and developing and marketing branded pharmaceutical products, having held leadership roles at major pharmaceutical firms like Boehringer Ingelheim, Novartis, Pfizer, Eli Lilly, and Sanofi-Aventis.

In vetting proposed buyers, the Commission staff interview the proposed acquirer’s executives, sales personnel, and corporate leadership, as well as third parties. The vetting of NHSc was no different. The investigation, including numerous interviews of doctors and health plans, found that Zenpep and Viokace are highly complementary to NHSc’s existing products, as both products treat gastrointestinal (“GI”) conditions that hinder the body’s ability to extract nutrients from food. NHSc’s current products target the same patients who require EPI treatments like Zenpep, including patients with cystic fibrosis. While NHSc’s nutrition products are not pharmaceuticals, they are prescribed by doctors, used in hospitals and clinics, and covered by health insurance. Thus, NHSc already has substantial experience marketing to and interacting

---

<sup>9</sup> Galderma Press Release, *Galderma to become the world’s largest independent global dermatology company after completion of CHF 10.2 billion carve-out of Nestlé Skin Health* (Oct. 2, 2019), <https://www.galderma.com/news/galderma-become-worlds-largest-independent-global-dermatology-company-after-completion-chf-102>.

<sup>10</sup> Stuart A. Thompson, N.Y. Times Opinion, *How Long Will a Vaccine Really Take?* (Apr. 30, 2020), <https://www.nytimes.com/interactive/2020/04/30/opinion/coronavirus-covid-vaccine.html?searchResultPosition=2> (“less than 10 percent of drug trials are ultimately approved”).

with the same group of healthcare providers and payors, and it has developed important relationships with these key decision-makers. But the experience does not end there. NHSc has an ongoing research and development partnership with Codexis, a protein engineering company that works with pharmaceutical firms. Building on NHSc's established expertise in medical nutrition, this partnership seeks to develop high-performing enzymes to help patients suffering from rare metabolic and GI-related conditions. Several therapeutic enzyme candidates from this collaboration are currently in preclinical development. In addition to NHSc's experience, its plans indicate it will commit more resources to the drugs than Allergan does today. The proposed divestiture of the Zenpep and Viokace assets will transfer Allergan's EPI sales force and other significant assets, augmenting NHSc's already strong capabilities and positioning it for success. NHSc plans, which staff scrutinized thoroughly, involve growing the sales team for these products substantially, and investing tens of millions of dollars to expand commercial, marketing, staffing, clinical studies and research and development activities related to Zenpep.

Commissioner Chopra claims that the divestiture of Zenpep to Nestlé will fail to restore competition in EPI drugs because Zenpep will "have little impact on Nestlé's overall financial results" and therefore "Nestlé's top management and board directors will not have an incentive to devote significant energy to make sure this divestiture is successful." This claim lacks any plausible basis. As a factual matter, the Zenpep assets represent significant value even for a company of Nestlé's size. In 2018, NHSc generated global sales of \$2.7 billion out of the total revenue of Nestlé S.A.'s worldwide sales of \$94 billion (*i.e.*, approximately 3% of Nestlé S.A.'s global sales). Approximately 47% of NHSc's 2018 sales were in the United States. NHSc's Strategic Advisory Committee and Management Team includes four of Nestlé's most senior executives, including the Chairman and CEO of Nestlé S.A. Moreover, purchasing assets generating sales of \$288 million in 2019<sup>11</sup> can hardly be described as a "minor" investment. In fact, the Nestlé Board had to approve the purchase here, given the significant initial investment it required. Ultimately, NHSc will be a well-financed entrant into the pharmaceutical space.

Moreover, Commissioner Chopra appears to claim that a large company cannot be successful at selling a product unless the product will "materially impact" the company's overall earnings. Commissioner Chopra offers no support for this claim. Like large pharmaceutical companies, large consumer products companies such as Nestlé and Procter & Gamble achieve success in selling hundreds of products in many countries around the world, even if individual products represent small shares of the company's overall sales.

For all of these reasons, we are confident that Nestlé is an appropriate divestiture buyer of the Zenpep and Viokace assets.

### **3. The Commission's Divestiture Process**

Commissioner Chopra's dissent criticizes the Commission's remedy process, arguing that the staff followed a flawed process for identifying Nestlé as a divestiture buyer for the Zenpep and Viokace assets by letting the parties pick the divestiture buyer. The Commission does ask parties requiring divestitures to do the work of supplying options, though the parties do not get their

---

<sup>11</sup> Allergan plc, 2019 Form 10-K at 57, [https://www.sec.gov/Archives/edgar/data/1578845/000156459019003111/agn-10k\\_20181231.htm](https://www.sec.gov/Archives/edgar/data/1578845/000156459019003111/agn-10k_20181231.htm).

pick. Our 2017 Merger Remedies Study confirmed that this practice, together with others related to designing, drafting and implementing the agency’s merger remedies, generally yields effective outcomes. Indeed, with respect to the 50 orders examined using the case study methodology, which included Hertz, more than 80 percent of the Commission’s orders across a wide variety of industries maintained or restored competition.

The dissent takes particular issue with the Commission’s approach to remedies in pharmaceutical mergers. In citing to unsuccessful divestitures, the dissent noticeably fails to mention any pharmaceutical divestitures. That omission is material, because the findings from the pharmaceutical portion of the 2017 Merger Remedies Study support the consent in this case. The study found that when remedies entailed the divestiture of on-market pharmaceuticals produced by a contract manufacturer and did not require transferring manufacturing capability, the buyers continued to sell the divested product in every instance. This result confirms the Commission’s long-standing practice of requiring divestiture of the overlap product that can be transferred to its purchaser most seamlessly and with fewest hurdles. Products made at a third-party manufacturing site, rather than those requiring a technology transfer, fall into this category. That is precisely the situation here. Currently, Allergan’s products are made at a third-party manufacturing facility and those arrangements will transfer to Nestlé. Similarly, the 2017 Remedy Study also found that for all in-development products, assets were successfully transferred to the buyers. Here, AstraZeneca is uniquely familiar with the brazikumab assets as it previously developed the technology itself and, therefore, is well positioned to reintegrate the assets into its operations.

The 2017 Study also showed that respondents were now more likely to propose buyers that fully satisfy the Commission’s criteria for strong, viable competitors, compared to findings from the 1999 Divestiture Study that revealed respondents sometimes proposed buyers that were marginally acceptable. The Commission made several changes in response to the 1999 findings. For example, the Commission began requiring an upfront buyer for divestitures of less than an ongoing business, thereby aligning the incentive to propose a Commission-approvable buyer with the respondents’ interest in receiving Commission clearance for their deal.

In addition, staff began a more in-depth review of proposed buyers, including requiring prospective buyers to submit detailed written business and financial plans for divested assets. While the 2017 Study indicated that these measures were working, the Commission has continued to refine its process, including by closely examining the buyer’s sources of financing, contingency planning, and ability to conduct adequate due diligence, among other factors.<sup>12</sup>

Staff applied its established practices to evaluate potential merger remedies in this case. Staff analyzed business plans, supply chain management and transition plans, the strategic fit of the assets with the buyers’ existing business, financial projections, deal financing and incentives, experience and management expertise. The 2017 Study found that buyers that “had a complementary product line into which the divested assets could easily fit” tended to succeed. Here, the evidence we studied, including extensive consultation with experts, buyers, and prescribers, indicated that NHSc’s line of medical nutrition products is a natural fit for Zenpep

---

<sup>12</sup> FTC Competition Blog, *Looking back (again) at FTC merger remedies* (Feb. 3, 2017), <https://www.ftc.gov/news-events/blogs/competition-matters/2017/02/looking-back-again-ftc-merger-remedies>.



and Viokace as these divestiture products target the same patients and providers as its existing product line, and that brazikumab will fit nicely back into AstraZeneca’s “Respiratory and Immunology” focus area.

#### 4. Scope of the Investigation

Commissioner Chopra’s claim that the Commission has a “myopic” focus on product overlaps misrepresents the scope of the investigation that staff conducted in this matter, and in other merger investigations. Commissioner Slaughter’s dissent does acknowledge the scope of the investigation, but nevertheless raises concerns that it failed to investigate enough. She does not specify what additional evidence she would have sought, or how it would have informed her theory of harm.

The Commission brings cases based on evidence, not beliefs. As the Commission has stated publicly, both the Commission and its staff look well beyond product overlaps in every pharmaceutical merger review; this case was no different. The Commission staff proactively sought information from the merging parties and third parties to facilitate exploration of a wide range of theories of competitive harm, including every one mentioned in the dissents. But the evidence did not support a reason to believe that the merger would lead to competitive harms beyond the overlaps that are being remedied via divestitures. It is simply untrue to claim that theories of harm other than straightforward overlaps were ignored, and untoward to suggest they were not investigated with adequate rigor. That the dissenters may not like the result is no reason to object, much less mischaracterize the comprehensive and meticulous merger review process.

Consistent with the Horizontal Merger Guidelines, staff investigated whether the “merger will diminish innovation competition by combining two of a very small number of firms with the strongest capabilities to successfully innovate in a specific direction.”<sup>13</sup> Other than the harm the

---

<sup>13</sup> Horizontal Merger Guidelines § 6.4. In Commissioner Slaughter’s dissent, she raises concerns about whether the Commission analyzes and addresses innovation competition issues in pharmaceutical merger investigations. The dissent ignores the Commission’s long record of addressing innovation competition concerns in pharmaceutical transactions. In recent years, for example, the Commission has taken enforcement actions to address harm to innovation competition in the Mallinckrodt, GSK/Novartis, and BMS/Celgene matters, as well as in several generic pharmaceutical mergers. See FTC Press Release, *FTC Requires Bristol-Myers Squibb Company and Celgene Corporation to Divest Psoriasis Drug Otezla as Condition of Acquisition* (Nov. 15, 2019), <https://www.ftc.gov/news-events/press-releases/2019/11/ftc-requires-bristol-myers-squibb-company-celgene-corporation> (alleging the acquisition would substantially lessen competition by eliminating future competition between BMS and Celgene in developing, manufacturing and selling oral products to treat moderate-to-severe psoriasis); FTC Press Release, *FTC, Mallinckrodt Will Pay \$100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants* (Jan. 18, 2017), <https://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it> (blocking acquisition because Questcor “acquired the rights to its greatest competitive threat, a synthetic version of Acthar, to forestall future competition”); FTC Press Release, *FTC Puts Conditions on Generic Drug Maker Lupin Ltd.’s Proposed Acquisition of Gavis Pharmaceuticals LLC* (Feb. 19, 2016), <https://www.ftc.gov/news-events/press-releases/2016/02/ftc-puts-conditions-generic-drug-marketer-lupin-ltds-proposed> (requiring divestitures to ensure continued development of generic mesalimine ER capsules, which Lupin and Gavis were developing independently at the time of the merger); FTC Press Release, *FTC Puts Conditions on Novartis AG’s Proposed Acquisition of GlaxoSmithKline’s Oncology Drugs* (Feb. 23, 2015), <https://www.ftc.gov/news-events/press-releases/2015/02/ftc-puts-conditions-novartis-ags-proposed-acquisition> (requiring divestitures of in-development BRAF and MEK inhibitor drugs to ensure development of the BRAF and MEK inhibitors continues uninterrupted, and competition in

merger would create related to the parties' ongoing development of IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis and Crohn's disease, the investigation yielded no evidence that other ongoing product development efforts would likely be altered because of a desire to diminish competition in any relevant market. Staff also evaluated in which therapeutic areas, as well as narrower disease areas and specific conditions, the parties were currently investing in research and development. A wide array of evidence gathered and reviewed by staff, including party forecasts and market analyses created in the ordinary course of business, interviews with third parties, and review of publicly available information, indicated that there is no therapeutic area, disease, or condition where the parties are two of a limited number of competitors. To the contrary, evidence indicates the parties face considerable competition in each area. The staff also investigated whether the merger eliminated competitive restraints on either AbbVie or Allergan that would allow for rebating practices that otherwise had failed due to the independence of the two companies, and did not find evidence to support such a theory.

As to other non-merger specific conduct that some have argued should be remedied through the merger review and order process, Section 7 does not afford the agency the authority to extract remedies unrelated to a proposed merger.

\* \* \* \* \*

We are committed to preserving competition in pharmaceutical and medical treatment markets. Sometimes, that means blocking a merger outright. Earlier this year, for example, staff recommended that the Commission block Johnson & Johnson's proposed acquisition of Takeda's surgical patch, TachoSil, and the parties subsequently abandoned the transaction.<sup>14</sup> But we are also committed to predicating enforcement decisions on evidence – not just some of the

---

BRAF and MEK inhibitor markets is not reduced). For an overview of the many other pharmaceutical mergers the Commission has challenged to protect innovation competition, see FTC Health Care Division Staff, *Overview of FTC Actions in Pharmaceutical Products and Distribution* (Sept. 2019),

[https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20190930\\_overview\\_pharma\\_final.pdf](https://www.ftc.gov/system/files/attachments/competition-policy-guidance/20190930_overview_pharma_final.pdf).

<sup>14</sup> The dissent asserts that the Commission has not challenged a proposed pharmaceutical merger or acquisition, but it ignores past Commission enforcement actions challenging entire transactions and FTC attempts to challenge acquisitions in court. For example, in 2017, the Commission challenged the consummated acquisition of Synacthen by Questcor Pharmaceuticals, Inc. and required its parent company, Mallinckrodt plc, to pay \$100 million to settle charges that the acquisition violated the antitrust laws. *FTC et al. v. Mallinckrodt Ard Inc. et al.*, No. 1:17-cv-120 (D.D.C. Jan. 30, 2017), <https://www.ftc.gov/enforcement/cases-proceedings/1310172/mallinckrodt-ard-inc-questcor-pharmaceuticals>. In 2008, the Commission filed a complaint in federal district court challenging Ovation Pharmaceuticals, Inc.'s acquisition of the drug NeoProfen. FTC Press Release, *FTC Sues Ovation Pharmaceuticals for Illegally Acquiring Drug Used to Treat Premature Babies with Life-Threatening Heart Condition* (Dec. 6, 2008), <https://www.ftc.gov/news-events/press-releases/2008/12/ftc-sues-ovation-pharmaceuticals-illegally-acquiring-drug-used>. The recommendation to challenge Johnson & Johnson's Tachosil acquisition is only the most recent evidence of this effort. FTC Press Release, *Federal Trade Commission Closes Investigation of Johnson & Johnson's Proposed Acquisition of TachoSil from Takeda Pharmaceutical Company* (Apr. 10, 2020), <https://www.ftc.gov/news-events/press-releases/2020/04/federal-trade-commission-closes-investigation-johnson-johnsons>. As noted above, the Commission also has required extensive product divestitures in dozens of pharmaceutical company mergers. Moreover, the Commission has conducted a twenty-five year campaign to stop anticompetitive conduct in the pharmaceutical industry, resulting in a seminal Supreme Court case, and settlements that well exceed \$1 billion. For a more extensive discussion of the FTC's vast array of efforts to maintain competition in the pharmaceutical industry, see Statement of Commissioner Christine S. Wilson, *In the Matter of Bristol-Myers Squibb/Celgene* (Nov. 15, 2019),

[https://www.ftc.gov/system/files/documents/public\\_statements/1554278/bms-celgene\\_-\\_wilson\\_statement.pdf](https://www.ftc.gov/system/files/documents/public_statements/1554278/bms-celgene_-_wilson_statement.pdf).

evidence, but all of the evidence. Our merger challenges must stay within the scope of the law and the facts of the case in front of us. Here, the law and the facts overwhelmingly support the proposed divestiture, not the dissenters' critiques.

In his conclusion, Commissioner Chopra proposes a long list of actions the Commission should undertake to overhaul its process for reviewing mergers and divestiture proposals. Most of those steps appear unrelated to any issue involving the transaction and divestiture currently before us. Nonetheless, as Chairman Simons has indicated on numerous occasions, the Commission has been and remains willing to engage in self-critical examination.<sup>15</sup> In fact, the Commission's predisposal to rigorous and routine self-assessment is demonstrated by the many merger retrospectives it has conducted, to determine retroactively its accuracy in calling balls and strikes; its willingness to assess with frankness and candor the efficacy of its merger remedies, as chronicled by the 2017 Mergers Remedy Study; and its no-holds-barred review of dozens of policy positions and enforcement approaches during the agency's Hearings on Competition and Consumer Protection in the 21st Century, which featured no shortage of voices critical of the FTC. While the Commission continues to strive for improvement, its empirically-based reviews do not reveal the kind of systemic failure to merger reviews and divestitures that would justify Commissioner Chopra's proposals. That said, we will continue to support the self-critical examination that typifies the agency's approach to all enforcement and policy issues.

---

<sup>15</sup> See, e.g., Joseph J. Simons, Keynote Address at American University Washington College of Law Conference on Themes of Professor Jonathan Baker's New Book, *The Antitrust Paradigm: Restoring a Competitive Economy* (Mar. 8, 2019), <https://www.ftc.gov/public-statements/2019/03/prepared-keynote-address-chairman-joseph-j-simons-american-university>.