



April 5, 2004

BY HAND

Federal Trade Commission
Office of the Secretary
Room 159-H (Annex A)
600 Pennsylvania Ave., N.W.
Washington, DC 20580

Re: Contact Lens Rule, Project No. R4110022

To Whom It May Concern:

1-800 CONTACTS, Inc. ("1-800") respectfully submits the comments attached hereto in response to the Federal Trade Commission's ("FTC's") request for comments on its proposed Contact Lens Rule; Ophthalmic Practice Rules, 69 Fed. Reg. 5440 (Feb. 4, 2004) (the "Contact Lens Rule"). 1-800 is the largest seller of contact lenses to consumers through its Internet website and toll-free telephone number.

Congress enacted the Fairness to Contact Lens Consumers Act (the "Fairness Act") to break down the barriers established by eye care practitioners ("ECPs") and mandate consumer choice and competition through meaningful prescription portability. These barriers are largely driven by the fundamental conflict of interest posed by the fact that ECPs – unlike most healthcare practitioners – sell what they prescribe. By promoting consumer choice and competition, the Fairness Act will also promote ocular health because, with less expensive lenses and greater accessibility, consumers are likely to change their lenses more frequently.

However, the question remains whether consumers will reap the benefits of an open market – lower prices, improved service, increased convenience, and improved ocular health. That question will be determined by how the FTC resolves a number of important issues raised by the proposed rule. To that end, the most critical issues addressed in 1-800's comments include:

- Expanding the Definition of "Business Hour" - The FTC's proposed definition of "business hour" in no way reflects actual business hours in the eye care industry, and thus constructively forces alternative sellers to be closed when competing ECPs are open. *1-800 recommends that the FTC: (1) expand the definition of "business hour" to 9 a.m. to 6:30 p.m., Monday through Friday, and to 9 a.m. to 4 p.m. on Saturday, in accordance with the results of the Synovate Survey of ECP Business Hours provided herein, and (2) provide an alternative "business hour" definition that permits sellers to verify the actual business hours of an ECP's office, on an ECP-by-ECP basis.*

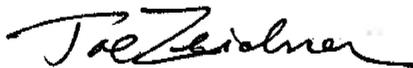
- Shortening the Length of the Prescription Verification Period - The FTC's proposed prescription verification period of 8 hours is too long because it imposes a waiting period on consumers who order from alternative sellers rather than ECPs, and it allows ECPs to continue to use the verification period to call consumers and interfere with the sales of alternative sellers. This situation is made worse by the proposed rule's interpretation of the period as 8-Hours-Plus-One-Day. *1-800 recommends that the prescription verification period, generally, should be 5 hours from the time that the seller makes the prescription verification request, and that it should be 2 hours if a live agent of the seller is able to communicate with a live agent of the prescriber via telephone.*
- Remedying the Anticompetitive Use of Private Label and Doctor Exclusive Contact Lenses - ECPs and manufacturers are already trying to defeat the private label substitution provision in the Fairness Act by making it extremely difficult for alternative sellers to get private label lenses or their equivalents, and by prescribing "doctor exclusive contact lenses," which are lenses distributed only to ECPs for which there is no available substitute. The FTC's proposed regulations provide for substitution for "private label contact lenses," but they do not ensure that alternative sellers can obtain private label substitutes, and they do not address "doctor exclusive contact lenses." *The FTC should require ECPs that prescribe private label lenses to include the name of another lens – one that is sold directly to alternative sellers – in the prescription. The FTC should also require ECPs that prescribe "doctor exclusive contact lenses" to issue a second prescription for a lens that is sold directly to alternative sellers.*
- Broadly Defining the Terms "Direct Communication" and "Completed Communication" - ECPs are already making a concerted nationwide effort to defeat their obligation under the Fairness Act to verify prescriptions by arguing for a narrow definition of "direct communication." Currently, ECPs are avoiding their obligation to verify by unplugging their facsimile (or "fax") machines, and they have a long history of hanging up on alternative sellers attempting to contact their offices. *To prevent ECPs from avoiding their statutory obligation to verify prescriptions, 1-800 recommends that the FTC: (1) broadly define the term "direct communication" to include existing communication technologies, such as telephone, facsimile, and electronic mail (or "e-mail") and future technologies, and (2) broadly define the term "completed communication" to include (a) affirmative evidence that a communication has been completed, (b) evidence that a communication by facsimile, electronic mail, or a substantially equivalent communication technology has been attempted twice, or (c) evidence that live telephone verification has been attempted.*
- Preemption – Several states have existing or pending legislation or regulations that arguably require anyone selling contact lenses to be a licensed ECP. As the FTC recently found in its report on *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, policymakers can advance both consumer health and consumer choice by rescinding or

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refraining from adopting such professional licensure requirements for alternative sellers. Although the Fairness Act preempts by implication any existing state requirements allowing only ECPs to sell contact lenses, that preemption should be made express to ensure that ECPs and their state boards do not undermine the very purpose of the Fairness Act to promote consumer choice and competition from alternative sellers through imposition of such requirements. Thus, 1-800 proposes that the FTC add a definition for "seller" to Section 315.2 of the proposed regulations that provides: "*A seller is any person or entity that sells or otherwise distributes contact lenses, and includes, but is not limited to, licensed professionals. Although a state or political division thereof may require a seller to register to sell contact lenses if such registration does not burden commerce in contact lenses, the Fairness to Contact Lens Consumers Act preempts any requirement that a seller must possess a professional license in order to perform the purely retail function of selling contact lenses.*"

Although 1-800 suggests a number of important revisions to the FTC's proposed rule, we greatly appreciate the FTC's efforts to date and its consideration of these comments. We urge the FTC to issue and vigorously enforce final regulations that prohibit the well-documented ECP misdeeds of the past, anticipate and prohibit similar behaviors that are likely to emerge in the future, and take care not to enshrine ECP conflicts and undue advantages. This would set an important example for other industries where entrenched interests have tried to defeat new modes of competition that benefit consumers.

Respectfully submitted,



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Federal Trade Commission

April 5, 2004

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BEFORE THE FEDERAL TRADE COMMISSION

Proposed Contact Lens Rule;
Ophthalmic Practice Rules
(69 Fed. Reg. 5440
(Feb. 4, 2004))

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) **Contact Lens Rule, Project No. R411002**
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Comments of



In addition to the cover letter and comment, there are 181 attachments available for public inspection in the Commission's public reading room, located at 600 Pennsylvania Avenue, NW, Room 130, Washington, DC

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**Comments on the Proposed Contact Lens Rule; Ophthalmic Practice Rules,
Contact Lens Rule, Project No. R411002 (69 Fed. Reg. 5440 (Feb. 4, 2004))**

1-800 CONTACTS, Inc. (“1-800”) respectfully submits these comments in response to the Federal Trade Commission’s (“FTC’s”) request for comments on its proposed Contact Lens Rule; Ophthalmic Practice Rules,¹ (the “Contact Lens Rule”). 1-800 is the largest seller of contact lenses to consumers through its Internet website and toll-free telephone number. Having filled over 10 million orders for approximately 3.5 million customers since its inception in 1995, 1-800 has a great deal of experience in the practical obstacles that exist in ensuring consumer choice in the market for contact lenses. 1-800 has a significant interest in ensuring that the final regulations promulgated under the Fairness to Contact Lens Consumers Act (the “Fairness Act”)² reflect the actual dynamics in the contact lens market and fulfill Congress’ goals in framing this legislation.

I. Executive Summary

The Fairness Act, by mandating meaningful contact lens prescription portability, is intended to increase consumer choice and competition from alternative sellers and make contact lenses cheaper and more convenient to obtain.³ However, the question remains whether consumers will reap the benefits of an open marketplace – lower prices, improved service, and increased convenience. That question will be determined by how the FTC resolves a number of critical issues raised by the proposed rule.

¹ 69 Fed. Reg. 5440 (Feb. 4, 2004).

² Fairness to Contact Lens Consumers Act, P.L. 108-164, 117 Stat. 2024-28 (2003).

³ See, e.g., Speech of the Hon. F. James Sensenbrenner, Jr. (R-WI) in the House of Representatives in Support of the Fairness Act (“Sensenbrenner Speech”), 149 Cong. Rec. E2434 (Nov. 19, 2003) ([Att. 1](#)); Statements by the Hon. Jan Schakowsky (D-IL), House of Representatives, 149 Cong. Rec. H11561-H11565 (Nov. 19, 2003) (“Schakowsky Speech”) ([Att. 2](#)); see also Plaintiff States’ Consolidated Statement of Facts, *In re: Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla.) (“SOF”), at 41 (citing a McKinsey report conducted for Johnson & Johnson Vision Care (Vistakon) (“Johnson & Johnson Vision Care”) in 1985, which concluded that consumers prefer obtaining their contact lenses through alternative sellers because of the low cost and the convenience) ([Att. 3](#)); Consumer Fact Pack, Prepared by McKinsey & Co. for Johnson & Johnson Vision Care (“McKinsey Study”) ([Att. 4](#)); Testimony of Robert L. Hubbard, Director of Litigation, Antitrust Bureau, New York State Department of Law, on H.R. 2221, before the Subcommittee on Commerce, Trade, and Consumer Protection, Energy and Commerce Committee, United States House of Representatives, Sept. 9, 2003 (“Hubbard Testimony, Sept. 9, 2003”), at 7 (“Obtaining contact lenses from [alternative sellers] may also spare consumers the cost of an extra unnecessary office visit to an [ECP]”) ([Att. 5](#)); Comments of the Attorneys General of Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Illinois, Iowa, Maryland, Michigan, Minnesota, New York, Ohio, Pennsylvania, West Virginia, and Wisconsin Concerning the Ophthalmic Practice Rules (“FTC Comments of the AGs”), dated Sept. 2, 1997, at 6 (“[T]he expanded distribution of contact lenses through traditionally lower cost suppliers, like pharmacies, buying clubs, mail order and mass merchandising, results in distribution cost savings, which normally will be passed on to consumers”) ([Att. 6](#)); Testimony of Ami V. Gadhia, Assistant Legislative Counsel, Consumers Union, Before the Subcommittee on Commerce, Trade, and Consumer Protection, House Committee on Energy and Commerce, Sept. 9, 2003, at 1-2 (noting that with the enactment of the Texas law for prescription release, consumers have more choice and contact lens prices have dropped) ([Att. 7](#)); Testimony of Maria Martinez (Consumer), before the Subcommittee on Commerce, Trade, and Consumer Protection, House Committee on Energy and Commerce, dated Sept. 9, 2003 (“Martinez Testimony”) ([Att. 8](#)).

If competition is permitted to flourish under the Fairness Act, consumers could reap significant savings. Consumers spend an estimated \$3.5 billion each year on replacement contact lenses, and consumers who purchase lenses from alternative sellers (e.g., pharmacies, mail-order, Internet, and discount sellers) save approximately 20%.⁴

Moreover, as Congress recognized, the Fairness Act, if implemented as Congress intended, would also promote ocular health because, with less expensive lenses and greater accessibility, consumers are likely to change their lenses more frequently.⁵ Indeed, in passing the Fairness Act, Congress recognized that consumer choice, cost savings, and consumer health were on the *same* end of the spectrum. The FTC also recognized this in its recent report entitled, “Possible Anticompetitive Barriers to E-Commerce: Contact Lenses,” stating that:

Adherence by eye care practitioners to the [Fairness Act’s] contact lens prescription release requirements and by contact lens sellers to the [Fairness Act’s] prescription verification requirements should *enhance consumer choice and protect consumer health*.⁶

The Fairness Act aims to promote consumer choice and competition from alternative sellers by eliminating barriers to competition established by eye care practitioners (“ECPs”) over the last 30 to 40 years. Most of these barriers have been driven by the fundamental conflict of interest posed by the fact that optometrists – unlike most health care practitioners – sell what they prescribe. Such barriers proscribed by the Fairness Act include local rules or regulations that purport to impose outright prohibitions on sales by alternative sellers (e.g., ECP license requirements) or which allow such sales only if the ECP – the alternative seller’s direct competitor – chooses to respond affirmatively to the alternative seller’s request to verify consumer prescriptions (i.e., affirmative verification). Similarly, ECPs have employed a wide variety of tactics designed to impede competition, including: (1) refusing to release or verify prescriptions, (2) falsely claiming that federal or state law prohibits prescription release, (3) writing prescriptions for lens brands that are not sold by the manufacturers to alternative sellers (i.e., “private label contact lenses” or “doctor exclusive contact lenses”), (4) requiring consumers to pay additional fees or sign waiver or release forms to obtain their prescriptions, and (5) forcing consumers to endure unnecessary delays or inconvenience in order to purchase their lenses elsewhere.

The long and complex history of ECP anticompetitive activities is extensively described in these comments because it is absolutely critical to – and must be addressed by the FTC in – this rulemaking. Congress clearly intended for the FTC to put a stop to these activities, and the ECPs

⁴ See, e.g., Comments of the Staff of the FTC, Intervenor before the Connecticut Board of Examiners for Opticians, Mar. 27, 2002, at 10 (finding a 19% cost savings based on a 1998 study) (Att. 9); *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, a Report from the Staff of the FTC (Mar. 2004), at 13 (finding a 19% difference); *Congress approves legislation to give wearers of contact lenses the right to their prescriptions*, Washington-AP, Nov. 20, 2003 (estimating a 20% savings) (Att. 10).

⁵ See FTC Comments of the AGs, at 7 (Att. 6); see also Letter to FDA Docket No. 2003P-0291, from 1-800, dated Jan. 13, 2004 (with attachments) (Att. 11); Hubbard Testimony, Sept. 9, 2003, at 5 (stating that prescription release lowers consumers costs and encourages the “healthier use of lenses by consumers”) (Att. 5).

⁶ *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, a Report from the Staff of the FTC (Mar. 2004), at 4 (emphasis added).

have proven to be enormously adept in arriving at new methods to thwart meaningful consumer choice and competition from alternative sellers.

Although we suggest many important revisions to the FTC's propose rule, 1-800 greatly appreciates the FTC's efforts to issue final regulations under the Fairness Act that will ensure Congress' intent is achieved. Since it enacted the Ophthalmic Practice Rules for eyeglass prescriptions ("Eyeglass Prescription Release Rule") in 1978,⁷ the FTC has had considerable experience policing the anticompetitive behaviors of ECPs. Accordingly, the FTC is well aware of the importance of educating ECPs and consumers about the requirements of prescription release laws and the need for enforcement, particularly in the face of willful ECP non-compliance.

The FTC itself recently reported that surveys taken in 1997 showed that – after almost 20 years of the Eyeglass Prescription Release Rule being in effect – 65.8% of consumers were not aware that they had a right to their eyeglass prescriptions; 29.3% of consumers did not automatically receive their prescriptions; and 10.1% of consumers did not receive their prescriptions even when they asked.⁸ The FTC also reported that anecdotal evidence in the Eyeglass Prescription Release Rule record indicates that the overwhelming majority of ECPs who dispense eyewear do not automatically release eyeglass prescriptions.⁹

Drawing on its expertise with the eye care industry, the FTC has in recent years advised that the way in which contact lens legislation is interpreted and enforced may "have competitive consequences," and that an agency "can maximize consumer welfare by following the most pro-competitive approach consistent with the protection of consumers' health."¹⁰ The FTC further advised that "it is desirable to accomplish regulatory objectives in a way that is least restrictive of innovative distribution methods [*i.e.*, alternative sellers]."¹¹

1-800 strongly agrees with these positions and urges the FTC to ensure that the final regulations eliminate anticompetitive behaviors in the contact lens industry once and for all, by promoting meaningful prescription portability and defeating the powerful conflict of interest presented by ECPs selling what they prescribe. To eliminate these anticompetitive behaviors, the FTC should not only prohibit the well-documented misdeeds of the past and take care not to enshrine ECP conflicts and undue advantages – the rules must also anticipate and prohibit similar behaviors likely to emerge in the future. Indeed, as will be detailed herein, the ECPs' anticompetitive behaviors are fluid, and they have already begun to evolve in an effort to circumvent and defeat the Fairness Act.

⁷ 16 C.F.R. pt. 456 (2003).

⁸ 69 Fed. Reg. 5451, 5452 (Feb. 4, 2004).

⁹ *See id.*

¹⁰ *See* Comments of the Staff of the FTC, Intervenor before the Connecticut Board of Examiners for Opticians, Mar. 27, 2002, at 2 (Att. 9).

¹¹ *See id.* *See also* Testimony of R. Ted Cruz, Director, Office of Policy Planning, FTC, before the Connecticut Board of Examiners for Opticians, June 12, 2002 ("Cruz Testimony"), at 208-209 (Att. 12).

To that end, the most critical issues addressed in these comments include:

- Expanding the Definition of “Business Hour” - The FTC’s proposed definition of “business hour” in no way reflects actual business hours in the eye care industry, and thus constructively forces alternative sellers to be closed when competing ECPs are open. *1-800 recommends that the FTC: (1) expand the definition of “business hour” to 9 a.m. to 6:30 p.m., Monday through Friday, and to 9 a.m. to 4 p.m. on Saturday, in accordance with the results of the Synovate Survey of ECP Business Hours provided herein, and (2) provide an alternative “business hour” definition that permits sellers to verify the actual business hours of an ECP’s office, on an ECP-by-ECP basis.*
- Shortening the Length of the Prescription Verification Period - The FTC’s proposed prescription verification period of 8 hours is too long because it imposes a waiting period on consumers who order from alternative sellers rather than ECPs, and it allows ECPs to continue to use the verification period to call consumers and interfere with the sales of alternative sellers. This situation is made worse by the proposed rule’s interpretation of the period as 8-Hours-Plus-One-Day. *1-800 recommends that the prescription verification period, generally, should be 5 hours from the time that the seller makes the prescription verification request, and that it should be 2 hours if a live agent of the seller is able to communicate with a live agent of the prescriber via telephone.*
- Remedying the Anticompetitive Use of Private Label and Doctor Exclusive Contact Lenses - ECPs and manufacturers have already begun to defeat the private label substitution provision in the Fairness Act by making it extremely difficult for alternative sellers to get private label lenses or their equivalents, and by prescribing “doctor exclusive contact lenses,” which are lenses distributed only to ECPs for which there is no available substitute. The FTC’s proposed regulations provide for substitution for “private label contact lenses,” but they do not ensure that alternative sellers can obtain private label substitutes, and they do not address “doctor exclusive contact lenses.” *The FTC should require ECPs that prescribe private label lenses to include the name of another lens – one that is sold directly to alternative sellers – in the prescription. The FTC should also require ECPs that prescribe “doctor exclusive contact lenses” to issue a second prescription for a lens that is sold directly to alternative sellers.*
- Broadly Defining the Terms “Direct Communication” and “Completed Communication” - ECPs are already making a concerted nationwide effort to defeat their obligation under the Fairness Act to verify prescriptions by arguing for a narrow definition of “direct communication.” Currently, ECPs are avoiding their obligation to verify by unplugging their facsimile (or “fax”) machines, and they have a long history of hanging up on alternative sellers attempting to contact their offices. Unbelievably, ECPs now would like to limit “direct communication” to live telephone calls, despite the clear provisions in the Fairness Act. *To prevent ECPs from avoiding their statutory obligation to verify prescriptions, 1-800 recommends that the FTC: (1) broadly define the term “direct communication” to include existing communication technologies, such as telephone, facsimile, and electronic mail (or “e-mail”) and future technologies, and (2) broadly define the term “completed communication” to include (a) affirmative evidence that a communication has been completed, (b) evidence that a communication by facsimile, electronic mail, or a substantially equivalent communication technology has been attempted twice, or (c) evidence that live telephone verification has been attempted.*

- **Preemption** – Several states have existing or pending legislation or regulations that arguably require anyone selling contact lenses to be a licensed ECP. As the FTC recently announced, policymakers can advance both consumer health and consumer choice by rescinding or refraining from adopting such professional licensure requirements for alternative sellers.¹² Although the Fairness Act preempts by implication any existing state requirements allowing only ECPs to sell contact lenses, that preemption should be made express to ensure that ECPs and their state boards do not undermine the very purpose of the Fairness Act to promote consumer choice and competition from alternative sellers through imposition of such requirements. 1-800 proposes that the FTC add a definition for “seller” to Section 315.2 of the proposed regulations that provides: *“A seller is any person or entity that sells or otherwise distributes contact lenses, and includes, but is not limited to, licensed professionals. Although a state or political division thereof may require a seller to register to sell contact lenses if such registration does not burden commerce in contact lenses, the Fairness to Contact Lens Consumers Act preempts any requirement that a seller must possess a professional license in order to perform the purely retail function of selling contact lenses.”*

Although ECPs may argue that the Fairness Act imposes a burden on them, the fact is that the Fairness Act would barely alter ECPs’ practices. The Fairness Act regulations, including 1-800’s proposed changes, would simply require that ECPs engage in responsible and fair prescribing practices, such as prescription release and associated documentation. The burden of the Fairness Act actually falls much more heavily on alternative sellers, even though the passage of the Fairness Act was a victory for alternative sellers in that it enables prescription portability. Under the Fairness Act, alternative sellers must notify their competitors of every sale and keep extensive records. Since the Fairness Act became effective, 1-800 is still canceling one in five orders.

Overall, it is critical that the final regulations not hinder the Fairness Act’s principle purpose of giving consumers both a meaningful choice of where to purchase their contact lenses and an opportunity to realize the benefits of competition from alternative sellers. Therefore, we ask that the FTC take vigorous action to enforce the Fairness Act, and most importantly consumers’ unfettered right to obtain their prescription, which is the critical factor for ensuring the success of this new law.

II. **General Background**

Eyeglass wearers have had the right to copies of their eyeglass prescriptions since the FTC promulgated the Eyeglass Prescription Release Rule in 1978. The 36 million Americans who wear contact lenses¹³ did not have a similar right until the passage of the Fairness Act.¹⁴ As explained by

¹² See *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, a Report from the Staff of the FTC (Mar. 2004), at 31.

¹³ See Testimony of J. Howard Beales, III, Director, Bureau of Consumer Protection, FTC, before the Subcommittee on Commerce, Trade, and Consumer Protection, House Committee on Energy and Commerce, Sept. 9, 2003 (“Beales Testimony”) (reporting that 36 million Americans (13% of the population) wear contacts) ([Att. 13](#)).

¹⁴ See Statements by the Hon. Pete Stark (D-CA), House of Representatives, 149 Cong. Rec. H11561-H11565 (Nov. 19, 2003) (“Stark Statement”) (stating that “consumers deserve to have [the law] in all parts of our country,” and that with the enactment of the Fairness Act, “the other 30 million people who do not reside in California will be pleased . . . and it will be of great convenience to them”) ([Att. 14](#)).

House Judiciary Committee Chairman, Representative James Sensenbrenner (R-WI), who co-sponsored the Fairness Act:

Contact lenses were understandably not included in [the Eyeglass Prescription Release Rule] because contacts were hard lenses, which were custom-made to fit each patient. Today, most contact lenses are mass produced, soft lenses that do not require manipulation by eye doctors. As a result of this improvement, today's contact lens wearers should have the same right as eyeglass wearers to obtain their prescription, at no additional charge.¹⁵

Prescription release fosters lower prices and convenience. During the debate, in the House of Representatives, Representative Pete Stark (D-CA), who also co-sponsored the Fairness Act, described his wife's frustration with an ECP in the District of Columbia who refused to release her prescription. The ECP's refusal inconvenienced the Congressman's wife and prevented her from getting her prescription filled in her home state of California.¹⁶

Notably, the prescription refusal was largely due to the fact that optometrists can sell what they prescribe. As Representative Stark told the House of Representatives:

The fact is that [ECPs] have a strong financial incentive to restrict consumer access to the contact lens market. Without their contact lens prescription in hand, consumers are forced to purchase their lenses from their prescribing [ECP] – who obviously profits from each and every sale.¹⁷

Unfortunately, Representative Stark's wife's experience is not uncommon. Testifying before Congress in support of a uniform federal prescription release law, Robert L. Hubbard, the Director of Antitrust Litigation for the State of New York, stated that “[a]lthough twenty-six states require release of contact lens prescriptions, the specific requirements vary and anti-consumer, anticompetitive practices persist concerning contact lenses.”¹⁸ Representative Jan Schakowsky (D-IL) echoed the need for a uniform law, stating that the “[the Fairness Act] establishes clear uniform rules that will guarantee *fairness and safety* to contact lens consumers in every State, regardless of existing laws.”¹⁹

Section II(B), herein, chronicles the anticompetitive practices in which ECPs have engaged and to which Mr. Hubbard referred. These practices include:

- Outright refusal to release or verify prescriptions,

¹⁵ See, e.g., Sensenbrenner Speech ([Att. 1](#)).

¹⁶ See Stark Statement, 149 Cong. Rec. H11561-H11565 (Nov. 19, 2003) ([Att. 14](#)).

¹⁷ *Id.*

¹⁸ Hubbard Testimony, Sept. 9, 2003, at 6-7 ([Att. 5](#)).

¹⁹ See Schakowsky Speech (emphasis added) ([Att. 2](#)).

- Evading or ignoring requests to release or verify prescriptions,
- Misleading consumers about their legal right to their prescription,
- Falsely claiming increased health risks from purchasing replacement lenses elsewhere,
- Conditioning eye care on the consumer's agreement to purchase lenses from the EPC,
- Utilizing a host of tactics to dissuade consumers from obtaining their prescription (*e.g.*, delay tactics, liability waiver forms, charging fees to release prescriptions),
- Rendering prescriptions useless for purchasing lenses elsewhere (*e.g.*, writing abbreviated expiration dates as short as one day, releasing eyeglass prescriptions, rather than contact lens prescriptions, and writing prescriptions for "private label contact lenses," or "doctor exclusive contact lenses"), and
- Otherwise interfering with contact lens sales by alternative sellers.

In addition, as chronicled in Section II(B), ECPs, both individually and their trade associations, have used their influence on state legislatures and optometry boards to establish laws and regulations that favor ECPs at the expense of alternative sellers. For example, certain states purport to require all sellers to hold ECP licenses,²⁰ whereas others attempt to permit alternative sellers to sell only if their ECP competitors choose to respond affirmatively to their requests to verify consumer prescriptions (*i.e.*, affirmative verification).²¹

By leveling the playing field for ECPs and alternative sellers, the provisions in the Fairness Act were designed to foster competition in the contact lens business and provide consumers with the benefits a competitive marketplace brings – lower prices, more choices, better service, and more convenience. The provisions check the anticompetitive practices that have plagued the eye care industry for the last 30 to 40 years. As Chairman Sensenbrenner told the House:

[The Fairness Act] ensures that unscrupulous eye doctors will no longer be able hold consumers' contact lens prescriptions hostage, forcing them to purchase lenses solely from their doctor's office. In addition, this legislation will make shopping for lenses simpler and cheaper. . . . Each year, these Americans spend an estimated \$3.5 billion on contact lenses. Providing consumers with an automatic right to their prescriptions will allow them to shop around for contact lenses based on price, service, and convenience. It is estimated that H.R. 3140 could save consumers approximately \$350 million annually, thanks in large part to increased competition. Competition among contact lens companies will result in

²⁰ See, *e.g.*, North Carolina, N.C. Gen. Stat. §§ 90-235, 90-236.1, 90-252 (Att. 15).

²¹ See Texas Contact Lens Prescription Act, § 353.101 (Att. 16); see also Settlement Agreement and General Release of Claims Between the Texas Optometry Board and 1-800, dated May 10, 2002 (Att. 17); Reporter's Record of Settlement Agreement between the Texas Optometry Board and 1-800, dated April 22, 2002 (Att. 18).

lower prices, a greater choice of lens providers, and more convenient ways to fill contact lens prescriptions.²²

The Fairness Act principle of mandatory prescription release enabling meaningful prescription portability has widespread support.²³ For example, the California Optometric Association (“COA”) has voiced support for prescription release in the context of similar California legislation,²⁴ and the California Board of Optometry has expressed its support in this docket.²⁵ In addition, multiple states, consumers, and industry have voiced support for federal legislation mandating prescription release.²⁶ Indeed, 39 state Attorneys General expressed their support to Congress for federal legislation mandating prescription release.²⁷ Moreover, the American Optometric Association (“AOA”) is under an injunction pursuant to a settlement with the state Attorneys General, as a result of the *In re: Disposable Contact Lens Antitrust Litigation*, prohibiting it from objecting to the release of contact lens prescriptions.²⁸

In addition, as discussed more fully in Section II(C), with respect to the success of the California legislation, the FTC, the COA, consumers, and industry have voiced strong support for permitting time-limited presumed verification.²⁹ It is now critical that the FTC make contact lens prescription release a reality for consumers in a manner that will allow them to obtain the benefits of the Fairness Act.

²² See Sensenbrenner Speech (Att. 1).

²³ See, e.g., Testimony of Peggy Venable, Director of Texas Citizens for a Sound Economy, before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, Sept. 9, 2003 (“Venable Testimony”) (“We have also gone on record recommending a two-year prescription requirement rather than the one-year expiration period currently mandated in Texas. That alone would save each Texas contact lens consumer around \$110 a year, the cost of an annual exam”) (Att. 19).

²⁴ See, e.g., *California Optometric Association Negotiates Contact Lens Legislation*, dated Aug. 21, 2002 (Att. 20).

²⁵ Letter to the FTC from the State of California Department of Consumer Affairs, Board of Optometry, dated Feb. 25, 2004 (Att. 21).

²⁶ See, e.g., Martínez Testimony (Att. 8); Gadhia Testimony (Att. 7); Testimony of Jonathan C. Coon, Chief Executive Officer of 1-800, before the Subcommittee on Commerce, Trade, and Consumer Protection, House Committee on Energy and Commerce, Sept. 9, 2003 (Att. 22); Hubbard Testimony, Sept. 9, 2003 (Att. 5); Letter to the Honorable Pete Stark (D-CA) from Consumers Union, dated July 26, 2001 (Att. 23); Letter to the Honorable Pete Stark (D-CA) from the National Association of Attorneys General, dated Mar. 18, 2002 (Att. 24); Letter to the Honorable James Sensenbrenner, Jr. (R-WI) from Texas Citizens for a Sound Economy, dated May 21, 2002 (Att. 25); Letter to the Honorable Pete Stark (D-CA) from Public Citizen, dated Mar. 14, 2002 (Att. 26).

²⁷ See Joseph P. Shovlin, O.D., *Passive Verification: What's It Mean?*, Nov. 2002, http://www.revoptom.com/index.asp?page=2_716.htm (Att. 27); see also Hubbard Testimony, Sept. 9, 2003 (Att. 5).

²⁸ See *In re: Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla.), AOA Settlement Agreement, dated May 22, 2001 (Att. 28).

²⁹ Letter from the COA to the Honorable Lou Correa, California Assemblyman, dated July 15, 2002 (Att. 29); Comments of the Staff of the FTC, Intervenor before the Connecticut Board of Examiners for Opticians, Mar. 27, 2002, at 12 (Att. 9); Cruz Testimony (Att. 12); Venable Testimony (Att. 19); Gadhia Testimony (Att. 7); Letter from Texas Citizens for a Sound Economy to the Honorable Richard Burr (R-NC), dated Aug. 27, 2003 (Att. 30).

A. Overview of the Current Eye Care Industry

1. Market Share and the Eye Care Business

Approximately 36 million Americans wear contact lenses.³⁰ They spend \$3.5 billion every year on replacement contact lenses alone. Approximately 66% of contact lens wearers are female; 10% are 18 or under; 15% are between the ages of 18-24; and 50% are between the ages of 25 to 44.³¹

ECPs dominate the contact lens market, despite the fact that contact lens consumers who purchase lenses from alternative sellers save approximately 20%.³² According to 1-800's marketing records, optometrists currently have 64.3% of the market; ophthalmologists have 4.3% of the market; mass merchandisers³³ have 13.9% of the market; retail chains³⁴ have 9.5% of the market; and mail order has 8.0% of the market.³⁵ Notably, mass merchandisers and retail chains generally have at least one ECP at each location, so non-ECP competitors have an extremely small percentage of the overall market. These numbers attest to the effectiveness of the anticompetitive behavior that has characterized this industry.

ECPs are primarily retailers, with the majority of their revenue coming from the retail sale of products, and the minority coming from eye care.³⁶ As a result, ECPs have a powerful economic motivation to prevent alternative sellers of ophthalmic goods from selling those goods.

The remaining one-third of ECP revenues are from eye examinations and fittings. When contact lenses initially came on the market decades ago, contact lenses were custom-made from rigid materials, so-called "hard" contacts. Dispensing these lenses required a lengthy fitting process

³⁰ See Beales Testimony (Att. 13).

³¹ American Optometric Association ("AOA"), Facts & Stats, <http://www.aoanet.org/eweb/DynamicPage.aspx?site=AOAStage&WebCode=CLFactsStats> (Att. 31).

³² See Comments of the Staff of the FTC, Intervenor before the Connecticut Board of Examiners for Opticians, Mar. 27, 2002, at 10 (finding a 19% cost savings based on a 1998 study) (Att. 9); *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, a Report from the Staff of the FTC (Mar. 2004), at 13 (finding a 19% difference). *Congress approves legislation to give wearers of contact lenses the right to their prescriptions*, Washington-AP, Nov. 20, 2003 (estimating a 20% savings) (Att. 10).

³³ The mass merchandisers in the Synovate Survey of ECP Business Hours discussed in Section III(A)(1)(a)(ii) included Wal-Mart Vision Center, Target Optical, Sam's Club Optical, Costco Optical, and Shopko Optical. See *Optical Goods Retail Hours of Operation Study*, Synovate, Mar. 2004 ("Synovate Survey of ECP Business Hours") (Att. 32). Synovate is one of the world's top research firms, and it is the market research arm of global communications specialist, Aegis Group plc.

³⁴ The retail chains in the Synovate Survey of ECP Business Hours included JCPenney Optical, Pearle Vision, Lenscrafters, Sears Optical, America's Best, BJ's Optical, Eyemasters, and Cohen Optical. See *id.*

³⁵ All numbers are approximate.

³⁶ See Jennifer Goodwin, *Mail Order: Public Benefit or Public Health Threat*, *Optometric Management* (Att. 33).

involving considerable expertise.³⁷ Given that the lenses were customized, consumers were effectively forced to buy contacts from ECPs, *and it made sense for optometrists to sell what they prescribed.*

There have been, however, fundamental technological developments in the field of contact lenses over the past twenty years. The “hard” contact lenses, which previously dominated the market and which effectively required optometrists to sell what they prescribed, are virtually obsolete. Today, approximately 15% of contact lens wearers wear gas permeable (GP) lenses, a more rigid lens made of firm, durable plastic that transmits oxygen. GP lenses, unlike soft lenses, are custom made for each individual, and require the ECP to measure the exact shape of the consumer’s cornea to prescribe lenses with appropriate curvature, size, and corrective power.

The vast majority of contact lens wearers (85%) now wear mass-produced, soft contact lenses,³⁸ which can be replaced on a daily or weekly basis and do not need ECP manipulation.³⁹ Technology in this industry has progressed to the point where for these consumers, there is no reason that contact lenses should not be treated the same as mass-produced pharmaceuticals, where a professional prescribes and a separate entity sells. However, the regulatory scheme governing the sale of contact lenses has failed to adjust with the changes in technology, and indeed in many states, has been manipulated by ECPs to prevent their customers from purchasing lenses from alternative sellers.

The current eye exam/fitting process for contact lenses generally includes a slit lamp assessment to determine general ocular health (*e.g.*, tear quality and presence of disease), refraction to determine the necessary lens power, and a fitting and measurement process to determine the lens curvature and diameter. The fitting process is generally fairly easy. A study on a group of patients, who had previously discontinued contact lens wear, found that only three of 229 patients could not be fit at the first trial fitting.⁴⁰ The three who could not be fit, could not be fit for non-lens related reasons. (One simply had an aversion to touching his eyes, and two were unsuitable for stock lenses and did not want custom lenses.) Notably, of the 226 patients who were fitted, there was a 77% overall success rate, with a 91% success rate for patients fitted in 2-weekly/monthly soft spherical lenses, and an 89% success rate for daily disposables. These success rates are remarkable given that everyone in the study had previously been unsuccessful wearing contact lenses.

Most initial exam/fitting fees also include a follow-up appointment 7-10 days after the initial appointment to ensure visual acuity, fit, and comfort.⁴¹ However, the follow-up appointment may

³⁷ See generally, *Kansas v. Doolin, et al.*, 497 P.2d 138 (Kan. Supr. Ct. 1972); see also Written Testimony of Jonathan Coon, Chief Executive Officer of 1-800, before the FTC Workshop: “Possible Anticompetitive Efforts to Restrict Competition on the Internet,” Oct. 9, 2002 (“Coon FTC Workshop Testimony”) (Att. 34).

³⁸ *Stark Introduces Contact Lens Prescription Release Act of 2001*, Statement of Congressman Pete Stark (D-CA), May 16, 2001, <http://www.house.gov/stark/documents/107th/contactstate.html> (Att. 35); Statistics on Contact Lens Wearers in the U.S., the Contact Lens Council, <http://www.contactlenscouncil.org/scon-stats.htm> (based on 2000 data) (Att. 36).

³⁹ See Hubbard Testimony, Sept. 9, 2003, at 5-6 (Att. 5).

⁴⁰ G. Young, *et al.*, *A multi-centre study of lapsed contact lens wearers*, 22 *Ophthal. Physiol. Opt.* 516 (2002) (Att. 37).

⁴¹ Interview with Larry Edelson, Industry Consultant for Opticare, dated Mar. 23, 2004 (“Edelson Interview”); Interview with Anthony J. Micale, M.D., dated Mar. 23, 2004 (“Micale Interview”) (Dr. Micale has been in private practice for over 30 years and specializes in contact lenses); Interview with Michael Cooper, O.D., dated Mar. 23, 2004 (“Cooper

be waived if the consumer is not a first time user, and if the prescription and the contact lens have not changed.⁴²

ECPs use diagnostic, or sample, contact lenses as part of the fitting process virtually 100% of the time.⁴³ It is our understanding that ECPs do not pay for these diagnostic, or sample, lenses. The manufacturers offer diagnostic lenses for free to ensure that their contact lenses are fitted, and therefore, prescribed.⁴⁴ Manufacturers have every incentive to maintain this practice. Generally, when a manufacturer introduces a new disposable lens, the manufacturer will offer a “fitting set” for free or for a nominal charge.⁴⁵

The “fitting set” is a cabinet of free lenses marked “sample, not for resale.”⁴⁶ The manufacturers replenish “fitting sets” based on the number of revenue lenses the ECP purchases. Generally, an ECP will receive one sample for every six revenue lenses (*i.e.*, for every box). Some manufacturers will automatically send the sample lenses with the revenue lenses, although others will simply keep track of the number of sample lenses to which an ECP is entitled and send them at the ECP’s request. ECPs who claim that they do not have enough sample lenses to use during contact lens examinations and fittings are likely inappropriately giving sample lenses to family, friends, and staff.⁴⁷ The only case where a manufacturer may no longer have samples is where the manufacturer is trying

Interview”) (Dr. Cooper has a diagnostic and therapeutic license in Ohio, Michigan, Washington, and California, and he is actively practicing in Ohio and Michigan. He has been in practice since 1983).

⁴² Micale Interview; Cooper Interview. The type of the lens ultimately dispensed will generally depend on several factors. Edelson Interview; Micale Interview; Cooper Interview. The first factor is whether the eye has a spherical shape, or whether there are some flat areas that create an astigmatism. Patients with any significant astigmatism generally receive soft toric lenses, which are mass produced by most major manufacturers just like soft lenses shaped to fit spherical eye shapes. The second factor is base curve. If the curve is too tight, it can compress the eye, and if the curve is too flat, the lens can slip. However, most of the major soft contact lenses only have one or two base curves. Notably, the median base curve ranges between 8.6 and 8.8. Notably, the median base curve ranges between 8.6 and 8.8. One expert optometrist (Cooper Interview), who has been practicing for over 20 years estimates that 75% of consumers can wear the median base curve, and an expert ophthalmologist (Micale Interview), who has been practicing over 30 years mentioned that some doctors for this reason do not even bother to measure curvature.

For some patients, such as those over 40, who need correction for short distances as well as long, there is a third factor – *i.e.*, lens power. For those patients, multifocal lenses or monovision lenses are appropriate. Notably, multifocal lenses do not work for everyone and require some trial and error, as opposed to monovision lenses, which work an estimated 80% of the time. Thus, patients with multifocal lenses require more “chair time” and ECPs generally charge more for those fittings. Edelson Interview.

⁴³ Micale Interview; Cooper Interview.

⁴⁴ See, *e.g.*, Memorandum to All US Vision Associated Doctors, dated Mar. 16, 2004 (stating that US Vision, a retailer, has had a policy of supplying sufficient diagnostic lenses, and that it plans to continue this policy) (Att. 38).

⁴⁵ Edelson Interview; Cooper Interview.

⁴⁶ Edelson Interview.

⁴⁷ Notably, J&J Vision Care, a major contact lens manufacturer, has an explicit policy to ensure that ECPs and other sellers do not sell diagnostic lenses or use them for commercial purposes. See J&J Vision Care Customer Policy, Nov. 12, 2002 (Att. 39).

to discontinue a contact lens line that uses an older technology (e.g. Surevue).⁴⁸ Indeed, the expert optometrist and expert ophthalmologist interviewed for this segment both stated that they had never paid out-of-pocket for sample lenses in their 20 and 30, respective, years of practice.⁴⁹

2. Consumers Value and Desire Convenience in Purchasing Contact Lenses as Well as Inexpensive Prices

As stated above, consumers who purchase contact lenses from alternative sellers may save approximately 20%.⁵⁰ However, convenience is also an extremely valuable component of the contact lens business.⁵¹ Convenience is particularly important to consumers who wait to replace their contact lenses until the last minute, consumers who may lose or tear lenses, and consumers who travel. Many consumers are willing to pay a premium for convenience. For example, approximately 33% of 1-800's customers choose to use express mail services, despite the additional fee of \$15-\$18.

To accommodate the needs of such consumers, 1-800 has worked hard to make the ordering and delivery of contact lenses as convenient and as reliable as possible. Customers can order from 1-800's website 24 hours a day, seven days a week ("24/7"), and 1-800's call center is open every day except Christmas, the 4th of July, and Thanksgiving, Monday through Thursday, from 6 a.m. to 10 p.m. MST, Saturday, from 6 a.m. to 9 p.m. MST, and Sunday, from 8 a.m. to 4 p.m. MST. 1-800 also stocks approximately 40,000 different SKUs – giving the company the ability to fill 95% of orders the same day (lengthy prescription verification delays now cause many consumers to wait even though their lenses are in stock and ready to ship).

1-800 takes pride in its exemplary customer service and its ability to delivery contact lenses to consumers quickly. The following comments from 1-800's customers represent thousands we have received over the last ten years:

- WOW!!!!!!! That was probably the quickest response I've ever gotten from a business I am getting ready to go out of town and wanted this order before I left. Now I will have them in time. Again, thank you so very much for being so prompt.
- You guys are AWESOME! I have always told all my friends and family how easy and fast it is to order contacts from you.

⁴⁸ Cooper Interview.

⁴⁹ Micale Interview; Cooper Interview.

⁵⁰ See, e.g., Comments of the Staff of the FTC, Intervenor before the Connecticut Board of Examiners for Opticians, Mar. 27, 2002, at 10 (finding a 19% cost savings based on a 1998 study) (Att. 9); *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, a Report from the Staff of the FTC (Mar. 2004) (finding a 19% difference); *Congress approves legislation to give wearers of contact lenses the right to their prescriptions*, Washington-AP, Nov. 20, 2003 (estimating a 20% savings) (Att. 10).

⁵¹ See, e.g., Karlen Lamperelli, *Eyecare Professionals Compete on Changing CL Playing Field*, VisionMonday.com, Mar. 24, 2003 (Att. 40).

- Good morning. I just wanted to drop you a note to say that I received my lens this morning already. Wow, what great service you have, I am so thrilled because I was told that it would not arrive until Tuesday, you have saved the day once again.
- WOW!!! I don't usually do this but I have to tell you . . . what a pleasure ordering contacts from you. I have never ordered contacts off the web. My kids always come to me at the last minute and tell me "We're out of contacts!" . . . So, when I ordered contacts this morning and faxed the doctor's prescription I thought it would take at least a couple weeks to get them. Now, only hours after I ordered I am getting an e-mail saying that they have been shipped. YOU GUYS ROCK!!! Thanks so much and I look forward to a long business relationship.⁵²

If the Fairness Act regulations are carefully framed to ensure meaningful prescription portability, many more consumers can obtain this level of value and convenience, both from alternative sellers and from ECPs, who will finally be required to compete based on the parameters of price and convenience.

3. Structural Deficiencies in the Eye Care Industry Foster Anticompetitive Behavior

The anticompetitive practices in which ECPs have engaged for the last 30 to 40 years are fostered by two structural problems in the eye care industry: (1) unlike most physicians, optometrists can sell what they prescribe,⁵³ giving optometrists incentive and opportunity to prevent competition from alternative sellers, and (2) ECPs dominate state boards, which establish and enforce state regulations affecting ophthalmic products and services, and have worked together for 30 to 40 years to influence state laws and regulations, giving ECPs significant competitive advantages over alternative sellers.

Unlike most physicians, optometrists can sell what they prescribe. The American Medical Association's ("AMA's") code of ethics for physicians properly advises against this practice. It makes an exception in extremely limited circumstances (*e.g.*, where traveling to the nearest pharmacy would jeopardize the welfare of the patient).⁵⁴ According to Section E-8.063 of that code:

In-office sale of health-related products by physicians presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians to serve the interests of their patients before their own.⁵⁵

⁵² See Miscellaneous 1-800 Fan Mail (names have been redacted for privacy reasons) (Att. 41).

⁵³ Even the more scrupulous ECPs concede that "[c]ontacts are commodities. Optometrists who think they are entitled to sell contacts at a profit may as well sell any and all other commodities at a profit. Do general practitioners profit from the drugs they prescribe? Health care practitioners should provide services. Retailers (or wholesalers) should provide goods. I don't understand the controversy." Paul Farkas, *Seniordoc - Profit from Service or Product*, ECP E-mail Forum, Nov. 28, 2003 (8:58 a.m.) (Att. 42).

⁵⁴ See AMA, E-8.063 Sale of Health-Related Products from Physicians' Offices (Att. 43); see also AMA, E-8.06 Prescribing and Dispensing Drugs and Devices (Att. 44).

⁵⁵ AMA, E-8.063 Sale of Health-Related Products from Physicians' Offices (Att. 43).

By writing a prescription, a physician is essentially making a decision as to how his or her patient will be spending money. The arrangement whereby a physician prescribes and leaves the patient to purchase from another entity protects the patient from potential conflicts of interest in this transaction, enhances confidence in the physician on the part of the patient, promotes competition, encourages innovation, and facilitates consumer choice.

Unfortunately, optometrists are free to settle in their own favor the conflict of interest between the optometrist's desire to make money and the consumer's desire to save money. The optometrist can select for a patient a contact lens that is only available from that particular optometrist, or a contact lens that the manufacturer refuses to make available to alternative sellers. Among equivalent lenses, an optometrist can even select the lens that makes him or her the most money.

Second, as summarized in 1-800's comments to the FTC regarding E-competition, ECPs dominate state boards, which establish and enforce regulations that affect ophthalmic products and services, and they have worked together for 30 to 40 years to influence state legislation.⁵⁶ Julianne D'Angelo Fellmeth, a law professor at an institute that has studied state regulation of professions for 21 years, observed that: "[w]hen a profession controls its own regulatory agency, it focuses on issues not of public protection and enforcement but of enhancing the barriers to entry and expanding its scope of practice."⁵⁷ It is routine for ECPs to rotate between membership on state boards and the leadership of ECP trade associations.⁵⁸

Indeed, these ECP influenced state laws and regulations often impose disproportionate burdens on alternative sellers, prevent competition, increase consumer prices, and actually compromise rather than promote ocular health.⁵⁹ In 1980, the FTC itself found that "the average cost of an eye exam is 35 percent higher in cities with restrictive commercial practices for optometrists."⁶⁰ Moreover, to

⁵⁶ See, e.g., Comments of Julianne D'Angelo Fellmeth, Administrative Director, Center for Public Interest Law, before the Joint Legislative Sunset Review Committee, Sunset Hearing Board of Optometry, Dec. 5, 2001 ("Fellmeth Comments") (Att. 45).

⁵⁷ See *id.*

⁵⁸ See Roger Seelye, an Optometrist in Owosso, Michigan, for example, serves as Vice-Chairperson on the Michigan Board of Optometry as well as the Chair of the Legislative Committee for the Michigan Optometric Association. See Michigan Optometric Association Website, <http://www.mioptasn.org/leadership.htm> (Att. 46); List of Michigan Board of Optometry Members, Michigan Board of Optometry Website, http://www.michigan.gov/cis/0,1607,7-154-10568_17671_17686-42773-,00.html (Att. 47).

⁵⁹ See *supra*, at note 3. See also 54 Fed. Reg. 10285, 10286 (Mar. 13, 1989).

⁶⁰ Ronald S. Bond, *et al.*, *Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry*, Staff Report, Bureau of Economics, FTC (1980) (Att. 48); see also Ronald S. Bond, *et al.*, *Executive Summary - Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry*, Staff Report, Bureau of Economics, FTC (1980) (Att. 49); Morris M. Kleiner, University of Minnesota and the National Bureau of Economic Research, *Occupational Licensing and the Internet: Issues for Policy Makers*, FTC Hearings on "Possible Anticompetitive Efforts to Restrict Competition on the Internet," Oct. 1, 2002 (Att. 50).

our knowledge, there is no “competent and reliable scientific evidence” that suggests that restrictive commercial practices have any countervailing health benefit.⁶¹

B. History of ECP Anticompetitive Practices

As the FTC itself has acknowledged, ECPs have a long history of anticompetitive practices.⁶² These practices have significantly injured consumers by raising prices, restricting consumer choice, impeding innovation in the eye care industry, and ultimately “depriv[ing] consumers of necessary eye care.”⁶³ The ECPs’ primary anticompetitive practices, which are summarized herein, have included:

- Refusing to release prescriptions (described by one ECP as the “what-can-I do-to-make-releasing-a-CL-Rx-the-hardest-thing-for-a-patient-to-obtain-game”⁶⁴ (the “avoid-prescription-release game”)),
- Refusing to verify prescription information provided to alternative sellers, and
- Influencing state legislative and regulatory bodies to promulgate legislation and regulations that prohibit alternative sellers from selling contact lenses, or that otherwise disfavor alternative sellers.

ECPs have commonly rationalized these anticompetitive behaviors as purportedly related to ocular health. ECPs are actually out to protect their profits. ECPs have long made unsubstantiated health risk claims regarding the purported risks of buying replacement lenses from alternative sellers. The only support for the health risk claims that ECPs have been able to find is self-serving anecdotal hearsay.⁶⁵ Such anecdotal evidence does not qualify as “competent and reliable scientific evidence,”⁶⁶ which the FTC generally requires to substantiate health-related claims. Indeed, ECPs

⁶¹ The FTC generally defines “competent and reliable scientific evidence” as “tests, analyses, studies, surveys, or other evidence based on the experience of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results. See, e.g., *Metagenics Inc.*, 124 F.T.C. 483, 497 (1997) (emphasis added); *Gracewood Fruit*, File. No. 922-3056 (June 17, 1992). See *infra*, at Section II(B) (dismissing ECP claims that buying contacts lenses from alternative sellers rather than ECPs poses any health risk).

⁶² See, e.g., Comments of the Staff of the FTC, Intervenor before the Connecticut Board of Examiners for Opticians, Mar. 27, 2002 (Att. 9); 54 Fed. Reg. at 10285; Ronald S. Bond, *et al.*, *Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry*, Staff Report, Bureau of Economics, FTC (1980) (Att. 48).

⁶³ 54 Fed. Reg. at 10285; see also Comments of the Staff of the FTC, Intervenor before the Connecticut Board of Examiners for Opticians, Mar. 27, 2002 (Att. 9); Ronald S. Bond, *et al.*, *Effects of Restrictions on Advertising and Commercial Practice in the Professions: The Case of Optometry*, Staff Report, Bureau of Economics, FTC (1980) (Att. 48).

⁶⁴ Jerry Geist, *Optcom – FCLCA/FCLACA Scenario. FCLA Charting*, ECP E-mail Forum, Feb. 1, 2004 (5:41 a.m.) (Att. 51).

⁶⁵ See, e.g., *Law Makes It Illegal to Sell Contacts Without Prescription*, CBS4, Denver, Colorado, Feb. 11, 2004, http://news4colorado.com/nationworld/local_story_049193250.html/resources_storyPrintableView, as of Feb. 18, 2004 (Att. 52).

⁶⁶ The FTC generally defines “competent and reliable scientific evidence” as “tests, analyses, studies, surveys, or other evidence based on the experience of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and

have characteristically avoided any comparison of complications with lenses purchased from ECPs versus lenses purchased from alternative sellers.⁶⁷ For example, a report on contact lens complications prepared by the Association of Regulatory Boards of Optometry merely provides raw data regarding complications. It does not indicate that these complications were caused by alternative sellers or that complications occur more frequently with lenses dispensed by alternative sellers than ECPs.⁶⁸

Moreover, these health risk claims have been repeatedly discredited. Most recently, the FTC itself found that there is “no systematic evidence that sales through alternative channels, such as Internet or mail order, pose any additional health risk as long as the retailer sells in accordance with a valid prescription.”⁶⁹ In addition, 17 state Attorneys General investigated these unsubstantiated health claims and concluded:

Purchasers from alternative channels have had no greater ocular health problems than purchasers from [ECPs]. Our multi-state investigation has failed to reveal any study showing any correlation between compromised ocular health and receipt of lenses through alternative channels.⁷⁰

To the contrary, the state Attorneys General found that competition from alternative sellers actually increased consumer safety. With alternative sellers, consumers were apt to replace their contact lenses more frequently because the lenses were cheaper and more accessible.⁷¹

Moreover, the state Attorneys General repeatedly have asked the leading optometric trade association, the AOA, to produce any valid clinical or scientific data of increased health complications associated with purchasing contact lenses from alternative sellers, but no such data has ever been produced.⁷² In addition, the state Attorneys General have never seen any such evidence of increased health complications despite the fact that alternative channels have been

reliable results. *See, e.g., Metagenics Inc.*, 124 F.T.C. 483, 497 (1997) (emphasis added); *Gracewood Fruit*, File. No. 922-3056 (June 17, 1992). The following documents, when read in complete context, reveal that no medical study or proof has been developed or identified that proves any correlation between where a consumer obtains his contact lenses and increased ocular health risk. *See* The American Optometric Association’s Response to “States’ Third Discovery Requests to the AOA,” *In re: Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla.) (Att. 53); Defendant Johnson & Johnson Vision Products, Inc.’s Response to Plaintiff States’ Fifth Set of Interrogatories and Document Requests, *In re: Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla.) (Att. 54).

⁶⁷ *See* SOF, at 60 (note 183) (Att. 3).

⁶⁸ *See* Association of Regulatory Boards of Optometry (“ARBO”), *2003 Report on Complication(s) Due to Contact Lenses Dispensed Without a Valid Prescription*, Feb. 18, 2004 (Att. 55).

⁶⁹ *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, a Report from the Staff of the FTC (Mar. 2004), at 12.

⁷⁰ FTC Comments of the AGs, at 8 (Att. 6).

⁷¹ *See id.* at 7; *see also* Letter to FDA Docket No. 2003P-0291, from 1-800, dated Jan. 13, 2004 (with attachments) (Att. 11).

⁷² *See* Hubbard Testimony, Sept. 9, 2003, at 7-10 (Att. 5).

selling contact lenses now for twenty years.⁷³ In testimony before the House Subcommittee on Commerce, Trade and Consumer Protection, a spokesperson for the state Attorneys General explained:

The States have a lot of experience in this industry. . . . We have over time become quite skeptical of the health care claims that are made about the kind of difficulties that consumers face and the justifications for those restraints on health care. We have asked for and never gotten the kind of evidentiary support that we would find necessary to give those health care claims credence. . . . [H]ealth care claims have been made ever since competition reared its head in this industry. And we would have expected there to have been a manifestation of those concerns and better documentation of them by now. . . . [A]s I mentioned before, there's no documented harm from consumers going to alternative [retailers], instead of their ECPs.⁷⁴

Indeed, the AOA and other ECP defendants in an antitrust case brought by 32 state Attorneys General, *In re Disposable Contact Lens Antitrust Litigation*, are presently under injunctions that prevent them from claiming that there are increased health risks associated with purchasing replacement contact lenses from alternative sellers rather than ECPs.⁷⁵

The complete absence of evidence of increased health complications associated with purchasing contact lenses from alternative sellers is consistent with the experience of 1-800. Since its inception in 1995, 1-800 has filled over 10 million orders to approximately 3.5 million customers. Not a single customer has filed a health-related claim against it for any reason, and to 1-800's knowledge, there has never been a report of any health incident attributable to the fact that the consumer purchased the contacts from 1-800, rather than from an ECP.

1. The History of Egregious Anticompetitive Behaviors by ECPs Began as Far Back as the 1960s

ECPs established their pattern and practice of anticompetitive behaviors as far back as the 1960s, forcing courts and the FTC to intervene. As is the case today, 30 and 40 years ago, optometrists could sell what they prescribed, and thus, they had a personal financial interest in establishing barriers to competition. These barriers to competition generally took two forms: (1) influencing state boards to enact or enforce rules that prevent competition, and (2) refusing to release prescriptions to prevent consumers from comparison shopping.

⁷³ See *id.* at 9.

⁷⁴ Excerpts from the Statement of Robert L. Hubbard, Director of Litigation, Antitrust Bureau, New York State Department of Law, Hearing before House Subcommittee on Commerce, Trade and Consumer Protection, dated Sept. 12, 2003 ("Hubbard Testimony, Sept. 12, 2003"), at 4-5 (Att. 56).

⁷⁵ *In re: Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla.), AOA Settlement Agreement, May 22, 2001, at 9 (Att. 28).

a. ECPs Have Worked Together for 30 to 40 Years to Influence State Legislation and Enforcement

State laws and regulations that favored certain ECPs existed even 30 and 40 years ago because those ECPs dominated the state optometry boards and worked together to influence state legislation and regulations.⁷⁶ Two cases, *Kansas v. Doolin, et al.*⁷⁷ and *Gibson v. Berryhill*,⁷⁸ provide prime examples of ECPs attempting to use their influence with state regulatory boards to exclude competitors.

In *Kansas v. Doolin, et al.*,⁷⁹ the State of Kansas and the Board of Optometry brought a case against several opticians in Kansas, in 1964, in an attempt to bar the opticians from fitting contact lenses. Traditionally, optical dispensers were known as “opticians,” and they usually merely ground lenses and fit eyeglasses upon the prescription of a physician. Then, certain opticians began refracting human eyes to determine the amount of power correction needed by the consumer. These “refracting opticians” became “optometrists,” and immediately “extended their sphere of influence [by] successfully obtain[ing] legislation in various states recognizing their right to examine eyes for the purpose of determining refractive error.”⁸⁰ In *Doolin*, Kansas and its Board of Optometry claimed that the “opticians” were practicing “optometry” without a license because they were fitting contacts on the order of a prescription. The Supreme Court of Kansas ultimately rejected the optometrists’ attempt to exclude opticians from fitting contact lenses, concluding that the opticians were not practicing optometry because they were not refracting eyes.⁸¹

Nine years later, in *Gibson v. Berryhill*,⁸² private practice optometrists who dominated the Alabama Board of Optometry began warring with corporate optometrists. In an attempt to put corporate optometrists out of business, the Alabama Board brought a disciplinary action against corporate optometrists who worked for Lee Optical, based simply on the fact they worked for a corporation. The corporate optometrists successfully sought an injunction against the Board, which was ultimately upheld by the U.S. Supreme Court, arguing that the Board members were motivated by personal profit and abused their governmental authority.⁸³ Even after the private optometrists lost that battle, they colluded to influence state optometry boards nationwide to adopt practices disfavoring corporate optometry and favoring private optometrists.⁸⁴ ECPs were so successful at this that it became their pattern and practice to influence state boards to adopt anticompetitive practices that preserved private ECPs’ profit margins.

⁷⁶ See generally, Fellmeth Comments (Att. 45).

⁷⁷ *Kansas v. Doolin, et al.*, 497 P.2d 138 (Kan. Supr. Ct. 1972).

⁷⁸ *Gibson v. Berryhill*, 411 U.S. 564 (1973).

⁷⁹ *Kansas v. Doolin, et al.*, 497 P.2d 138 (Kan. Supr. Ct. 1972).

⁸⁰ *Id.* at 141.

⁸¹ See *id.* at 152.

⁸² *Gibson v. Berryhill*, 411 U.S. 564 (1973).

⁸³ *Id.*

⁸⁴ See Fellmeth Comments (Att. 45).

In 1989, the FTC was forced to intervene to reign in the anticompetitive behaviors of state optometry boards, such as limiting the number of branch offices that can be owned or operated by an optometrist and prohibiting the practice of optometry in commercial locations.⁸⁵ At that time, the FTC issued a rule barring state legislatures and state boards from issuing certain anticompetitive laws, finding that:

Some state-imposed restrictions on the commercial practice of optometry cause significant injury to consumers. While justified as necessary to protect consumers, these restrictions actually work to deprive consumers of necessary eye care, restrict consumer choice, and impede innovation in the eye care industry.

The monetary cost—likely to be millions of dollars annually—is great. Over half of all Americans and more than 90 percent of elderly consumers use corrective eyewear, and over eight billion dollars was spent on eye exams and eyewear in 1983. A significant proportion of these costs can be attributed to the inefficiencies of an industry protected from competition by state regulation. A study done by the FTC’s Bureau of Economics shows that prices for eye care are 18 percent higher in markets where chain firms are totally restricted than in markets where chain firms operate freely.⁸⁶

Ultimately, the FTC’s rule was struck down on the grounds that the FTC lacked statutory authority, but the FTC’s findings were left intact.⁸⁷

b. To Prevent Consumers from Comparison Shopping, ECPs Have Been Refusing to Release Eyeglass Prescriptions for Years

In the 1970s, in an attempt to deter competition, the ECPs came up with the “avoid-prescription-release game.” At that time, ECPs had a pattern and practice of refusing to release eyeglass prescriptions, charging additional fees for prescription release, and/or refusing to conduct eye exams unless the consumer also agreed to purchase eyeglasses from the ECP. In 1978, the FTC intervened by promulgating the Eyeglass Prescription Release Rule,⁸⁸ after concluding that the refusal to release an eyeglass prescription was an unfair act under Section 5 of the Federal Trade Commission Act (“FTCA”).⁸⁹ Specifically, the FTC determined that the inability to obtain prescriptions, the surcharges for obtaining the prescriptions, and the subsequent “lost opportunity” costs attributable

⁸⁵ 54 Fed. Reg. at 10285.

⁸⁶ *Id.* at 10285-86.

⁸⁷ *California State Board of Optometry v. FTC*, 910 F.2d 976 (D.C. Cir. 1990).

⁸⁸ 43 Fed. Reg. 23992 (June 2, 1978), codified at 16 C.F.R. pt. 456 (2003).

⁸⁹ 15 U.S.C. § 45 (Supp. 2003).

to the lack of comparison shopping subjected consumers to substantial economic loss.⁹⁰ Indeed, with no ability to comparison shop, convenience and lower prices were sacrificed.

Although the centerpiece of the Eyeglass Prescription Release rule was mandating the automatic release of eyeglass prescriptions and prohibiting ECPs from conditioning the availability of an eye exam upon purchasing ophthalmic goods from the ECP, the rule also prohibited ECPs from engaging in other anticompetitive practices.⁹¹ For example, it prohibited ECPs from issuing to the consumer any waiver or disclaimer of liability for the accuracy of the prescription if the consumer purchased ophthalmic goods from other dispensers.⁹² The FTC included this provision to prevent ECPs from erroneously implying that other dispensers may be less qualified.⁹³

As noted, despite the fact that the Eyeglass Prescription Release Rule has been in effect for more than twenty-five years, surveys conducted in 1997 indicated that 68.5% of consumers were unaware of the rule, and that a substantial number of ECPs still refused to comply with the rule. With regard to non-compliance, a survey found that 29.3% of patients still did not receive their prescriptions and 10.1% were refused prescriptions even when the consumers specifically requested them. Moreover, anecdotal evidence compiled by the FTC during its recent review of the rule indicates that the overwhelming majority of ECPs who dispense eyewear do not automatically release eyeglass prescriptions.⁹⁴ Ironically, despite this overwhelming evidence, self-interested ECP associations such as the AOA, now actually contend that the Eyeglass Prescription Release Rule has done its job of educating consumers and increasing competition so well, that a prescription release rule is no longer needed.⁹⁵

2. *In re: Disposable Contact Lens Antitrust Litigation*

More recently, ECPs have also conspired amongst themselves and with contact lens manufacturers to protect ECPs from competition from alternative sellers. State Attorneys General from 32 states⁹⁶ and a national class of consumers brought an action against the AOA and various other ECP associations, individual ECPs, and contact lens manufacturers (*e.g.*, Johnson & Johnson Vision Care (Vistakon) (“J&J Vision Care”), Ciba Vision, and Bausch & Lomb), for conspiring to impede competition from alternative sellers -- *In re: Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M. D. Fla.).

⁹⁰ 43 Fed. Reg. at 24003.

⁹¹ 16 C.F.R. pt. 456 (2003).

⁹² *See id.*

⁹³ *See* 69 Fed. Reg. at 5452.

⁹⁴ *See id.*

⁹⁵ *See id.*

⁹⁶ Plaintiff States included: Alabama, Alaska, Arizona, Arkansas, California, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nevada, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Texas, Utah, Virginia, West Virginia, and Wisconsin.

No longer content to engage in anticompetitive practices alone, ECPs and ECP trade associations coerced manufacturers into colluding with them by threatening to boycott the manufacturers. For example, one prominent ECP wrote to manufacturer J&J Vision Care a letter that included the following threats:

Because of our role as early Acuvue innovators, our colleagues are turning to us to help them cope with the erosion of their Acuvue market. Unless we can get some answers in the very near future, we might be the “first in, first out”. With no other alternatives, I suspect that my colleagues will follow suit

[Regarding J&J Vision Care’s “ECP Only” sales policy] This is not enough! I believe it will require extraordinary measures to reverse this downward spiral of the Acuvue market. The salvation of the disposable lens market will require an eyecare practitioner/manufacturer partnership and a willingness to be aggressive and dynamic.⁹⁷

The evidence compiled by the state Attorneys General in *In re: Disposable Contact Lens Antitrust Litigation* documented how the defendants conspired to artificially inflate the price of contact lenses and to protect their profits from lens sales by: (1) restricting the demand for replacement lenses from alternative sellers, and (2) restricting the sale of replacement lenses from manufacturers or diverters to alternative sellers (*i.e.*, the supply), in violation of antitrust laws.⁹⁸ The state Attorneys General also had evidence that the defendants’ anticompetitive practices caused substantial economic injury to consumers.⁹⁹

a. Efforts to Suppress Consumer Demand from Alternative Sellers

The state Attorneys General had evidence that the defendant ECPs, AOA, and/or the other defendant trade associations targeted ECPs, state legislatures, regulatory bodies, and even manufacturers, in an attempt to suppress consumer demand for lenses from alternative sellers. The ECPs and trade associations continued their pattern and practice of anticompetitive behaviors developed in the 1970s, urging ECPs to:

- Play the “avoid-prescription-release game”
 - Never let the prescription leave the office,¹⁰⁰

⁹⁷ See SOF, at 66-67 (quoting a letter from Dr. Ron Snyder to J&J Vision Care) (Att. 3).

⁹⁸ See generally, SOF (Att. 3); see also Letter to the Honorable Donald Clark, Secretary, FTC, from Representative Pete Stark (D-CA), dated Sept. 2, 1997 (Att. 57).

⁹⁹ See Declaration of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, *In re: Disposable Contact Lens Antitrust Litigation*, Case No. MDL 1030 (M.D. Fla.), May 1999 (Att. 58); see also Douglas F. Greer, Ph.D., Supplemental Declaration on Damages in the Contact Lens Case, March 2001 (Att. 59); *Nationwide Survey of Contact Lens Wearers*, SRI Consulting, Apr. 27, 1999 (Att. 60).

¹⁰⁰ SOF, at 6, 24 (citing the Wisconsin Optometric Association’s 1988, “Never let the prescription leave the office,” advice to ECPs on how to combat demand for lenses from alternative sellers) (Att. 3).

- Hide prescription information from lens wearers by using removable labels and/or bar coding on product labels,¹⁰¹
- Require patients to enter into year long contracts with ECPs for lenses,¹⁰²
- Use prescription release forms with unnecessary and unreasonable restrictions, and/or “liability release forms,” sometimes with references to possible prosecutions under fabricated laws if the laws were not followed,¹⁰³ and
- Continue to assist in legislative efforts in states that are working to control the sale of contact lenses by non-licensed, over-the-counter or mail order vendors.¹⁰⁴

Worse yet, the state Attorneys General had evidence that the AOA even published an article entitled, “Making Contact,” which presented misleading data from a survey to suggest that there were health risks associated with purchasing replacement lenses from alternative sellers. The article falsely stated that “[s]ixty percent of those who obtained their lenses through unconventional sources were found to have clinical problems”¹⁰⁵ The article used this false and misleading information to urge ECPs to continue to lobby state legislatures to prevent alternative sellers from selling contacts.¹⁰⁶

Notably, the survey’s own author testified that he did not consider it a scientifically valid survey or a fair and honest representation of the actual state of medical affairs.¹⁰⁷ Moreover, discovery revealed that the ECPs and their associations had considered doing a legitimate study comparing the safety of purchasing contact lenses from alternative sellers versus ECPs, but rejected the idea, in part, out of fear that it would not support their health risk claims.¹⁰⁸

The AOA also went to great lengths to design a model policy to help members and state associations enact laws that would restrict the ability of alternative sellers to sell contact lenses. Over the objections of the AOA’s legal counsel, who raised antitrust concerns, the AOA Contact Lens Section recommended that the AOA Board enact a policy that stated: “it is the position of the [AOA] that the dispensing of contact lenses be provided only by eye care practitioners who are

¹⁰¹ *See id.* at 23.

¹⁰² *See id.*

¹⁰³ *See id.* 34-36 (In fact, the authors of one of the most restrictive forms admitted that “We just made it up”); *see also In re: Disposable Contact Lens Antitrust Litigation*, Case No. MDL 1030 (M.D. Fla.), Order of Feb. 26, 2001, at 6 (Att. 61); Hubbard Testimony, Sept. 9, 2003, at 2-3 (Att. 5).

¹⁰⁴ SOF at 26 (quoting an article published in “Making Contact” by the Chairman of the AOA Contact Lens Section, in the Spring of 1989) (Att. 3).

¹⁰⁵ *Id.* at 19-20, 57-60.

¹⁰⁶ *See id.* at 7.

¹⁰⁷ *See id.* at 60.

¹⁰⁸ *See id.* (note 183).

licensed to prescribe contact lenses.”¹⁰⁹ Because of antitrust concerns the language was softened, and “health risk” pretexts were added, such that the policy stated:

RESOLVED, that the sale of replacement or duplicate contact lenses without verification and ongoing evaluation of the contact lenses is detrimental to the health and welfare of the patient; thus, replacement or duplicate contact lenses should be evaluated on the eye by a practitioner authorized to do so pursuant to state law.¹¹⁰

Eventually, the AOA settled on a more facially legal policy, but the policy retained the health risk pretext, calling for: “the adoption of laws or regulations prohibiting the sale of contact lenses directly to the consumer without proper patient management, examination, and ongoing evaluation by a practitioner authorized to do so pursuant to state law.”¹¹¹

Moreover, the state Attorneys General had evidence that the AOA, in conjunction with state associations in Wisconsin, California, Michigan, and Illinois, among others, was working to cut off demand for alternative sellers, dealing with the issue of prescription release at the state level.¹¹² In addition, the Wisconsin Optometric Association was working on state regulations and “model” prescription terminology that would keep alternative sellers from being able to sell contact lenses.¹¹³ Similarly, the COA was actively pushing California legislation that would bar alternative sellers from selling contact lenses altogether, and the COA even tried to enlist the support of contact lens manufacturers, such as Bausch & Lomb.¹¹⁴

The AOA and state associations, such as the COA, also colluded with *manufacturers* to fight off competition from alternative sellers. For example, J&J Vision Care discussed various methods of suppressing the demand from alternative sellers, including, producing “*private label contact lenses*” that could only be purchased by ECPs,¹¹⁵ and manufacturer advertising campaigns urging consumers to see ECPs.¹¹⁶ Similarly, Bausch & Lomb advertised to ECPs that its Seequence® lenses used coded prescription information on the packaging to prevent consumer access, and artificially short expiration dates printed on the packaging to force consumers to return to an ECP sooner than would otherwise be necessary.¹¹⁷

¹⁰⁹ *Id.* at 23 (quoting the Proposed Resolution from the Florida Consolidated Facts).

¹¹⁰ *Id.* at 23-24.

¹¹¹ *Id.* at 25 (quoting the Resolution Passed July 1, 1988, Florida Consolidated Facts).

¹¹² *See id.* at 33.

¹¹³ *See id.* at 23-24.

¹¹⁴ *See id.* at 25.

¹¹⁵ *See id.* at 68; *see also* Elyse Krasnogok, *Making Contacts Worth It*, <http://www.2020mag.com/Issues/1998/Sept/makecontacts.htm> (Att. 62).

¹¹⁶ *See* SOF, at 68 (Att. 3).

¹¹⁷ *See id.* at 29.

In addition, Bausch & Lomb launched a “B&L University” effort, the “B&L Dream Team” program, and “Patient Loyalty” programs to teach ECPs, among other things, how best to deflect prescription requests from consumers.¹¹⁸ Moreover, on July 15, 1992, Bausch & Lomb issued a press release announcing that it would include a new advisory in product inserts stating that:

*To safeguard your eye health, Bausch & Lomb recommends that you purchase your contact lenses only from your eye care practitioner and that you see your eye care practitioner regularly for checkups.*¹¹⁹

Further, Bausch & Lomb assisted state optometric associations “in their *economic*, rather than health care based, efforts to change their state laws and regulations regarding ‘prescribing and dispensing of contact lenses.’”¹²⁰

b. Efforts to Restrict the Sale of Replacement Lenses to Alternative Sellers (i.e., Supply)

The evidence compiled by the state Attorneys General also indicated that the defendants sought to prevent the sale of contact lenses to alternative sellers by coercing “manufacturers into adopting and more actively enforcing ECP-only distribution policies for their replacement lenses,”¹²¹ and by making an “effort to sanction those ECPs that supplied lenses to alternative channels.”¹²²

For example, regarding collusion with manufacturers, the state Attorneys General had evidence that on October 5, 1989, the AOA met with J&J Vision Care to discuss a plan to eliminate sales to alternative sellers. This plan included, among other things: (1) J&J Vision Care changing the labeling for Acuvue to make it clear that the product was only for prescription use by licensed ECPs, (2) J&J Vision Care sending a letter to pharmacy associations to announce a policy of only selling lenses to ECPs, (3) AOA sending the J&J Vision Care pharmacy association letter to state optometry boards commending J&J Vision Care’s action, and (4) J&J Vision Care potentially giving the names of ECPs who are diverters to AOA so that the AOA could discuss this behavior with state boards.¹²³

Soon after this meeting, J&J Vision Care in fact changed the Acuvue labeling, sent the letters to pharmacy associations in accordance with the plan, cut off sales to Contact Lens Supply, an alternative seller, and barred Lens Express, another alternative seller, from opening an account even though the company had a pre-existing relationship with J&J Vision Care.¹²⁴ J&J Vision Care also

¹¹⁸ See *id.* at 98.

¹¹⁹ *Id.* at 99 (quotations omitted).

¹²⁰ *Id.* (emphasis added) (quotations omitted).

¹²¹ *In re: Disposable Contact Lens Antitrust Litigation*, Case No. MDL 1030 (M.D. Fla.), Order of Feb. 26, 2001, at 6 (Att. 61).

¹²² *Id.*

¹²³ See SOF, at 47-48 (Att. 3).

¹²⁴ See *id.* at 49-51.

announced its intent to cut off diverters. Furthermore, by February 1990, the AOA announced in its publication that it would follow up on the policing agreement. Once J&J Vision Care made its policy announcements, the AOA used the announcements to convince other manufacturers, such as Wesley-Jessen, CIBA Vision, and Cooper Vision to announce similar policies.¹²⁵

c. The Settlements With All of the Defendants Included Injunctive Relief and Monetary Payments

In the end, the various ECP and manufacturer defendants settled by agreeing to injunctive relief requiring them to discontinue a wide array of anticompetitive practices, and to pay collectively over \$80 million in compensation.¹²⁶

- CIBA Vision - CIBA Vision agreed to pay approximately \$5 million, and agreed to sell to alternative sellers and ECPs on a non-discriminatory basis.¹²⁷
- Bausch & Lomb - Bausch & Lomb agreed to pay \$8 million, provide customers with a package of goods and services worth \$9.5 million, and sell replacement lenses to alternative sellers and ECPs on a non-discriminatory basis.¹²⁸
- J&J Vision Care - J&J Vision Care agreed to pay \$25 million, provide customers with a package of goods and service worth \$30 million, and sell replacement lenses to alternative sellers on a non-discriminatory basis.¹²⁹
- AOA - The AOA agreed to injunctive relief and a monetary payment of \$750,000.¹³⁰

Notably, the AOA, among other things, expressly agreed not to: (1) object to the release of contact lens prescriptions to patients, unless an optometrist believes that not releasing a prescription is necessary to protect the health of a specific patient, (2) represent directly or indirectly that ocular health may be compromised by purchasing contact lenses from an alternative seller rather than an

¹²⁵ See *id.* at 55-56.

¹²⁶ See, e.g., Press Releases re: Bausch & Lomb, Office of the New York State Attorney General Eliot Spitzer, dated Feb. 20, 2001, www.oag.state.ny.us/press/2001/feb/feb20a_01.html (Att. 63); Press Release re: Ciba Vision, Office of the New York State Attorney General Eliot Spitzer, dated Nov. 3, 2000, http://www.oag.state.ny.us/press/2000/nov/nov03a_00.html (Att. 64); *Contact Lens Antitrust Lawsuit Settles – Lens Wearers Eligible for Benefits*, News Release Iowa Dept. of Justice, May 23, 2001, www.state.iowa.us/government/ag/contact_lenses_J_J.htm (Att. 65).

¹²⁷ Hubbard Testimony, Sept. 12, 2003, at 8 (Att. 56).

¹²⁸ See Press Release re: Ciba Vision, Office of the New York State Attorney General Eliot Spitzer, dated Nov. 3, 2000, http://www.oag.state.ny.us/press/2000/nov/nov03a_00.html (Att. 64).

¹²⁹ See *In re: Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla.), Settlement Agreement with J&J Vision Care, dated May 10, 2001, at 11-12 (Att. 66); *Contact Lens Antitrust Lawsuit Settles – Lens Wearers Eligible for Benefits*, News Release Iowa Dept. of Justice, May 23, 2001, www.state.iowa.us/government/ag/contact_lenses_J_J.htm (Att. 65).

¹³⁰ *In re: Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla.), AOA Settlement Agreement, dated May 22, 2001 (Att. 28).

ECP, (3) encourage ECPs to boycott certain lens manufacturers or to write prescriptions for lenses based on the lens manufacturer's relationship with alternative sellers, or (4) enter into an agreement with any manufacturer to restrict the supply of contact lenses to alternative sellers.¹³¹

The fact that the AOA was enjoined from making unsubstantiated claims regarding the health risks associated with purchasing contact lenses from alternative sellers is highly significant. As mentioned, ECP claims that purchasing contact lenses from alternative sellers somehow compromises ocular health have been discredited.¹³² Since the AOA settlement, the state Attorneys General repeatedly have asked the AOA to produce any valid clinical or scientific data of increased health complications associated with purchasing contact lenses from alternative sellers, but no such data has ever been produced.¹³³

3. Post *In re: Disposable Contact Lens Antitrust Litigation* – ECPs Continue Their Anticompetitive Practices

Unfortunately, the settlement agreements in *In re: Disposable Contact Lens Antitrust Litigation* did not curb the anticompetitive activities of most ECPs. The contact lens industry has continued to be victimized by the anticompetitive practices of ECPs and related market inefficiencies, largely driven by: (1) optometrists' inherent conflict of interest in being allowed to sell what they prescribe, and (2) the fact that ECPs still dominate state boards and work fervently to establish regulations that hinder rather than promote competition from alternative sellers.

a. ECPs Still Engage In Anticompetitive Practices

As mentioned, the fact that optometrists can sell what they prescribe creates a fundamental conflict of interest that works to the detriment of consumers and competition.¹³⁴ Given that ECPs rely on the sale of ophthalmic goods, including eyeglasses and contact lenses, for the majority of their revenue, they have a powerful economic incentive to exclude others from the market. Similarly, given that ECPs are the gatekeepers of contact lens prescriptions and that they have access to their customers, they have ample opportunity to engage in behaviors that prevent fair competition.

Indeed, even after *In re: Disposable Contact Lens Antitrust Litigation*, ECPs continued to engage in tactics, such as:

¹³¹ Specifically, the settlement agreement stated: "The AOA shall not represent directly or indirectly that the incidence or likelihood of eye health problems arising from the use of replacement disposable contact lenses is affected by or causally related to the channel of trade from which the buyer obtains such lenses. Specifically, the AOA shall not represent directly or indirectly that increased eye health risk is inherent in the distribution of replacement disposable contact lenses by mail order, pharmacies, or drug stores. This paragraph shall not prohibit the AOA from making such representations where such representations are supported by valid, clinical or scientific data." *Id.* at 9.

¹³² *See supra*, discussion at Section II(B).

¹³³ Hubbard Testimony, Sept. 9, 2003, at 7-10 (Att. 5).

¹³⁴ Fellmeth Comments (Att. 45); Letter to the Joint Legislative Sunset Review Committee from Julianne D'Angelo Fellmeth, dated Jan. 4, 2002 ("Fellmeth Letter") (Att. 67).

- (1) Outright refusal to release or verify prescriptions;¹³⁵
- (2) Evading or ignoring requests to release or verify prescriptions;¹³⁶
- (3) Misleading consumers about their legal right to their prescription;¹³⁷
- (4) Falsely claiming increased health risks from purchasing replacement lenses elsewhere;¹³⁸
- (5) Conditioning eye care on the consumer's agreement to purchase lenses from the EPC;
- (6) Utilizing a host of tactics to dissuade consumers from obtaining their prescription (*e.g.*, delay tactics, liability waiver forms,¹³⁹ charging fees to release prescriptions);
- (7) Rendering prescriptions useless for purchasing lenses elsewhere (*e.g.*, writing abbreviated expiration dates as short as one day,¹⁴⁰ releasing eyeglass prescriptions, rather than contact

¹³⁵ See, *e.g.*, *Lens Users Pay Higher Prices Buying Contact Lenses from Someone Other than Your Doctor Can Save You Big Bucks. But It's Not Easy In Michigan, Where Many Offices Simply Won't Hand Over the Prescription*, Detroit Free Press, Dec. 4, 1998 ("Of 50 optometry offices surveyed . . . , only one would release a contact lens prescription to patients after an exam") (Att. 68); Ronald P. Snyder, O.D., F.A.A.O., *Winning the War Against Mail-Order Contact Lenses*, Optometry Today (Jan./Feb. 1993) (Att. 69); Hubbard Testimony, Sept. 9, 2003, at 3, 6 (Att. 5).

¹³⁶ See, *e.g.*, Martinez Testimony (reporting that some consumers that she interviewed, who asked their ECPs for a prescription "were stalled until their prescription expired, [or otherwise] treated deceptively") (Att. 8); see also 1-800 Conflicting Responses to Verification Requests (indicating that ECPs are playing games to thwart alternative sellers' sales) (Att. 70); Rich Kirkner, *When Mail-Order Calls, How to Verify an Rx- or Not*, Review of Optometry Online (Sept. 15, 2002) (Att. 71).

¹³⁷ See, *e.g.*, Hubbard Testimony, Sept. 9, 2003, at 3, 6 (Att. 5); *infra*, discussion at Section IV (discussing the Texas Optometric Association Website, <http://texas.optometry.net/public/patientrights/index.asp>) (Att. 72); see also 1-800 Letter to Beverly Rothstein, Office of the Chief Counsel, Food and Drug Administration, dated Sept. 24, 2002 (chronicling J&J Vision Care's misstatements about prescription verification) (Att. 73).

¹³⁸ See, *e.g.*, Letter from Eliot Spitzer, Attorney General of New York State to Counsel for the AOA, dated Sept. 4, 2003 (chronicling incidents where AOA has recently claimed or implied that alternative sellers jeopardize consumer eye health, in violation of the injunction) (Att. 74). The AOA also continued to lobby for state laws that favored private ECPs, to the detriment of alternative sellers, such as affirmative verification laws, using ocular health as a pretext for its support, in violation of the injunction. See E-mail from Robert Hubbard to Biard MacGuineas, *et al.*, *AOA Bulletin 42, Vol. 61*, dated Apr. 30, 2003 (Att. 75); 61(43) AOA Bulletin from the State Government Relations Center, dated Apr. 7, 2003 (Att. 76); Arkansas H.B. 2286, *An Act to Amend Provisions of the Arkansas Code Pertaining to the Practice of Optometry*, Mar. 31, 2003 (Att. 77); AOA State Legislation Monthly Newsletter, dated Apr. 2, 2003 (Att. 78); AOA News Online, dated Apr. 21, 2003 (Att. 79); AOA News Online, dated Mar. 24, 2003 (Att. 80); AOA News Online, dated May 5, 2003 (Att. 81).

¹³⁹ See, *e.g.*, Hubbard Testimony, Sept. 9, 2003, at 3, 6 (Att. 5).

¹⁴⁰ See, *e.g.*, Joe B. Goldberg, O.D., F.A.A.P., *If You Can't Beat Mail Order Companies, Join Them*, Contact Lens Spectrum: Readers' Forum (June 2002) (Att. 82).

lens prescriptions,¹⁴¹ and writing prescriptions for “private label contact lenses,”¹⁴² or “doctor exclusive contact lenses”);¹⁴³ and

(8) Otherwise interfering with contact lens sales by alternative sellers.¹⁴⁴

ECPs routinely publish articles in their trade publications and post notices on Internet bulletin boards giving tips on how to discourage consumers from obtaining their prescription and on how to prevent competition from alternative sellers.¹⁴⁵

Several ECP articles go so far as to recommend using an alternative seller’s verification request as an opportunity for the ECP to interfere with a transaction and make the sale himself.¹⁴⁶ ECPs typically accomplish this either by: (1) contacting consumers directly to persuade them to cancel their contracts with the alternative seller, a practice that arguably amounts to tortious interference with contract, or (2) causing the alternative seller to cancel the order by improperly refusing to release or verify the prescription and then contacting the consumer to make the sale.¹⁴⁷ Examples of such ECP advice include:

- We’ll call the patient and tell him we’re not going to release this information without his permission. Then we say, “Actually, we’re a little surprised because we can get you contact lenses more competitively than you can get them there.”¹⁴⁸

¹⁴¹ See, e.g., Martinez Testimony (“One individual asked for their contact lens prescription and received instead an eyeglass prescription. Unfortunately, this individual had always been a contact lens wearer and had never received an examination for eyeglasses”) (Att. 8).

¹⁴² See, e.g., Hubbard Testimony, Sept. 9, 2003, at 3, 6 (Att. 5).

¹⁴³ See, e.g., *Using Private Label Lenses to Keep Patients in the Practice*, Contact Lens Spectrum (Jan. 2002) (Att. 83).

¹⁴⁴ See, e.g., Michelle Boyles, *Cole to Give Exams to 1-800 Customers*, 140 Review of Optometry 4 (Aug. 15, 2003) (Att. 84).

¹⁴⁵ See, e.g., *Using Private Label Lenses to Keep Patients in the Practice*, Contact Lens Spectrum (Jan. 2002) (Att. 83); Ronald P. Snyder, O.D., F.A.A.O., *Winning the War Against Mail-Order Contact Lenses*, Optometry Today (Jan./Feb. 1993) (Att. 69); Joe B. Goldberg, O.D., F.A.A.P., *If You Can’t Beat Mail Order Companies, Join Them*, Contact Lens Spectrum: Readers’ Forum (June 2002) (Att. 82); Michelle Boyles, *Cole to Give Exams to 1-800 Customers*, 140 Review of Optometry 4 (Aug. 15, 2003) (Att. 84).

¹⁴⁶ The Restatement (Second) of Torts provides that “one who intentionally and improperly interferes with the performance of a contract (except a contract to marry) between another and a third person by inducing or otherwise causing the third person not to perform the contract, is subject to liability to the other for the pecuniary loss resulting to the other from the failure of the third person to perform the contract.” *The Restatement (Second) of Torts* § 766 (1979) (Att. 85).

¹⁴⁷ Ronald P. Snyder, O.D., F.A.A.O., *Winning the War Against Mail-Order Contact Lenses*, Optometry Today (Jan./Feb. 1993) (Att. 69); see also Gary Gerber, OD, *Patient “Cheapskate” and The New Law*, Review of Contact Lenses (Jan. 2004) (Att. 86); Michelle Boyles, *Cole to Give Exams to 1-800 Customers*, 140 Review of Optometry 4 (Aug. 15, 2003) (Att. 84); Joseph Barr, O.D., M.S., F.A.A.O., *Annual Report: 2003*, Contact Lens Spectrum (Jan. 2004) (Att. 87).

¹⁴⁸ Rich Kirkner, *Can You Survive the Ultimate Challenge*, Review of Optometry, Apr. 15, 2001 (Att. 88).

- If a direct-to-consumer service calls to verify a prescription, contact the patient about your own website. Patients can order any time, night or day, and they do not have to *wait* for your approval as they would with services such as 1-800 Contacts. (You can control which options are available to them).¹⁴⁹

b. ECPs Still Develop, Promote and Obtain State Laws and Regulations that Prevent Competition, Increase Consumer Prices, and Compromise Ocular Health

As summarized in the comments that 1-800 submitted to the FTC regarding E-competition, on January 13, 2003,¹⁵⁰ ECPs and their trade associations still dominate state boards and work fervently to influence state legislation and regulations.¹⁵¹ Current state barriers to competition in the contact lens industry include: (1) prescription release and verification requirements, (2) restrictions on who can sell, (3) prescription expiration requirements, (4) prescription brand specification requirements, and (5) disparate enforcement of state requirements by state boards.

Notably, to the extent these state laws or regulations discriminate against out-of-state businesses or otherwise impose an undue burden on interstate commerce, they likely run afoul of the Dormant Commerce Clause.¹⁵² In addition, to the extent that these state laws or regulations conflict with the objectives of the Fairness Act, they are preempted thereby, as discussed more fully below.

i. Prescription Release and Verification Requirements

Many states purport to require sellers to obtain or verify prescriptions with the consumer's ECP before selling replacement lenses without *any* corresponding duty on the part of the ECP to release or verify valid prescriptions. Indeed, prior to the Fairness Act, in many states ECPs were not required to release prescriptions at all,¹⁵³ and other states required that consumers specifically request a prescription, sometimes in writing.¹⁵⁴

¹⁴⁹ Christopher Kent, *Strategic Dispensing*, Ophthalmology Management (Feb. 2003) (quotations omitted, emphasis added) (Att. 89).

¹⁵⁰ Letter to Donald S. Clark, Office of the Secretary, FTC, from Jonathan C. Coon, Chief Executive Officer of 1-800, dated Jan. 13, 2003 (Att. 90).

¹⁵¹ See *supra*, discussion at Section II(A)(3).

¹⁵² See Const. Art. 1, § 8, cl. 3; see also *West Lynn Creamery Inc. v. Healy*, 512 U.S. 186, 192 (1994) (“The Commerce Clause also limits the power of the [states] to adopt regulations that discriminate against interstate commerce. This negative aspect of the Commerce Clause prohibits economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors Thus, state statutes that clearly discriminate against interstate commerce are routinely struck down . . . unless the discrimination is demonstrably justified by a valid factor unrelated to economic protectionism”) (quotations and citations omitted).

¹⁵³ See, e.g., Alaska State Medical Board, Admin. Code, 12 AAC § 40.967 (providing that patients can receive only copies of “patient records” within 90 days of a written request) (Att. 91); Arizona Board of Optometry Rules and Regulations, AAC § R4-21-305 (vague rule only inferentially addresses prescription release, suggesting that ECPs have discretion to release) (Att. 92); Connecticut, Conn. Gen. Stat. § 20-7c (only requires that ECPs provide “records of prescriptions” within 30 days, upon written request) (Att. 93); Hawaii, WCHR 16-92-49 (gives optometrists power to refuse to release, but states that it is unprofessional misconduct to fail to make patient documents available upon request) (Att. 94); Idaho,

Many ECPs, in the absence of state law mandating automatic release, do not release contact lens prescriptions. Notably, the results of a survey in Michigan, a state that did not require prescription release, showed that only 1 in 50 optometry offices released prescriptions.¹⁵⁵ Similarly, in 1997, prior to the enactment of a Texas law that required optometrists to release contact lens prescriptions upon request, a Consumers Union survey showed that 65% percent of optometrists were unwilling to release contact lens prescriptions.¹⁵⁶ Even after the release-upon-request provision was enacted in Texas, a follow-up Consumers Union Survey showed that 57% of optometrists would not release prescriptions “unless patients came back for a follow-up visit.”¹⁵⁷

Furthermore, a number of state laws and regulations overly restrict the ways in which prescriptions are communicated - e.g., requiring original, hand-signed copies,¹⁵⁸ requiring sellers to obtain a physical copy of the prescription,¹⁵⁹ requiring a “face-to-face transaction,” (i.e., which prohibits telephone and electronic transmissions),¹⁶⁰ and requiring sellers to wait indefinitely for an affirmative response from ECPs before selling replacement lenses.¹⁶¹ These types of restrictions increase the already disparate burden placed on alternative sellers, who have to obtain information from their competitors before they sell.

Rules of the State Board of Optometry, IDAPA §§ 24.10.01.425, 24.10.01.475 (requiring the release of eyeglass prescriptions, but not contacts, and requiring optometrists to maintain the patient's complete record, including copies of the prescription given to patients) (Att. 95); Missouri, Optometrists, R.S. Mo. §§ 336.010 – 336.225 (Att. 96), State Board of Optometry, 4 CSR §§ 210-2.010 – 210-2.081 (silent as to prescription release) (among other states) (Att. 97).

¹⁵⁴ See, e.g., New Jersey, N.J. Stat. § 52:17B-41.30 (Att. 98); N.J.A.C. 13:38-6.1(c) (requiring the prescription to be accompanied by a written warning to see an eye doctor regularly) (Att. 99); Texas Contact Lens Prescription Act, § 353.156 (Att. 16).

¹⁵⁵ *Lens Users Pay Higher Prices Buying Contact Lenses from Someone Other than Your Doctor Can Save You Big Bucks. But It's Not Easy In Michigan, Where Many Offices Simply Won't Hand Over the Prescription*, Detroit Free Press, Dec. 4, 1998 (“Of 50 optometry offices surveyed . . . , only one would release a contact lens prescription to patients after an exam”) (Att. 68).

¹⁵⁶ See *Out of Focus: Contact Lens Policy in Texas*, Consumers Union, Southwest Regional Office, Mar. 1997 (Att. 100).

¹⁵⁷ See, e.g., *The Eyes Don't Have It Yet*, Consumers Union, Southwest Regional Office (Jan. 2001) (Att. 101); *Prescription for Change*, Consumer Reports (June 2001) (Att. 102); see also 1-800 Conflicting Responses to Verification Requests (indicating that ECPs are playing games to thwart alternative sellers' sales) (Att. 70).

¹⁵⁸ See, e.g., Texas Contact Lens Prescription Act §§ 353.101, 353.152 (Att. 16); Amy Borrus, *The Broad Backlash Against E-Tailers*, Business Week (Feb. 5, 2001) (Att. 103).

¹⁵⁹ See, e.g., Georgia Health Statutes, O.C.G.A. §§ 31-12-12(h) (Att. 104); Mississippi State Board of Optometry, Board Rule 8.1(a) (Att. 105).

¹⁶⁰ See, e.g., Georgia Health Statutes, O.C.G.A. §§ 31-12-12(h) (Att. 104); Mississippi State Board of Optometry, Board Rule 8.1(a) (Att. 105).

¹⁶¹ See, e.g., Texas Contact Lens Prescription Act, § 353.101 (Att. 16); see also Settlement Agreement and General Release of Claims Between the Texas Optometry Board and 1-800, dated May 10, 2002 (Att. 17); Reporter's Record of Settlement Agreement between the Texas Optometry Board and 1-800, dated April 22, 2002 (Att. 18).

ii. Restrictions on Who Can Sell

A number of state laws or regulations purport to prohibit or unduly restrict the ability of alternative sellers to compete in the retail sale of contact lenses. Such laws effectively operate either to bar entry into the contact lens market altogether or to impose substantially heavier burdens on alternative sellers than ECPs, to the detriment of both consumers and competition.

For example, a number of state laws or regulations purport to require anyone selling contact lenses to hold a valid ECP license issued by their state (*i.e.*, to be an ECP). States arguably falling within this category include, among others, North Carolina,¹⁶² Tennessee,¹⁶³ Mississippi,¹⁶⁴ and Washington,¹⁶⁵ (with similar laws pending in Alaska¹⁶⁶ and Georgia¹⁶⁷).¹⁶⁸ As the FTC has repeatedly recognized, imposition of professional licensure requirements on alternative sellers who provide no such professional services (*e.g.*, do not fit or prescribe lenses) but are engaged in a purely retail function (*i.e.*, selling replacement lenses) creates substantial costs and wholly unnecessary burdens on alternative sellers.¹⁶⁹ As discussed more fully below, prohibiting anyone other than a licensed ECP from selling contact lenses to consumers also directly conflicts with the primary objective of the Fairness Act to ensure meaningful consumer choice and competition from non-ECPs.

Likewise, there are a number of state laws and regulations that attempt to directly restrict interstate sales of contact lenses.¹⁷⁰ Georgia, for example, requires that contact lens sales take place in a “face-to-face transaction.”¹⁷¹ Similarly, Arizona requires that nonresident sellers both register with their state optometry board and hold a valid pharmacy license, but imposes no such pharmacy licensure

¹⁶² See N.C. Gen. Stat. §§ 90-235, 90-236.1, 90.252 (Att. 15).

¹⁶³ Tennessee Optometry Practice Act, Tenn. Code Ann. §§ 63-8-102, 63-8-113 (Att. 106); Tennessee Dispensing Opticians, § 63-14-102 (Att. 107).

¹⁶⁴ Mississippi Optometry Statutes, Miss. Code Ann. § 73-19-61 (Att. 108); Mississippi State Board of Optometry Board Rule 8.1(a) (Att. 105).

¹⁶⁵ Washington Consumer Access to Vision Care Act, ARWC §§ 18.195.020 (Att. 109); The Dispensing Opticians Act, ARWC § 18.34.141 (Att. 110).

¹⁶⁶ Alaska House Bill 502, “An Act relating to dispensing opticians and dispensing optician apprentices,” introduced Feb. 16, 2004 (legislation pending) (Att. 111).

¹⁶⁷ Georgia, S.B. 513, dated Feb. 13, 2004 (Att. 112).

¹⁶⁸ 1-800 continues to dispute the applicability and enforceability of these and other state laws to nonresident sellers of replacement contact lenses.

¹⁶⁹ See, *e.g.*, *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, a Report from the Staff of the FTC (Mar. 2004), at 16-23, 31; Comments of the Staff of the FTC, Intervenor before the Connecticut Board of Examiners for Opticians, Mar. 27, 2002 (Att. 9).

¹⁷⁰ Not coincidentally, nonresident sellers are almost exclusively alternative sellers (*i.e.*, mail-order, Internet, or pharmacy), whereas resident sellers consist primarily of ECPs.

¹⁷¹ See Georgia Health Statutes, O.C.G.A. §§ 31-12-12(h) (Att. 104).

requirement on resident sellers.¹⁷² Other states have licensure or registration requirements that attempt to impose residency requirements or otherwise restrict the ability of nonresidents (*i.e.*, primarily alternative sellers) from competing with residents (*i.e.*, primarily ECPs) in the retail of contact lenses.

iii. Prescription Expiration Requirements

Many states do not set a minimum time period for the expiration of contact lens prescriptions.¹⁷³ This problem, addressed in the Fairness Act, allows ECPs to issue prescriptions with abbreviated expiration dates to preclude the consumer from purchasing replacement lenses elsewhere. This activity ranges from the use of such short expiration dates to render the prescription essentially useless for purchasing lenses elsewhere (*e.g.*, expiration dates as short as one day) to the use of several month intervals. Either tactic forces the consumer to come in for unnecessary eye exams, at which time the ECP can make a sales pitch for sufficient replacement lenses to last until the next interval.

This tactic has been widely discussed in optometric trade journals as an effective technique to prevent competition from alternative sellers of replacement lenses.¹⁷⁴ One article, published in the June 2002 issue of the Contact Lens Spectrum, entitled “If You Can’t Beat Mail Order Companies, Join Them,” recommended:

We can’t eliminate mail order replacement businesses, but we can use our professional ingenuity and patients’ contact lens prescriptions to challenge them. Beat Them [P]ractitioners must limit the service life of a lens prescription Each practitioner can determine the expiration date of a lens prescription. I recommend a six-month interval It may also inhibit mail order houses from filling orders for replacement lenses once the prescription has expired.¹⁷⁵

Notably, the six month expiration period suggested by this article has no medical basis and is substantially shorter than the period recommended by leading professional associations (generally 2 years) and state Medicaid statutes (generally 1 or 2 years).¹⁷⁶

¹⁷² See Arizona Optometry Statutes, A.R.S. § 32-1773 (Att. 113).

¹⁷³ See, *e.g.*, Alabama Board of Optometry Rules and Regulations, Chapter 630-X-12-.03 (requiring a “reasonable expiration date”) (Att. 114); Notice of Proposed Rulemaking for Oregon Admin. Rules, § 852-20-030 (Mar. 2004) (Att. 115). Other states, such as, Tennessee, Connecticut, and Hawaii do not mention expiration date in their statutes or rules.

¹⁷⁴ See, *e.g.*, Joe B. Goldberg, O.D., F.A.A.P., *If You Can’t Beat Mail Order Companies, Join Them*, Contact Lens Spectrum: Readers’ Forum (June 2002) (Att. 82).

¹⁷⁵ See *id.*

¹⁷⁶ See *infra*, Section III(C)(2) (discussing AOA recommendation for exam frequency). The majority of states that cover regular refractive eye exams under their Medicaid programs allow adult Medicaid recipients to receive one eye exam every 2 years. See Survey of 50 States, District of Columbia and Territories Released Jointly by the Kaiser Commission on Medicaid and Uninsured with the National Conference of State Legislatures, Jan. 2003 (Att. 116); see, *e.g.*, Alabama Medicaid Agency Administrative Code Ch. 560-X-17.03 (authorizes Medicaid recipients over the age of 21

iv. Prescription Brand Specification Requirements

Some states require contact lens prescriptions to be brand-specific (*i.e.*, the prescription effectively locks the consumer into a particular brand), with no ability to substitute.¹⁷⁷ ECPs have taken advantage of these laws by writing prescriptions for a brand that only they sell – *i.e.*, a “private label contact lens.” This technique is also described in *Contact Lens Spectrum*: “I often do not give my patients a choice. I don’t say this is a private label lens. I just say, “This is the best lens for you. It’s the one you should be wearing.”¹⁷⁸

This technique, which effectively forces consumers to buy lenses at premium prices from the prescribing ECP, is deceptive because “private label contact lenses” are not actually unique. Although the manufacturers sell the lenses to certain ECPs under “private label” names, the manufacturers also sell the same lenses to alternative sellers under another name.

In addition, because contact lens prescriptions are often brand specific, manufacturers are often far more concerned with persuading ECPs to prescribe their particular brand than satisfying the ultimate consumer. Indeed, as discussed in Section II(B)(2), regarding *In re: Disposable Contact Lens Litigation*, manufacturers historically have attempted to persuade ECPs to prescribe their brand by impeding the ability of alternative sellers, such as 1-800, to compete with ECPs in the retail sale of their lenses.

Despite the injunctions imposed in the *In re: Disposable Contact Lens Antitrust Litigation* settlements,¹⁷⁹ prohibiting J&J Vision Care, Ciba Vision, and Bausch & Lomb, from engaging in these activities, some manufacturers are still unabashedly building their entire marketing programs around promises to insulate ECPs who prescribe their lenses from competition by tracking and cutting off alternative sellers’ sources of supply. A sampling of these types of ads directed at ECPs follow:

- Ocular Sciences now stands as the only major soft contact lens manufacturer to sell exclusively to eye care professionals. Ocular Sciences does not sell to alternative non-authorized channels of distribution, such as 1-800 Contacts and other mail order and Internet replacement services. . . . We employ a unique tracking system to monitor and minimize diversion into alternative non-authorized channels. We will continue to cut off diverters. . . . “No Practitioner. No Slit Lamp. No Lenses.” This was our policy when we started. This is our policy today. And, we have no intention of changing this policy in the future.¹⁸⁰

to receive one complete eye exam each 2 calendar years; recipients under 21 are authorized one complete eye exam each calendar year) (Att. 117).

¹⁷⁷ See, e.g., Arizona Optometry Statutes, ARS § 32-1774(B)(3) (Att. 118); Arizona Board of Optometry Rules and Regulations, § R4-21-305(A)(4) (Att. 92); Alaska Administrative Code, 12 AAC 48.920 (requiring the name of the manufacturer for soft contact lenses, but not hard) (Att. 119).

¹⁷⁸ *Using Private Label Lenses to Keep Patients in the Practice*, *Contact Lens Spectrum* (Jan. 2002) (Att. 83).

¹⁷⁹ See *supra*, at Section II(B)(2)(c).

¹⁸⁰ See Miscellaneous Ocular Science, Proactive 55, Proclear, and Extreme H20 Ads (Att. 120).

- Traditional eye care is being challenged. Mail order is rampant. Every Tom, Dick, and Harry is offering your patients “low priced” disposables. The system is broken! . . . No practitioner, no slit lamp, no Biomedics lens. (Our special bar coding tracks every six pack-divert to mail order and we cut you off).¹⁸¹
- If it threatens your practice, we’ll see it. As the only major contact lens manufacturer that does not sell to non-professional Internet and mail-order resellers, we’re on red alert for market predators who divert our lenses. We promote patient loyalty . . . (Over 90% of Biomedics wearers return to their prescribing professional). . . . The way we see it, keeping our eyes wide open keeps your practice well protected.¹⁸²
- Sorry mailorder guys, our monthly PROACTIVE 55 blister packs will be barcoded just like our disposable lenses. . . . Product Coding To Help You Retain Your Patients.¹⁸³

v. Disparate Enforcement of State Requirements by State Boards

As mentioned in Section II(B)(1)(a) herein, laws and regulations governing the prescribing and selling of replacement contact lenses are not only erected and maintained by state boards dominated by ECPs, but they are also disparately enforced – or not enforced at all – against the ECPs they license. 1-800’s experience in Texas is perhaps the best example of a state board refusing to take action even against truly widespread and blatantly anticompetitive conduct by the ECPs it licenses.

In 2002, 1-800 reached an agreement with the Texas Optometry Board (“TOB”), whereby the TOB committed to require ECPs to respond to written prescription verification requests from alternative sellers, and 1-800 agreed to secure affirmative verification from optometrists before selling.¹⁸⁴ Yet, as of February 2003, Texas ECPs still refused to respond to written verification requests *nearly half the time*,¹⁸⁵ preventing 1-800 from shipping to those consumers. Moreover, many of those who did respond gave invalid excuses for not releasing valid, unexpired prescriptions, such as: “A copy of the patient presc. is available to patient in office.”¹⁸⁶

¹⁸⁰ *See id.*

¹⁸¹ *See id.*

¹⁸² *See id.*

¹⁸³ *See id.*

¹⁸⁴ *See* Letter to Dewey Helmcamp, Esq., Assistant Attorney General, Administrative Law Division, Texas Attorney General’s Office, from Garth T. Vincent, Munger, Tolles & Olsen LLP, dated Feb. 27, 2003 (Att. 121); *see also* Letter to Dewey Helmcamp, Esq., Assistant Attorney General, Administrative Law Division, Texas Attorney General’s Office, from Garth T. Vincent, Munger, Tolles & Olsen LLP, dated Aug. 27, 2002 (Att. 122); 1-800 Contacts and the Texas Optometry Board (summary with attachments) (Att. 123).

¹⁸⁵ *See id.*

¹⁸⁶ *See* Attachment A to Letter to Dewey Helmcamp, Esq., Assistant Attorney General, Administrative Law Division, Texas Attorney General’s Office, from Garth T. Vincent, Munger, Tolles & Olsen LLP, dated Feb. 27, 2003 (Att. 121).

In addition, increasing numbers of Texas ECPs have attempted to justify their violation of Texas law by claiming that the regulations issued under the Health Insurance Portability and Accountability Act of 1996 (the "HIPAA Privacy Rule")¹⁸⁷ bars them from providing prescription information to anyone other than the consumer.¹⁸⁸ As discussed in Section III(B)(3)(c) herein, this argument is both false and frivolous.

Remarkably, from the time that the TOB agreement became effective through February 27, 2003, 1-800 had lost approximately 33,000 orders due to such widespread violations of Texas law by Texas ECPs. During this period, literally tens of thousands of consumers were wrongly denied the right to purchase replacement contact lenses from the provider of their choice. Approximately 3,100 of those consumers filed with the TOB, hand signed complaints against their ECPs.¹⁸⁹

To the best of 1-800's knowledge, however, the TOB to date has failed to take action against a single ECP for these pervasive violations of Texas law, a fact which is particularly ironic given that the TOB represented to the FTC in 1997 that "there is no need for a [f]ederal prescription release rule."¹⁹⁰

C. Legislative Success Story: California

California, state legislators, ECPs, consumer groups, and alternative sellers were able to overcome the disparate interests in the contact lens industry and work together to craft a system that protects both consumer health and competition.¹⁹¹

In response to the widespread refusal of California ECPs to respond affirmatively to its verification requests, 1-800 initiated the presumed verification method in California in 1998, with the approval of the California Medical Board. Although this practice initially spawned litigation with California ECPs, the litigation ultimately settled with an agreement that expressly allowed presumed verification with a waiting period of *three business hours*.¹⁹²

In September 2002, Governor Davis signed legislation that codified this system with some modifications. That legislation provided for the presumed verification system as follows:

¹⁸⁷ See generally, 45 C.F.R. pts. 160, 164 (2003).

¹⁸⁸ See Attachment A to Letter to Dewey Helmcamp, Esq., Assistant Attorney General, Administrative Law Division, Texas Attorney General's Office, from Garth T. Vincent, Munger, Tolles & Olsen LLP, dated Feb. 27, 2003 (Att. 121).

¹⁸⁹ See Letter to Dewey Helmcamp, Esq., Assistant Attorney General, Administrative Law Division, Texas Attorney General's Office, from Garth T. Vincent, Munger, Tolles & Olsen LLP, dated Feb. 27, 2003 (Att. 121); see also Letter to the Members of the Texas House Public Health Committee, from Texas Citizens for a Sound Economy, dated May 5, 2003; Venable Testimony (Att 19).

¹⁹⁰ See Letter from the Texas Optometry Board to the FTC, dated Sept. 2, 1997 (Att. 124).

¹⁹¹ See *California Optometric Association Negotiates Contact Lens Legislation*, Aug. 21, 2002 (Att. 20); Letter to The Honorable Lou Correa, California Assemblyman, from the California Optometric Assoc., dated July 15, 2002 (Att. 29).

¹⁹² *Craig S. Steinberg, et al. v. 1-800 Contacts*, Los Angeles Superior Court Case No. BC 194243.

A prescription shall be deemed confirmed upon the occurrence of one of the following: . . . (2) The prescriber fails to communicate with the seller by 2 p.m. of the next business day after the seller requests confirmation, or the prescriber fails to communicate with the seller by the next business day on or before the same time of day that the seller requested confirmation, whichever is sooner. For purposes of this paragraph, "business day" means each day except a Sunday or a federal holiday.¹⁹³

Under this system, if the seller contacts the prescriber before 2 p.m., then the prescriber has 24 hours to respond, and if the seller contacts the prescriber after 2 p.m., then the prescriber has at least 5 business hours to respond, given that the average ECP opens at 9 a.m.¹⁹⁴ The largest state optometric association in the nation - the COA - supported this legislation, praising it as supporting "safe and responsible patient access to contact lens prescriptions as well as the safe and responsible filling of those prescriptions," and for striking "a reasonable balance between access and accountability."¹⁹⁵ In addition, consumers groups, such as Citizens for a Sound Economy and the Consumers Union have testified before Congress expressing unqualified support for presumed verification.¹⁹⁶

Notably, other states, such as Mississippi and Utah, have adopted similar presumed verification systems. Mississippi has a one hour waiting period for sellers. In other words, it permits prescribing ECPs one hour to respond to prescription confirmation requests.¹⁹⁷ Utah has no waiting period, but it requires sellers to inform patients that the contact lens prescription is invalid if the seller receives such information from the prescriber within 72 hours of the initial prescription verification request.¹⁹⁸

Other important provisions in the California legislation provide for:

- Mandatory release of contact lens prescriptions after the eye examination or lens fitting process (*i.e.*, the initial examination, confirming the lens fit, the trial lens period, and any necessary follow-up to ensure lens accuracy),
- Prescription expiration date of one to two years from the date of issuance (*i.e.*, the date on which the consumer receives a copy of the prescription),

¹⁹³ California Assembly Bill No. 2020, signed into law on September 23, 2002, codified at Calif. Business and Professions Code § 2546.6(a) ([Att. 125](#)).

¹⁹⁴ *See* Synovate Survey of ECP Business Hours ([Att. 32](#)).

¹⁹⁵ Letter from the COA to the Honorable Lou Correa, California Assemblyman, dated July 15, 2002 ([Att. 29](#)).

¹⁹⁶ *See* Venable Testimony ([Att 19](#)); *see also* Gadhia Testimony ([Att. 7](#)).

¹⁹⁷ *See* Mississippi Code § 73-10-14 ([Att. 126](#)).

¹⁹⁸ *See* Utah Code Ann. § 58-16a-801 ([Att. 127](#)).

- Mandatory inclusion of trade name and manufacturer on prescriptions for “private label contact lenses,”
- Prohibition of charging additional fees beyond the price of the contact lens exam as a condition of releasing the prescription,
- Prohibition of requiring patients to sign any disclaimer as a condition of receiving a prescription,
- Prescription verification obligations for ECPs,
- ECP specification of the basis for reporting that a prescription is invalid to a seller, and
- Private label substitution.¹⁹⁹

1-800’s experience with the California law has been successful. 1-800’s sales data demonstrates that this system works approximately 96.5% of the time. In only approximately 0.4% of the cases, 1-800 receives information outside of the California time frame indicating that a prescription is actually incorrect. The remaining responses received outside the time frame (3.1%) are simply uncooperative ECP responses or reports that a prescription has expired. This error rate is better than pharmacy dispensing error rates in hospitals, which has been estimated to be approximately 3-4%.²⁰⁰

Notably, even in the 0.4% of cases where the prescription is incorrect, the consumer is not harmed because it is 1-800’s policy to notify the consumer that his or her prescription is invalid, to attach any correspondence received from the ECP, and to allow the customer to return unused product that was received.

III. Comments Regarding Specific Provisions of the Proposed Contact Lens Rule

To ensure meaningful consumer choice and competition from alternative sellers, Congress enacted the Fairness Act, which provides for countermeasures to many of the anticompetitive behaviors that ECPs have been engaging in over the last 30 to 40 years. As Chairman Sensenbrenner aptly observed: “[The Fairness Act] ensures that unscrupulous eye doctors will no longer be able to hold consumers’ contact lens prescriptions hostage, forcing them to purchase lenses solely from their doctor’s office.”²⁰¹

¹⁹⁹ See Calif. Business and Professions Code § 2541 *et seq.* (Att. 128).

²⁰⁰ See, e.g., Elizabeth Allan Flynn, *et al.*, *Relationships Between Ambient Sounds and the Accuracy of Pharmacists’ Prescription-Filling Performance*, 38(4) *Human Factors* 614 (1996) (finding an error rate of 3.23%, and noting that medication dispensing error rates ranging from 2% to 24% have been detected) (Att. 129); Richard A. Knox, *Prescription Errors Tied to Lack of Advice Pharmacists Skirting Law, Mass. Study Finds*, *Boston Globe*, Feb. 10, 1999 (summarizing a Massachusetts study that found a 4% error rate) (Att. 130).

²⁰¹ See Sensenbrenner Speech (Att. 1).

ECPs, however, in an attempt to circumvent the countermeasures in the Fairness Act, have already begun to develop new variations of old anticompetitive games. Although 1-800 applauds the FTC's efforts to propose rules that would implement the Fairness Act's primary countermeasures, it believes that the proposed rule does not adequately address more recent variations of ECP anticompetitive behavior, as would be necessary to eliminate once and for all these impediments to meaningful competition from alternative sellers. Even worse, 1-800 is concerned that certain provisions, such as the proposed definition of "business hour," would actually enshrine years of ECP anticompetitive behavior to the detriment of consumers, rather than level the playing field.

A. Definitions

The manner in which certain terms are defined in Section 315.2 of the proposed Contact Lens Rule²⁰² could determine whether the Fairness Act fulfills its objective of allowing for more contact lens retail competition and more choices for consumers, or whether the accessibility of contact lenses becomes even more restricted than it is presently. In particular, the definition of "business hour" is critical.

1. Business Hour

The definition of "business hour" is central to the Fairness Act. It will determine how convenient it is for consumers to purchase their lenses – whether it be from a prescriber or an alternative seller. It will impact the business hours kept by prescribers. If left as is, it could lead to the elimination of alternative sellers, dramatically impacting the range of choices available to consumers.

How long a consumer must wait for his or her lenses is frequently an important component of the contact lens business. This is particularly true for consumers who replace their contact lenses at the last minute, consumers who lose or tear a lens, and consumers who travel. A full 33% of 1-800's customers elect to pay additional fees to have their lenses shipped via express mail.

Alternative sellers who operate on the Internet 24/7, and who have expanded telephone hours, make the purchase of contact lenses more convenient for their customers – especially for those needing quick service. Traditional ECPs and associated retailers have responded by expanding their hours of business. Some have also moved into Internet sales to compete with alternative sellers.

The ability of alternative sellers to respond to the consumers' need to order lenses at the time of day most convenient to the consumer and to ship the lenses promptly, has made the market for contact lenses more competitive and more convenient for consumers. However, to the extent the definition of "business hour" restricts the ability of alternative sellers to respond to the needs of their customers, the ability of such sellers to compete will be hampered, and the marketplace for lenses will move in the direction of less choice and convenience for consumers.

²⁰² 69 Fed. Reg. at 5448, 5449.

Under the proposed rule, a prescription is presumed verified if the prescriber “fails to communicate with the seller within eight (8) business hours” after receiving prescription verification information.²⁰³ The proposed rule defines “business hour” as:

[A]n hour between 9 a.m. and 5 p.m., during a weekday (Monday through Friday), excluding Federal holidays. For purposes of Sec. 315.5(d)(3) [sic], “eight (8) business hours” shall be calculated from the first business hour that occurs after the seller provides the prescription verification request to the prescriber, and shall conclude after eight (8) business hours have elapsed. For verification requests received by a prescriber during non-business hours, the calculation of “eight (8) business hours” shall begin at 9 a.m. on the next weekday that is not a Federal holiday.²⁰⁴

The proposed rule then clarifies the definition of “business hour” with the following examples:

(1) A response to a verification request received at 10:30 a.m. on Monday morning would be required by 10:30 a.m. on Tuesday morning; (2) a response to a verification request received at 10 p.m. on Monday night would be required by 9:00 a.m. on Wednesday morning, *i.e.*, eight business hours after the verification period commences at 9 a.m. on Tuesday morning; (3) a response to a verification request received at 2 p.m. on Saturday afternoon would be required by 9 a.m. on Tuesday morning, *i.e.*, eight business hours after the verification period begins at 9 a.m. on Monday morning; and (4) a response to a verification request received at 10:30 a.m. in the morning on Columbus Day (a Monday) would be required by 9 a.m. on Wednesday morning, *i.e.*, eight business hours after the verification period commenced at 9 a.m. on Tuesday morning.²⁰⁵

In its proposed rule, the FTC questions: “(a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way? [and] (c) Should the definition include provisions addressing (i) prescriber vacation days, (ii) State or local holidays, (iii) weekend days, or (iv) other exceptions to normal business hours?”²⁰⁶

a. 1-800’s Concerns About the Proposed Definition of “Business Hour”

1-800 is troubled by the proposed definition of “business hour” and its accompanying examples. Taken together, they threaten to take legislation intended to make the industry more competitive and turn it on its head, potentially driving alternative sellers out of business and leaving consumers with fewer choices, less convenience, and higher prices.

²⁰³ *Id.* at 5449.

²⁰⁴ *Id.* at 5448.

²⁰⁵ *Id.* at 5441.

²⁰⁶ *Id.* at 5446.

Specifically: (1) three of the four examples in the proposed rule are mathematically inconsistent, (2) the proposed definition gives ECPs a distinct and wholly unfair hours of operation advantage and imposes a unwarranted waiting period on alternative sellers and all of their customers without any significant corresponding benefit, and (3) experience in California has demonstrated that a 5 hour verification period is actually more than sufficient and that an 8 hour period is both inefficient and unnecessary as a practical matter.

i. Three of the Four Examples in the Proposed Rule Are Mathematically Inconsistent with the Statutory 8 Hour Verification Period

Based on the language in the definition of “business hour,” examples (2), (3), and (4) in the proposed rule are mathematically inconsistent with the Fairness Act and internally inconsistent with the proposed regulation. The proposed definition provides that eight business hours “shall be calculated from the first business hour that occurs after the seller provides the prescription verification request to the prescriber, and shall conclude after eight (8) business hours have elapsed.”²⁰⁷

Example (2) incorrectly interprets the “business hour” definition as requiring alternative sellers to wait well beyond the statutory 8 hours. If a verification request is received at 10 p.m. on Monday night, then the clock starts at 9 a.m. the next day. The eight hours run throughout the day, and expire at 5 p.m. Therefore, the alternative seller *should* be able to ship at 5 p.m. But, according to the interpretation in example (2), the seller is barred from shipping at that time, and instead must wait 15 *more* hours - until 9 a.m. the next morning, Wednesday.

Since shippers, such as UPS and Federal Express, typically ship their products only once a day and at night, this unique 8 hours plus 15 additional hours formulation, will in practice force a consumer purchasing from an alternative seller to wait to receive his or her lenses an additional 24 hours beyond the time period intended by Congress. So, the FTC’s proposed interpretation of the 8 hour verification period is effectively an “8-Hours-Plus-One-Day” period.

Examples (3) and (4) similarly apply this unique 8-Hours-Plus-One-Day waiting period. Example (3) takes this to an extreme. In instances where the verification request is received at 2 p.m. on Saturday, an alternative seller would be barred from shipping until 9 a.m. on Tuesday (almost 3 days (67 hours)) after the verification request. Under the plain, and we believe intended meaning of 8 hours, the alternative seller would be able to ship on Monday at 5 p.m. (51 hours after the prescriber (or ECP)²⁰⁸ receives the verification request).

We understand that ECPs have argued that this 8-Hours-Plus-One-Day waiting period is necessary to ensure that ECPs have at least two days on which to respond to a verification request. The purported concern is that a specific ECP may close his office every Wednesday and that there would be nobody in the office to verify prescriptions received after 5 p.m. Tuesday evening. According to

²⁰⁷ *Id.* at 5448.

²⁰⁸ Section III of these comments uses the term “prescriber” and ECP interchangeably.

the ECPs, the 8-Hours-Plus-One-Day waiting period would give that particular ECP who keeps an irregular schedule an opportunity to respond.

An independent survey commissioned by 1-800, the Synovate Survey of ECP Business Hours, revealed that the hypothetical ECP with the irregular schedule for whom the tortured standard has been developed is not representative of the industry. The Synovate Survey found that only 0.8% - 5.3% of mass merchandisers,²⁰⁹ retail chains,²¹⁰ independent optometrists, and independent ophthalmologists are actually closed on a given weekday.²¹¹

Furthermore, the legislation is intended to make the act of purchasing contact lenses more convenient for consumers. However, in order to protect the interests of the relatively rare ECP who does not, for whatever reason, work a full work week, the proposed 8-Hours-Plus-One-Day waiting period will make purchasing contact lenses less convenient for millions of consumers.

At the end of the day, what this 8-Hours-Plus-One-Day definition represents is a relatively small handful of ECPs who do not work a full work week demanding that the federal government force all alternative sellers and consumers to accommodate their desire to work less – regardless of whether the consumers effected are actually their customers.

What these ECPs seek represents a major policy decision that is not supported by the Fairness Act or its legislative history. There is no indication whatsoever that by stating “8 business hours, or a similar time as defined by the Federal Trade Commission,”²¹² that Congress either intended or authorized the FTC to more than double the effective waiting period or that Congress had any interest in so accommodating, at the expense of all American contact lens consumers, ECPs not wishing to work a full work week.

There is good reason Congress did not enact this accommodation as set forth in the proposed rule. Beyond being unfair to consumers, especially those who do not patronize “short-week” ECPs, adding time to the 8 hour period has been proven to be unnecessary. There is no indication that any ECPs in California have been unable to respond to prescription verification requests because of irregular office closings, and California gives ECPs a minimum of 5 hours to respond,²¹³ Monday through Saturday. Indeed, the California system works 96.5% of the time.²¹⁴ Notably, the California

²⁰⁹ The mass merchandisers in the Synovate Survey of ECP Business Hours included Wal-Mart Vision Center, Target Optical, Sam’s Club Optical, Costco Optical, and Shopko Optical. *See* Synovate Survey of ECP Business Hours (Att. 32).

²¹⁰ The retail chains in the Synovate Survey of ECP Business Hours included JCPenney Optical, Pearle Vision, Lenscrafters, Sears Optical, America’s Best, BJ’s Optical, Eyemasters, and Cohen Optical (Att. 32). *See id.*

²¹¹ *See id.*

²¹² Fairness to Contact Lens Consumers Act, P.L. 108-164, § 4(d)(3), 117 Stat. 2025 (2003).

²¹³ In California, if a prescription verification is faxed to an ECP after business hours, then the ECP has to respond by 2 p.m. the next day. *See* Calif. Business and Professions Code § 2546.6(a) (Att. 125). 1-800’s survey indicates that, on average, ECPs open at approximately 9 a.m. Monday through Saturday. *See* Synovate Survey of ECP Business Hours. Accordingly, most ECPs would have, at minimum, from 9 a.m. to 2 p.m. to respond – *i.e.*, 5 hours (Att. 32).

²¹⁴ *See supra*, discussion at Section II(C).

law had the full support of the COA, which praised it as supporting “safe and responsible filling of [contact lens] prescriptions,” and for striking “a reasonable balance between access and accountability.”²¹⁵

Furthermore, as the FTC is aware, the California Board of Optometry has filed comments calling upon the FTC to conform its formulation of hours to those which have been in effect in California for over a year.²¹⁶ It is safe to assume that if there were any issue with the “short week ECP” for whom the FTC’s proposed definition was crafted, the Board would not have taken that position. Accordingly, contrary to the assertions of self-interested ECPs, there is no need to give ECPs two days to respond.

It should not be lost on the FTC that the 8-Hours-Plus-One-Day rule being promoted by ECPs can serve to stifle competition. The ECPs want to use the additional waiting period imposed on alternative sellers as a marketing tool. They want to be able to tell their customers that if they order from alternative sellers, it will be less convenient because alternative sellers have a waiting period that does not apply to ECPs. ECPs also want to have a longer period to interfere with alternative sellers’ contact lens sales. As an article entitled “Strategic Dispensing” from the February 2003 issue of Ophthalmology Management advised ECPs:

If a direct-to-consumer service calls to verify a prescription, contact the patient about your own website. Patients can order any time, night or day, and they do not have to *wait* for your approval as they would with services such as 1-800 Contacts. (You can control which options are available to them).²¹⁷

ECPs also presumably want to have a longer period in which to interfere with the sales made to their customers by alternative sellers. For example, Contact Lens Spectrum characterized the verification period in the Fairness Act as allowing “the prescriber time to contact the patient to attempt to provide the lenses before the mail order firm processes the order.”²¹⁸

The 8-Hours-Plus-One-Day rule will make the contact lens industry less, rather than more, competitive. The need for such a rule is not supported by the evidence and needlessly penalizes millions of consumers – many of whom rely on the convenience alternative sellers offer precisely because they cannot simply take time off from work during the week.

California is the largest state in the Union. More than any other state, it is a microcosm of our nation. The state’s experience with its contact lens law suggests that the waiting period should actually be less than the statutory 8 hours, not more.

²¹⁵ Letter from the COA to the Honorable Lou Correa, California Assemblyman, dated July 15, 2002 (Att. 29).

²¹⁶ Letter to the FTC from the State of California Department of Consumer Affairs, Board of Optometry, dated Feb. 25, 2004 (Att. 21).

²¹⁷ See Christopher Kent, *Strategic Dispensing*, Ophthalmology Management (Feb. 2003) (Att. 89).

²¹⁸ See Joseph Barr, O.D., M.S., F.A.A.O., *Annual Report: 2003*, Contact Lens Spectrum (Jan. 2004) (Att. 87).

ii. The Proposed Rule Inconveniences Consumers, Deters Competition, Gives ECPs a Distinct and Unwarranted Hours of Operations Advantage, and Imposes a Constructive Waiting Period on Alternative Sellers

Even assuming that the mathematical inconsistencies in the proposed rule's examples will be corrected, 1-800 is troubled by the definition of "business hour" inasmuch as it gives ECPs a distinct, unwarranted, and unnecessary advantage in hours of operation. The proposed definition is entirely arbitrary. It bears no relation to *actual* business hours. 1-800 is unaware of any recent precedent for the FTC directly imposing a limit on the business hours of one class of seller at the expense of another. Such a mandate would infringe on competition. However, the FTC's proposed definition of "business hour" is doing, indirectly, just that.

According to the proposed rule, the business hours during which the 8 hour period can run are 9 a.m. to 5 p.m., Monday through Friday. These hours do not take into account industry realities – they do not reflect *actual* business hours. The Synovate Survey of ECP Business Hours²¹⁹ determined mass merchandisers and retail chains are generally open from approximately 9:14 a.m. to 8:34 p.m. and 9:43 a.m. to 7:24 p.m., respectively, Monday through Friday. These expanded hours are significant because mass merchandisers and retail chains have approximately 23.4% of the contact lens market (13.9% and 9.5%, respectively). Overall, ECPs (including independent ECPs) are open on average, from approximately 9:04 a.m. to 6:15 p.m., Monday through Thursday, and from approximately 8:59 a.m. to 5:59 p.m. on Friday.

With respect to Saturdays, approximately 69% of ECPs are open, on average, from 9:01 a.m. to 4:12 p.m. 99.7% of mass merchandisers and 98% of retail chains are open on Saturdays, from approximately 8:47 a.m. through 7:23 p.m., and 9:41 a.m. through 6:07 p.m., respectively. Even on Sundays, 93.7% of mass merchandisers and 51% of retail chains are open, both on average from approximately 11:30 a.m. to 5 p.m. In addition, many ECPs are moving to web-based sales, which permits them to operate 24/7.

Accordingly, under the proposed rule, ECPs, including retailers associated with ECPs (retail chains and mass merchandisers), would have a distinct hours of operation advantage. ECPs could continue to operate from approximately 9 a.m. to 6:15 p.m. Monday through Friday, and from approximately 9 a.m. to 4 p.m. on Saturdays. Under the rule, ECPs could open on any federal holiday, run 24/7 websites, and even expand their walk-in hours Monday through Sunday. Alternative sellers, however, would be forced to verify prescriptions and ship based upon the artificial business hours of 9 a.m. to 5 p.m. Monday through Friday. Alternative sellers effectively would be closed before 9 a.m. and after 5 p.m. on weekdays, during the entire weekend, and during all federal holidays. Put another way, the average ECP could continue to operate approximately 52 hours a week; the average mass merchandiser, such as Costco Optical, could continue to operate approximately 70 hours a week; but alternative sellers could only operate 40 hours a week.

This constructive closure is potentially devastating to alternative sellers that attract consumers based on convenience. Such retailers typically operate 24/7, including most holidays. In addition to offering constant Internet service, 1-800, for example, keeps its call center open from 6 a.m. through

²¹⁹ Synovate Survey of ECP Business Hours (Att. 32).

10 p.m. MST, Monday through Thursday, from 6 a.m. through 9 p.m. Friday through Saturday, and from 8 a.m. through 4 p.m. on Sunday. Notably, fewer than two-thirds (approximately 64.02%) of 1-800's orders come in between the hours of 9 a.m. and 5 p.m. (Even fewer (approximately 59%) come in during the proposed rule's "business hours," 9 a.m. to 5 p.m., Monday through Friday).²²⁰

Granting ECPs an hours of operation advantage over alternative sellers would also impose a longer waiting period on alternative sellers and inconvenience consumers. As mentioned in Section II(A)(2), consumers who use alternative sellers do so not only for lower prices, but also for *convenience*.²²¹ This fact is not lost on ECPs, who have already begun advising each other to take advantage of the prolonged waiting period by advertising to consumers that ECPs can get consumers contact lenses more quickly.²²² If the definition of "business hour" eliminates alternative sellers' ability to compete based on convenience, the definition would undermine the very objective of the Fairness Act to promote meaningful consumer choice and competition from alternative sellers.

Also, the greater the waiting period for alternative sellers, the greater the opportunity for ECPs to misuse the prescription verification process. As previously mentioned, it has become common for leading ECP publications to advise ECPs to use the verification period to interfere with alternative sellers' sales.²²³ 1-800 estimates that it has lost significant sales from such practices, based on prescription verification responses that actually documented ECP interference.²²⁴ In one case, a 1-800 call center representative observed this interference directly:

I just had an interesting experience with a Lenscrafters location. . . . The ECP faxes us saying the rx was expired. I talked to Kim, Shawn's mom. She said he was there yesterday. I called the ECP, they said that they had made a mistake and would fax us the correct info. I tried to call the customer back, it was busy. When I finally reached Kim again, she said that Lenscrafters just called her to offer her a lower price if she would order through them.²²⁵

In all probability, however, the vast majority of instances of sales interference go undocumented.

²²⁰ See 1-800 Chart Regarding Hours Breakdown for Incoming Orders (1-800's chart included the number of orders that came in every day from February 4-25, 2004, *including weekends and holidays*) (Att. 131).

²²¹ See *supra*, discussion at Section II(A)(2) (regarding convenience).

²²² Christopher Kent, *Strategic Dispensing*, Ophthalmology Management (Feb. 2003) ("If a direct-to-consumer service calls to verify a prescription, contact the patient about your own website. Patients can order any time, night or day, and they do not have to *wait* for your approval as they would with services such as 1-800 Contacts. (You can control which options are available to them)") (quotations omitted) (Att. 89).

²²³ See, e.g., Ronald P. Snyder, O.D., F.A.A.O., *Winning the War Against Mail-Order Contact Lenses*, Optometry Today (Jan./Feb. 1993) (Att. 69); see also Michelle Boyles, *Cole to Give Exams to 1-800 Customers*, 140 Review of Optometry 4 (Aug. 15, 2003) (Att. 84).

²²⁴ See 1-800 Sales Interference Responses (Att. 132).

²²⁵ Internal 1-800 E-mail, dated Feb. 11, 2004 (names redacted) (Att. 133).

The disparate impact of the proposed “business hour” definition on alternative sellers would enshrine years of ECP anticompetitive behavior, rather than leveling the playing field. Notably, if the proposed definition of “business hour” were redrafted to ensure that alternative sellers could generally ship on the same day, or at least by the next day if the verification request is communicated after hours, it would facilitate competition and benefit consumers. It would also, as the Fairness Act intends, force ECPs to be more responsive to consumers needs regarding price, convenience, and inventory.²²⁶

iii. The 8 Hour Prescription Verification Period Is Too Long, Given that 5 Hours in California has Proven to Be Sufficient.

In enacting the Fairness Act, Congress determined that using a presumed verification system that requires prescribers to verify prescriptions within “8 business hours, or a similar time as defined by the [FTC]”²²⁷ adequately protects consumer health.²²⁸ Accordingly, the FTC’s task is to identify a verification period that gives ECPs sufficient time to respond to verification requests. An 8 hour verification period is too long. ECPs have long been using prescription verification as an opportunity to interfere with an alternative sellers’ sales,²²⁹ and ECPs are still advising each other that 8 hours provides more than enough time “to contact the patient to attempt to provide the lenses before the mail-order firm processes the order.”²³⁰ One prominent ECP urged:

[Y]ou should USE THE 8 HOUR WINDOW to contact the patient and let them know that you have their lenses in stock for the same price or less than the mail order companies charge!! The verification is a MARKETING OPPORTUNITY if you work with it [emphasis in the original].²³¹

Moreover, the longer the prescription verification period, the less ability alternative sellers will have to compete on the basis of convenience.

The FTC has a distinct advantage in identifying an adequate prescription verification time period. It can look to California, the largest state in the country, which has already implemented - and had the ability to monitor for over a year - a prescription verification period that works. The experience under the California law is an ideal source for developing regulations under the Fairness Act for the presumed verification process because it served as a basis for the Fairness Act itself. As Congressman Pete Stark (D-CA) explained to his colleagues, the Fairness Act was enacted to ensure

²²⁶ See, e.g., Joe B. Goldberg, O.D., F.A.A.P., *If You Can’t Beat Mail Order Companies, Join Them*, Contact Lens Spectrum: Readers’ Forum (June 2002) ([Att. 82](#)).

²²⁷ Fairness to Contact Lens Consumers Act, P.L. 108-164, § 4(d)(3), 117 Stat. 2025 (2003).

²²⁸ See Schakowsky Speech (“[the Fairness Act] establishes clear uniform rules that will guarantee *fairness and safety* to contact lens consumers in every State, regardless of existing laws”) (emphasis added) ([Att. 2](#)).

²²⁹ See *supra*, discussion at Section II(B)(3)(a).

²³⁰ Joseph Barr, O.D., M.S., F.A.A.O., *Annual Report: 2003*, Contact Lens Spectrum (Jan. 2004) ([Att. 87](#)).

²³¹ Craig Steinberg, *Optcom*, ECP E-mail Forum, Nov. 22, 2003 (11:40 a.m.) ([Att. 134](#)).

that consumers in all areas of the country have the same convenience and the same protection from anticompetitive ECP practices that Californians have under the California law.²³²

As described in Section II(C), the California system does not get entangled in the concept of “business hour.” Rather, it simply provides that:

A prescription shall be deemed confirmed upon the occurrence of one of the following: . . . (2) The prescriber fails to communicate with the seller by 2 p.m. of the next business day after the seller requests confirmation, or the prescriber fails to communicate with the seller by the next business day on or before the same time of day that the seller requested confirmation, whichever is sooner. For purposes of this paragraph, “business day” means each day except a Sunday or a federal holiday.²³³

Under this system, if the seller contacts the prescriber before 2 p.m., then the prescriber has 24 hours to respond, and if the seller contacts the prescriber after 2 p.m., then the prescriber, at minimum, has 5 business hours to respond (1-800’s survey results show that on average, ECPs open at 9 a.m. Monday-Saturday). Importantly, the California law also reflects the reality that most retail businesses are open on *Saturday*.

As noted, 1-800’s sales data demonstrates that this system works approximately 96.5% of the time. In only approximately 0.4% of the cases, 1-800 receives information outside of the California time frame indicating that a prescription is actually incorrect.²³⁴ Notably, even under these unusual circumstances, the consumer is not harmed because 1-800: (1) notifies the consumer of the correspondence received from his or her ECP, and (2) permits the consumer to return unused product to 1-800.

It is not surprising that a 5 hour verification period works, because 5 hours is more than sufficient. Importantly, on average a prescriber receives only 1.3 verification requests a week from 1-800, which is by far the largest alternative seller.²³⁵ Given that 1-800 has approximately 70% of the mail order business, the average prescriber would receive approximately 1.8 verification requests a week. Therefore, any claim that the volume of prescription verification requests received would slow down prescriber response time is not supported by the evidence. Further, because it only takes only a few

²³² See Stark Statement, 149 Cong. Rec. H11561-H11565 (Nov. 19, 2003) (Att. 14).

²³³ California Assembly Bill No. 2020, signed into law on September 23, 2002, codified at Calif. Business and Professions Code § 2546.6(a) (Att. 125).

²³⁴ The remaining responses received outside the time frame (3.1%) are simply uncooperative ECP responses or reports that a prescription has expired. Notably, the 0.4% error rate is less than pharmacy dispensing error rates. See, e.g., Elizabeth Allan Flynn, et al., *Relationships Between Ambient Sounds and the Accuracy of Pharmacists’ Prescription-Filling Performance*, 38(4) Human Factors 614 (1996) (finding an error rate of 3.23%, and noting that medication dispensing error rates ranging from 2% to 24% have been detected) (Att. 129); Richard A. Knox, *Prescription Errors Tied to Lack of Advice Pharmacists Skirting Law, Mass. Study Finds*, Boston Globe (Feb. 10, 1999) (summarizing a Massachusetts study that found a 4% error rate) (Att. 130).

²³⁵ 1-800’s database revealed that from February 4-25, 2004, it sent 130,349 faxes to 30,934 ECP offices, for an average of 4 calls to each ECP office over a 3 week period, or 1.3 contacts a week.

minutes to respond, actual response time is fluid. If prescribers had 8 hours to respond, the vast majority of responses would be made within 8 hours, but if they had 2 hours to respond, the vast majority of responses would be made within that time frame. The California model has proven to be a reasonable compromise, providing prescribers with more than adequate time to respond.

iv. With Live Communication, the Waiting Period Should Be Only 2 Hours

The Fairness Act regulations should give prescribers 2 hours to respond if a seller's live agent reaches a prescriber's live agent via telephone. This would give alternative sellers a way to expedite orders for consumers who need their lenses immediately, and it guarantees that the ECP and seller have notice that the verification period is running. In addition, giving alternative sellers an incentive to use live communication would increase its use and alleviate ECP complaints that verification requests are received after hours. Again, it should take a matter of minutes to verify a prescription, and thus 2 hours is a more than adequate time period for sellers to respond under these circumstances.

b. 1-800's Proposed Definition of "Business Hour"

1-800 proposes an alternative "business hour" definition, that is fully consistent with the Fairness Act and would ameliorate concerns that: (1) the proposed definition of "business hour" does not reflect actual business hours in the eye care industry, and (2) that an 8-hour verification period is too long. 1-800 urges the FTC to adopt its proposed "business hour" definition, given that too restrictive a definition would defeat the objective of the Fairness Act to promote meaningful consumer choice and competition from alternative sellers.

First, to better reflect actual business hours, the FTC should expand the definition of "business hour" to be 9 a.m. to 6:30 p.m. Monday through Friday, and 9 a.m. to 4 p.m. on Saturday, in accordance with the survey results. This definition, however, should be the default business hours - *i.e.*, the "safe harbor" only - because it still does not take into account expanded weekday hours, expanded Saturday hours, Sunday hours, and holidays. Moreover, this default definition should be revisited if ECP hours expand in response to the Fairness Act.

The definition of "business hour" also should provide an alternative to this "safe harbor" that permits sellers, at their option, to verify actual business hours of an ECP's office (*i.e.*, the business hours of an ECP's *office*, not the number of hours that the ECP is present in the office) on an ECP-by-ECP basis.²³⁶ To use this "verified hours" definition of "business hour," a seller would have to verify the business hours of an ECP office at the time this option is chosen (*e.g.*, by communicating with the ECP or by documenting publicly posted hours for an independent ECP or a corporate entity). After verifying the actual hours, the seller would be required to place the "verified hours" on faxed prescription verification requests, so that an ECP has the opportunity to contact the seller if its actual, posted business hours have changed.

²³⁶ The "verified hours" definition of "business hour" would take into account the actual number of hours that an ECP's office is open (*i.e.*, the number of hours that an office can respond to a verification request).

Once a seller has verified the business hours of an ECP office, the seller could choose, at its option and on a case by case basis, to use the default “business hour” safe harbor or the actual “verified hours” to determine whether sufficient time has passed to presume that a prescription is verified. This rule would benefit consumers and assure fairer competition by permitting sellers to be open whenever their competing ECPs are open, whether that be at 7 p.m. on a weekday, or a Sunday, or a Federal holiday.

The rule should require sellers who use the “verified hours” approach for any given ECP to maintain records regarding hours verification, and it should expressly prohibit ECPs from falsely representing their business hours. This system places the burden and risk of actual hours verification on the seller who chooses to use the “verified hours” definition. It does not place any additional burdens on the ECP.

Moreover, the rule would memorialize 1-800’s existing policy for handling ECP responses, which are received after the verification period has elapsed, requiring sellers to: (1) notify the consumer of the correspondence received from his or her ECP, and (2) permit the consumer to return unused product to the seller. Therefore, regardless of whether the seller used the default “business hour” definition or the “verified hours” alternative, the consumer would be notified if there were a problem with the consumer’s prescription. Accordingly, the default safe harbor “business hour”/verified “business hour” system would not burden consumers in any way.

Second, the prescription verification period, generally, should be 5 business hours after the seller makes the prescription request, and it should be 2 business hours if a live agent of the seller makes contact with a live agent of the ECP by telephone. Further, the FTC should revisit the 5/2 hour verification period if future technology develops that makes the 5/2 hour verification period excessive (*e.g.*, for e-mail, a technology that notifies the sender that an e-mail has been opened).

1-800’s recommended approach would require several changes to the proposed regulations. Specifically, the language would change in proposed Section 315.2 regarding the definition of “business hour,” proposed Section 315.3(b), regarding limitations on prescriber behavior, proposed Section 315.5(c)(3), regarding the number of hours required for presumed verification, and proposed Section 315.5(d), regarding invalid prescriptions. The final definition of “business hour” should provide:

Business hour means an hour between 9 a.m. and 6:30 p.m., during a weekday (Monday through Friday), excluding Federal holidays, *and an hour between 9 a.m. and 4 p.m. on Saturday, or in the alternative, the actual verified business hours of a prescriber’s office, whichever covers a greater time period.* For purposes of Sec. 315.5(c)(3), “five (5) business hours,” and “two (2) business hours,” shall be calculated from the first business hour that occurs after the seller provides the prescription verification request to the prescriber, and shall conclude *after the specified time has elapsed.* For verification requests received by a prescriber during non-business hours, the calculation of “five (5) business hours” shall begin at 9 a.m. on the following day that is not a Sunday or a Federal holiday (*except that verified business hours may run on Sundays or Federal holidays if the prescriber’s office is open on those days*).²³⁷

²³⁷ 69 Fed. Reg. at 5448.

Sellers using verified business hours must verify the business hours of a prescriber's office upon initially exercising the verified business hour option (e.g., by communicating with the prescriber or by documenting the publicly posted business hours), and sellers must include the verified business hours on prescription verification requests sent to prescribers so that prescribers have the opportunity to update the seller's records. Sellers that use the verified hours alternative must maintain records regarding verified hours for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

In addition, the FTC should add paragraph (8) to Section 315.3(b) as follows²³⁸:

Limitations. A prescriber shall²³⁹ not: . . . (8) Provide false information to sellers regarding actual business hours of the prescriber's office, or avoid providing information regarding actual business hours of the prescriber's office to sellers.

Furthermore, language should be added to Section 315.5(c)(3), such that the final provision reads:

The prescriber fails to communicate with the seller within five (5) business hours after receiving from the seller the information described in paragraph (b) of this section, or if a live agent for the seller communicates with a live agent for the prescriber via telephone (or a substantially equivalent technology that permits immediate communication between the seller and the prescriber), and the prescriber fails to verify the prescription within two (2) business hours after receiving from the seller the information described in paragraph (b) of this section.

Finally, the following language should be added to the end of Section 315.5(d)²⁴⁰:

Sellers that receive notification from a prescriber outside of the verification period that a prescription is inaccurate, must notify the patient, and permit the patient to return any unused resaleable product.²⁴¹

Notably, any examples of the default “business hour”/ verified “business hour” system in the final rule should reflect these changes.

²³⁸ 1-800 recommended paragraphs (4) through (7) are discussed in detail in Sections III(A)(4) and III(B)(1)(b)(i), (ii) herein.

²³⁹ 1-800 proposes that FTC use the word “shall,” rather than the word “may” because “shall” connotes that the provision is mandatory, whereas “may” connotes that the provision is permissive.

²⁴⁰ Proposed Section 315.5(d) should be further revised in accordance with Section III(B)(3)(d) herein.

²⁴¹ *Cf.* Utah has no waiting period, but it requires sellers to inform patients that the contact lens prescription is invalid if the seller receives such information from the prescriber within 72 hours of the initial prescription verification request. Utah Code Ann. § 58-16a-801. (Att. 127).

2. Contact Lens Fitting

Section 315.2 of the proposed Contact Lens Rule defines “contact lens fitting” as:

[T]he process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required, and such term may include: (1) An examination to determine lens specifications; (2) Except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and (3) Medically necessary follow-up examinations.²⁴²

In its proposed rule, the FTC questions: “(a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way? [and] (c) Should the term “medically necessary follow-up examinations” be defined, and, if so, how?”²⁴³

At this time, 1-800 does not have any concerns with the definition of “contact lens fitting” *per se*, and it believes that the definition in the proposed rule is sufficiently clear. 1-800, however, is concerned about the operation of this definition in conjunction with Sections 315.3 and 315.4 of the regulations, regarding prescription release timing and limitations on requiring immediate payment for eye examinations and fittings. These concerns are discussed in detail in Section III(B)(1)(b)(i) herein.

3. Contact Lens Prescription

Section 315.2 of the proposed Contact Lens Rule defines “contact lens prescription” as:

[A] prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following:

- (1) The name of the patient;
- (2) The date of examination;
- (3) The issue date and expiration date of prescription;
- (4) The name, postal address, telephone number, and facsimile telephone number of prescriber;
- (5) The power, material or manufacturer or both of the prescribed contact lens;
- (6) The base curve or appropriate designation of the prescribed contact lens;

²⁴² 69 Fed. Reg. at 5449.

²⁴³ *Id.* at 5446-47.

- (7) The diameter, when appropriate, of the prescribed contact lens; and
- (8) In the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.²⁴⁴

In its proposed rule, the FTC questions: “(a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way? (c) Should the definition include the prescriber’s e-mail address, if any? [and] (d) Should the definition include anything else?”²⁴⁵

1-800 believes that the definition of “contact lens prescription” is sufficiently clear. The definition is detailed enough for the consumer to be able to provide the seller with the information necessary for the seller to contact the ECP to verify the prescription, in accordance with Section 315.5(b) of the proposed rule.

As an initial matter, however, 1-800 would like to take this opportunity to note that the exam date, the issue date, and the expiration date are critically important. If ECPs did not have to include these, it would be too easy for ECPs to sabotage prescription portability with false expiration dates or with false reports to alternative sellers that a prescription is expired.

1-800 also notes that paragraph (8) of the “contact lens prescription” definition is essential for the operation of Section 315.5(e) of the proposed regulation,²⁴⁶ which permits substitution for private label lenses. As mentioned, ECPs have taken advantage of the fact that some states require prescriptions to be brand specific, by prescribing brands that only they sell – *i.e.*, private label or doctor exclusive lenses – even though identical lenses are sometimes made by the same manufacturer and sold under other names (*i.e.*, private label lenses). An advertisement in an ECP journal, *Contact Lens Spectrum*, advises ECPs to use private label lenses to prevent giving “patients a choice. I don’t say this is a private label lens. I just say, ‘This is the best lens for you. It’s the one you should be wearing.’”²⁴⁷

Using private label lenses in this manner is coercive and it prevents meaningful prescription portability. Moreover, even more scrupulous ECPs have recognized that “to fit a lens brand (or type, *e.g.*, RGP), simply BECAUSE it’s not available elsewhere than your office is ethically suspect behavior.”²⁴⁸

²⁴⁴ *Id.* at 5449.

²⁴⁵ *Id.* at 5447.

²⁴⁶ *Id.* at 5449.

²⁴⁷ *Using Private Label Lenses to Keep Patients in the Practice*, *Contact Lens Spectrum* (Jan. 2002) (Att. 83).

²⁴⁸ Christopher Press, *Optcom – Subject Fitting Contact Lenses*, ECP E-mail Forum, Oct. 2003 (Att. 135).

The private label substitution authorized by Section 4(f) of the Fairness Act, and provided for in paragraph (8) of the proposed “contact lens prescription” definition and proposed Section 315.5(e), *attempt to provide a check for this behavior*. Indeed, the FTC recently stated in its e-commerce report on contact lenses that:

Adherence to statutory provisions regarding private label lenses and prescription lengths should ensure that contact lens seller and contact lens prescriber practices generally promote consumer health and do not hamper consumer choice in a way that ultimately harms consumers.²⁴⁹

Even ECPs seem to believe that the Fairness Act provides an adequate countermeasure for the private label problem, with one ECP in an optometry chat room stating: “[Y]ou can’t go private label anymore . . . some of the old tricks aren’t going to work.”²⁵⁰

However, it is important to recognize that the “private label” ruse *still does work*. The Fairness Act assumes that alternative sellers can easily obtain equivalent national brands for private label lenses. This is absolutely not the case. Private label manufacturers have stepped up their efforts to cut off those who supply alternative sellers with the lenses. 1-800 goes to great lengths to obtain products equivalent to private label lenses, often paying grossly inflated prices, yet, in some cases, 1-800 cannot get all the lenses it needs. Thus, despite Congress’ clear intent to remedy the private label problem, private label substitution is not a reality unless private label lenses are equally available to all sellers, or at minimum, all consumers have access to a contact lens sold to both alternative sellers and prescribers.

In addition, ECPs have already begun to undermine private label substitution in the Fairness Act, with “doctor exclusive contact lenses.” A “doctor exclusive contact lens” is a lens that is available for purchase only through an ECP, due to a manufacturer’s restricted distribution policy, that *does not have a substitute that is available to alternative sellers*. Indeed, due to contractual restrictions, an ECP will typically refuse to fill a “doctor exclusive” lens prescription written by another authorized ECP. With these lenses, ECPs and manufacturers are playing the same anticompetitive games that they have been playing with private label lenses to coerce consumers into purchasing contact lenses from them. For example, ads for doctor exclusive lenses boast:

- “Let’s see. You’ll make more money. . . . And since Proclear Compatibles are only available through your practice, you’ll get what you’re looking for: increased patient loyalty and greater profitability.”²⁵¹

²⁴⁹ *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, a Report from the Staff of the FTC (Mar. 2004), at 4.

²⁵⁰ Timothy Milburn, O.D., *Seniordoc – An Interview with Phil Kaefer*, ECP E-mail Forum, Nov. 20, 2003 (7:12 p.m.) ([Att. 136](#)).

²⁵¹ See *Miscellaneous Ocular Science*, Proactive 55, Proclear, and Extreme H2O Ads ([Att. 120](#)); see also *Prescribing a High Water Content Lens*, Contact Lens Spectrum (Jan. 2002) (with doctor exclusive lenses “[w]e know that patients are going to come back”) ([Att. 137](#)).

- “Protects End-of-the-Year Profit. Only available through independent Eye Care Providers Extreme H2O lenses are distributed exclusively via an intellectual property licensing agreement to qualified independent eye care providers.”²⁵²
- “It’s time to stop the revolving door in your practice and begin to regain patient loyalty. Patients are your most valuable asset. We can help you protect your practice from eroding margins and keep contact lens patients coming back to see you instead of a website, 800 number or a discount store.”²⁵³

Notably, the arrangements between the manufacturers of doctor exclusive lenses and the ECPs who sell the lenses are similar to the arrangements between the defendant ECPs and trade associations in *In re: Disposable Contact Lens Antitrust Litigation* and the manufacturers in that case. In *In re: Disposable Contact Lens Antitrust Litigation*, the ECPs and trade associations coerced the manufacturers into implementing ECP-only distribution policies to prevent alternative sellers from competing. Here, with the doctor exclusive lenses, it is the manufacturers who are enticing individual ECPs to join with them to prevent alternative sellers from competing. 1-800 believes that these doctor exclusive lens arrangements, like those in *In re: Disposable Lens Antitrust Litigation*, restrain trade in violation of the antitrust laws.²⁵⁴

Accordingly, the rule should provide a countermeasure to prevent ECPs from coercing consumers into purchasing doctor exclusive lenses, as well as private label lenses. 1-800 proposes that language addressing doctor exclusive lenses be added to paragraph (8) of the definition of “contact lens prescription,” such that it reads:

- (8) In the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, *trade name of a brand name sold to alternative sellers. In the case of a doctor exclusive contact lens (i.e., a lens sold only to prescribers or retailers with an on site prescriber), the prescriber shall also provide the consumer with another prescription for a lens that is sold to alternative sellers.*

Notably, this provision would not prevent doctor exclusive lenses from competing with other contact lenses on their merits. To the extent that the lenses actually provide an advantage over other lenses, consumers could weigh the additional costs of the lenses against the benefits and decide for themselves whether to purchase the doctor exclusive lenses or an alternative.

1-800 also proposes that the FTC add a definition of “doctor exclusive contact lenses” to Section 315.2. The definition of “doctor exclusive contact lenses” should be as follows: “*a lens that is available for purchase only through a prescriber or a prescriber location, due to a manufacturer’s restricted distribution policy, that does not have a substitute that is sold to sellers who are not also prescribers.*”

²⁵² See *Miscellaneous Ocular Science, Proactive 55, Proclear, and Extreme H2O Ads* (Att. 120).

²⁵³ See *id.*

²⁵⁴ See Sherman Act § 1, 15 U.S.C. § 1 (Supp. 2003); *United States v. General Motors*, 384 U.S. 127 (1966) (holding that joint collaborative action by dealers, associations, and General Motors to eliminate a class of competitors by terminating dealings with them and a minority of Chevrolet dealers and to deprive franchised dealers of their freedom to deal through discounters was a classic conspiracy in restraint of trade).

4. Direct Communication

Section 315.2 of the proposed Contact Lens Rule defines “direct communication” as “completed communication by telephone, facsimile, or electronic mail.”²⁵⁵ In its proposed rule, the FTC questions:

“(a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way? (c) Is it appropriate to include messages left on telephone answering machines in this definition? (d) Should the definition expressly require, for communication by facsimile or e-mail, the receipt of a confirmation that the communication was successful? [and] (e) Should the definition include any other means of direct communication?”²⁵⁶

Unfortunately, ECPs are already making a concerted, nationwide effort to defeat their obligation to verify prescriptions, by arguing that the terms “direct communication” and “completed communication” be interpreted narrowly for the purposes of Section 315.5 of the proposed rule, which requires that prescriptions be verified by the seller with “direct communication.”²⁵⁷ For example, Craig S. Steinberg, O.D., J.D. has circulated form comments for other ECPs to submit, which have already made it into the docket,²⁵⁸ that claim that: (1) a “direct communication” should only be a communication made by telephone, and (2) a “complete communication” can only be a telephone call that is affirmatively answered by a person. According to Steinberg, electronic mail (or “e-mail”) and facsimile (or “fax”) are inferior because there is no way for a sender to know whether a fax or an e-mail is complete. E-mails can be “lost in cyberspace” and faxes can jam or run out of ink or paper.²⁵⁹

These complaints about fax and e-mail prescription verification epitomize the problem with optometrists being permitted to sell what they prescribe. The technology “excuses” are pretext – ECPs want to prevent alternative sellers from selling to their customers. The truth is that the verification obligation places little burden on ECPs. Accordingly, 1-800 believes that the terms “direct communication” and “completed communication” should be defined broadly.

²⁵⁵ 69 Fed. Reg. at 5449.

²⁵⁶ *Id.* at 5447.

²⁵⁷ *Id.* at 5449.

²⁵⁸ Craig S. Steinberg, O.D., J.D., *Optcom - IMPORTANT: FTC Wants Your Comments About Contact Lens Act*, Feb. 11, 2004 (9:41 a.m.) ([Att. 138](#)); *see, e.g.*, Steinberg Forms Submitted to the Docket (FTC Comments from Michael P. Walker, OD ([Att. 139](#)), FTC Comments from Michael I. Davis, O.D. ([Att. 140](#)), FTC Comments from Catherine Smith ([Att. 141](#))).

²⁵⁹ *See, e.g.*, Steinberg Forms Submitted to the Docket (FTC Comments from Michael P. Walker, O.D. ([Att. 139](#)), FTC Comments from Michael I. Davis, O.D. ([Att. 140](#)), FTC Comments from Catherine Smith ([Att. 141](#))); *see also* FTC Comments of Kevin J. Green, O.D. ([Att. 142](#))).

a. “Direct Communication” Should be Defined Broadly to Include Existing and Future Communication Technologies

1-800’s verification protocol does not generally involve e-mail at all, and it places an incidental burden on ECP fax machines. Generally, 1-800 faxes ECP offices to verify prescriptions, attempting to fax the ECP up to three times if the initial faxes are not successful. If none of the faxes is successful, then a live agent makes a telephone call. Using a fax machine is the preferred method because it gives the ECPs all of the prescription information they need in writing, which eases the ECPs’ ability to locate consumer information and recordkeeping for the seller and the ECP. Indeed, one ECP, in her comments to the docket, concedes that faxes work because they “allow[] you the time to [get alternative sellers] the information and send it back.”²⁶⁰

Importantly, on average, an ECP receives only 1.8 verification requests a week.²⁶¹ 1.8 requests a week does not place undue burdens on fax machines. Requiring ECPs to be responsive to their consumers’ needs by maintaining fax machines is not excessive. Medical doctors handle far more requests for prescription verification.

Accordingly, the term “direct communication” should be defined broadly. “Direct communication” should include communication by telephone, fax, e-mail, and any other future technology that develops that would expedite the prescription verification process. Toward that end, 1-800 proposes that “direct communication be defined as “completed communication by telephone, facsimile, electronic mail, or a *substantially equivalent communication technology*.” Notably, the FTC has already stated in its comments before the Connecticut Board of Examiners for Opticians that a “multiplicity of ways to satisfy a prescription requirement is procompetitive,” and it has specifically endorsed lens ordering and prescription verification “by phone, mail, or Internet.”²⁶²

1-800’s proposed definition would not only give sellers more options for ways to request prescription verification, it would also give ECPs more options to confirm prescription information, under Section 315.5(c)(1) of the proposed rule.²⁶³ This could ameliorate ECP concerns, which have been logged in the FTC docket, that ECPs are having difficulty contacting alternative sellers.²⁶⁴ A broad definition of “direct communication” would ensure that ECPs could contact alternative sellers via the mechanisms currently used by 1-800 – *i.e.*, fax, a toll-free number, and the Internet as well as incorporating any future technologies which may be rapidly developed and adopted in the future.

²⁶⁰ FTC Comments from Marilyn Przybyłowski (Att. 143).

²⁶¹ 1-800’s database revealed that from February 4-25, 2004, it sent 130,349 faxes to 30,934 ECP offices, for an average of 4 calls to each ECP office over a 3 week period, or 1.3 contacts a week. Given that 1-800 has approximately 70% of the mail order business, the average prescriber would receive approximately 1.8 verification requests a week.

²⁶² Comments of the Staff of the FTC, Intervenor before the Connecticut Board of Examiners for Opticians, Mar. 27, 2002, at 12 (Att. 9).

²⁶³ 69 Fed Reg. at 5449.

²⁶⁴ FTC Comments from Robert B. Garfield, O.D. (Att. 144).

b. The Term “Completed Communication” Should Be Defined Broadly

In addition, the term “completed communication” as it is used in the current definition of “direct communication” is vague.²⁶⁵ This permits ECPs to interpret the term narrowly – to require evidence that an ECP has affirmatively received the communication. This is really just the next iteration of an old ECP anticompetitive tactic. As noted in Section II(B)(3)(b)(i) herein, ECPs have attempted to overly restrict the ways in which prescriptions can be communicated for years (*e.g.*, requiring original, hand-signed copies, requiring sellers to obtain a physical copy of the prescription, requiring a “face-to-face transaction,” and requiring sellers to wait indefinitely for an affirmative response from ECPs before selling replacement lenses).²⁶⁶

In chat rooms, ECPs eagerly embrace restrictions on prescription communication, noting that restrictions, such as requiring physical possession of the prescription “would kill [1-800]. In fact, I understand that [1-800] chooses not to do business in the two states that have that requirement. That kind of requirement would do two good things ... [like] put a crimp in the internet trade of medical devices.”²⁶⁷

Worse yet, interpreting “completed communication,” to require affirmative evidence of receipt of communication permits ECPs to avoid the obligation to verify prescriptions under Section 2(a)(2) of the Fairness Act²⁶⁸ altogether by intentionally unplugging fax machines or answering machines, or hanging up the telephone. Indeed, in the ECP chat rooms, ECPs have already begun to advise each other to do so:

- That is why we disconnect our fax machine when we leave the office. They can’t contact us if they can’t send a fax. I don’t know what they do in that case.²⁶⁹
- [This is] a great idea about the fax machine, my staff must manually turn it on to receive a fax, otherwise it rings over to the answering machine. [What] if they leave a message on my answering machine does that count as a notification?²⁷⁰
- FAX is a weak link here. I suggest that we all unplug our fax machines and keep them on hand for send-only purposes. In the unlikely event someone wants to send you a FAX that

²⁶⁵ 69 Fed. Reg. at 5448.

²⁶⁶ See *supra*, discussion at Section II(B)(3)(b)(i).

²⁶⁷ Jeffrey Kiener, O.D., *New Rx Release Law*, Review of Optometry Forum, Feb. 27, 2004 (1:07 p.m.) (Att. 145).

²⁶⁸ Fairness to Contact Lens Consumers Act, P.L. 108-164, § 2(a)(2), 117 Stat. 2024 (2003).

²⁶⁹ Rosemary Kafka, *Optcom – Vision Direct Sells CLs w/o Valid Rx*, ECP E-mail Forum, Feb. 16, 2004 (7:31 p.m.) (Att. 146).

²⁷⁰ Brad Lindsey, *Optcom*, ECP E-mail Forum, Nov. 21, 2003 (1:36 p.m.) (Att. 147).

you really wanted, you could always plug it into a free phone line at send time and then unplug it right after.²⁷¹

- So the moral is: try turning off your fax machine or unplugging it or dialing up with your modem on it...they will then be unable to reach you²⁷²

Accordingly, the FTC should define the term “completed communication” in Section 315.2 of the rule, and it should define the term broadly. 1-800 proposes that the term “completed communication” be expressly defined as:

Affirmative evidence that a communication has been completed (e.g., evidence that a facsimile has been received or that a message has been left on an answering machine), evidence that a communication by facsimile, electronic mail, or a substantially equivalent communication technology has been attempted twice, or evidence that live telephone verification has been attempted.

Moreover, to prevent ECPs from strategically avoiding a seller communication, a limitation should be added to Section 315.3(b) as follows:

A prescriber shall²⁷³ not . . . (5) Fail to keep an open line of communication or otherwise avoid seller attempts to verify a prescription.”

5. Issue Date

Section 315.2 of the proposed Contact Lens Rule defines “issue date” as “the date on which the patient receives a copy of the prescription.”²⁷⁴ In its proposed rule, the FTC questions whether this definition is sufficiently clear and the impact of the definition.²⁷⁵

In general, 1-800 supports the proposed rule’s definition of “issue date.” The definition, when read in conjunction with the minimum expiration period of 1 year, in Section 315.6 of the proposed rule, is pro-consumer because the prescription will not expire until at least 1 year after the consumer has had an opportunity to use it.

Some states, such as Texas, make it clear that the prescription expires on the “first anniversary of the date the patient’s parameters were determined.”²⁷⁶ Laws, such as the Texas law, provide an incentive for ECPs to withhold prescriptions or back-date prescriptions. If ECPs back-date prescriptions by

²⁷¹ Christopher Feahr, *Optcom - Subject: (1800) What a Farce (Alternative to Fax)*, Oct. 6, 2003 (6:31 p.m.) ([Att. 148](#)).

²⁷² MS McMeekin, *Optcom - Subject (1800) What a Farce (Alternative to Fax)*, Oct. 6, 2003 (11:33 a.m.) ([Att. 149](#)).

²⁷³ 1-800 proposes that FTC use the word “shall,” rather than the word “may” because “shall” connotes that the provision is mandatory, whereas “may” connotes that the provision is permissive.

²⁷⁴ 69 Fed. Reg. at 5448.

²⁷⁵ *See id.* at 5447.

²⁷⁶ Texas Contact Lens Prescription Act, § 353.153 ([Att. 16](#)).

three months, for example, then the consumers can only use the prescriptions to purchase lenses elsewhere for nine months.

The definition of “issue date” in the proposed rule, however, provides a self-enforcing mechanism. Under that definition, the expiration period does not begin running until the prescription is released to the consumer. Accordingly, the ECP has no incentive to withhold the prescription for a certain period of time or to back-date it. As one ECP stated:

The ISSUE DATE is the date the patient received a copy of their Rx . . . You have to remember that you must place it in their hands when the fitting is complete. YOU know when that is. You can try and act dumb and come up with all kinds of excuses and rationale for it being some obscure time in the future, but all that will happen is you'll look like you are acting, AND you may find yourself having to defend against a \$1000 + fine by the FTC!²⁷⁷

However, 1-800 believes that the rule would be clearer if it more precisely tracked the language in Section 315.3(a) of the proposed rule, which permits the prescriber to release the prescription by giving it directly to the consumer, or by giving the prescription information to the consumer’s agent. Accordingly, 1-800 believes that the definition of “issue date” should read: “the date on which the patient, or any person designated to act on behalf of the patient, first receives a copy of the prescription.”

6. Ophthalmic Goods

Section 315.2 of the proposed Contact Lens Rule defines “ophthalmic goods” as “contact lenses, eyeglasses, or any component of eyeglasses.”²⁷⁸ At this time, 1-800 has no comments on this provision.

7. Ophthalmic Services

Section 315.2 of the proposed Contact Lens Rule defines “ophthalmic services” as “the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination.”²⁷⁹ At this time, 1-800 has no comments on this provision.

8. Prescriber v. Seller

Section 315.2 of the proposed Contact Lens Rule defines “prescriber,” with respect to contact lenses, as “an ophthalmologist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration [“FDA”].”²⁸⁰ In its proposed rule, the FTC questions: “(a) Is this

²⁷⁷ Craig Steinberg, O.D., *Opticom – Discount Contact Lenses/ New CL Law*, ECP E-mail Forum, Nov. 22, 2003 (11:50 a.m.) (Att. 150).

²⁷⁸ 69 Fed. Reg. at 5449.

²⁷⁹ *Id.*

²⁸⁰ *Id.*

definition sufficiently clear? [and] (b) What is the impact, including costs and benefits, of defining the term in this way?”²⁸¹

1-800 has no comments on the FTC’s proposed definition of “prescriber” *per se*. However, 1-800 believes that the FTC should also define the term “seller” to make it clear that a seller need not be an ECP in order to sell contact lenses. As mentioned in Section II(B)(3)(b)(ii) herein, several states have existing or pending legislation or regulations that arguably require anyone selling contact lenses to be licensed ECPs.²⁸²

Such state laws or regulations have no beneficial impact on consumer health, and indeed, the AOA and other ECP associations are under a nationwide injunction prohibiting them from even making such a specious health argument.²⁸³ Since there is no evidence that it is safer for an ECP to sell a sealed box of contact lenses than for a non-ECP to do so, these laws have no real purpose other than to shield ECPs from competition by alternative sellers. Indeed, as the FTC recently announced:

[P]olicymakers and other officials can advance both [consumer health and consumer choice] if they: rescind, or refrain from adopting, requirements that an Internet seller have a professional license to sell replacement contact lenses. If states want to regulate such seller beyond prescription requirements and general state and federal consumer protection laws, they should adopt a simple registration requirement.²⁸⁴

Moreover, any requirement permitting only ECPs to sell contact lenses directly conflicts with the primary objective of the Fairness Act to ensure meaningful consumer choice and competition from alternative sellers (or non-ECPs).

It is well settled that federal enactments preempt conflicting state laws or regulations.²⁸⁵ Specifically, a state law is preempted when “under the circumstances of [a] particular case, it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”²⁸⁶ Although states generally may license and regulate trade within their borders, courts have repeatedly found state licensing laws preempted where they are at odds with the purposes or

²⁸¹ *Id.* at 5447.

²⁸² 1-800 continues to dispute the applicability and enforceability of these and other state laws to nonresident sellers of replacement contact lenses.

²⁸³ See *In re: Disposable Contact Lens Antitrust Litigation*, MDL 1030 (M.D. Fla.), AOA Settlement Agreement, dated May 22, 2001 (Att. 28).

²⁸⁴ *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*, a Report from the Staff of the FTC (Mar. 2004), at 31.

²⁸⁵ See, e.g., *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372-73 (2000); *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000).

²⁸⁶ *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

objectives of a federal enactment.²⁸⁷ As discussed in detail above, the purpose of the Fairness Act is to promote meaningful consumer choice and competition from alternative sellers. State laws or regulations that purport to impose an outright prohibition on sales from alternative sellers (*i.e.*, anyone other than an ECP) frustrate those very objectives and would render the Fairness Act's various protections meaningless.²⁸⁸

Although the Fairness Act preempts by implication any state requirement allowing only ECPs to sell contact lenses, that preemption should be made express to ensure that ECPs and their state boards do not undermine the very purpose of the Fairness Act - to promote consumer choice and competition from alternative channels - through imposition of such requirements. 1-800 proposes that the FTC add a definition for "seller" to Section 315.2 of the proposed regulations that provides:

A seller is any person or entity that sells or otherwise distributes contact lenses, and includes, but is not limited to, licensed professionals. Although a state or political division thereof may require a seller to register to sell contact lenses if such registration does not burden commerce in contact lenses, the Fairness to Contact Lens Consumers Act preempts any requirement that a seller must possess a professional license in order to perform the purely retail function of selling contact lenses.

9. "Private Label Contact Lens"

Section 315.2 of the proposed Contact Lens Rule defines "Private Label Contact Lenses" as "contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers."²⁸⁹ In its proposed rule, the FTC questions: "(a) Is this definition sufficiently clear? (b) What is the impact, including costs and benefits, of defining the term in this way?"²⁹⁰

At this time, 1-800 has no comments on the FTC's proposed definition of "private label contact lenses." However, as mentioned in Section III(A)(3) discussing the definition of "contact lens prescription," the FTC should add the definition of "doctor exclusive contact lenses" recommended by 1-800 to Section 315.2 of the regulations. The FTC should also revise the definition of "contact lens prescription" to ensure that ECPs who prescribe private label and doctor exclusive lenses also

²⁸⁷ See, e.g., *Gade v. Nat'l Solid Waste Management Ass'n*, 505 U.S. 88, 108-109 (1992) (holding that Illinois laws providing for licensing, training and testing of hazardous waste site workers were preempted by the Occupational Safety and Health Act to the extent they established health and safety standards for training such workers); *Gartrell Const. Inc. v. Aubry*, 940 F.2d 437, 438-441 (9th Cir. 1991) (holding that federal law preempted application of California's licensing requirements to contractors performing work for the federal government).

²⁸⁸ For example, a consumer's right to have his or her ECP release or verify a prescription to an alternative seller is entirely meaningless if alternative sellers cannot sell contact lenses in the first place. See, e.g., H.R. Rep. No. 108-318, at 4 (2003) (Consumers "continue to face a difficult time getting prescriptions filled by alternative third party sellers" and "[t]he consumer's right to a copy of their contact lens prescription means nothing unless consumers can fill that prescription at the business of their choice") (Att. 151).

²⁸⁹ 69 Fed. Reg. at 5449.

²⁹⁰ *Id.* at 5447.

provide the consumer with a way to purchase contact lenses sold to alternative sellers as well as prescribers.

B. Availability of Contact Lens Prescriptions to Patients

1. Prescriber Duties: Prescription Release and Verification

a. Section 315.3(a)

Section 315.3(a) of the proposed Contact Lens Rule requires prescribers to release and verify contact lens prescriptions to their patients and to any person designated to act on behalf of the patient. Specifically, Section 315.3(a) provides:

- (a) In general. When a prescriber completes a contact lens fitting, the prescriber:
 - (1) Whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and
 - (2) Shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.²⁹¹

In its proposed rule, the FTC questions: “(a) Is Section 315.3(a) sufficiently clear? [and] (b) Is it clear the means by which a prescriber shall provide or verify a contact lens prescription as directed by a third party authorized to act on behalf of the patient?”²⁹²

This provision implements one of the centerpieces of the Fairness Act – automatic prescription release. The FTC should make it clear in the preamble of the final regulations that sellers or other agents, such as family members, need not have a written agency agreement in order to act on behalf of the patient.

Moreover, requiring an alternative seller to prove written authority would be contrary to Section 315.5(a) of the proposed regulations, which permits sellers to verify prescriptions via direct communication, and Section 315.2 of the proposed regulations, which defines “direct communication” as including telephone communication. If a seller has to prove written authority in person or via fax before he or she can verify the prescription, then the ability to use the telephone to verify the prescription becomes meaningless. In addition, requiring written authority would undermine the Fairness Act’s goal of prescription portability. A patient should be able to authorize orally a family member to pick up his or her prescriptions, and the process of ordering contact lenses through an alternative seller should authorize the seller to act on the patient’s behalf.

²⁹¹ *Id.* at 5449.

²⁹² *Id.* at 5447.

b. Section 315.3(b)

Section 315.3(b) prohibits prescribers from imposing certain requirements or conditions on patients prior to releasing or verifying contact lens prescriptions, including charging them any fee for the prescription in addition to the fee for an eye examination, fitting, or evaluation. Specifically, that section provides:

- (b) *Limitations.* A prescriber may not:
- (1) Require the purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section;
 - (2) Require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section; or
 - (3) Require the patient to sign a waiver or release as a condition of releasing or verifying a prescription under paragraph (a)(1) or (a)(2) of this section.²⁹³

In its proposed rule, the FTC questions: “(a) Do prescribers itemize charges and fees in a manner that distinguishes the amount a patient is paying for an eye examination, fitting, and evaluation, from the amount she or she is paying for other goods and services? (b) Are there additional requirements or conditions that should be prohibited to facilitate the release and verification of contact lens prescriptions, [and] (b) What would be the impact, including costs and benefits, of such additional prohibitions?”²⁹⁴

1-800 is troubled by the FTC’s proposed Section 315.3(b) because it: (1) permits ECPs to bundle eye examinations/ fittings and contact lenses, which undermines the intent of Section 2 of the Fairness Act²⁹⁵ and coerces consumers to purchase contact lenses from ECPs prior to the release of the prescription, and (2) fails to prohibit other behaviors that ECPs are currently using, or may use in the future, to undermine the Fairness Act’s central objective of meaningful prescription portability.

²⁹³ *Id.* at 5449.

²⁹⁴ *Id.* at 5447.

²⁹⁵ Fairness to Contact Lens Consumers Act, P.L. 108-164, § 2, 117 Stat. 2024 (2003).

i. FTC's Fairness Act Regulations Must Provide a Countermeasure Against Bundling Eye Examinations/ Fittings and Contact Lenses, Or Otherwise Coercing the Consumer To Purchase Contact Lenses from the Prescribers

The objective of Sections 315.3²⁹⁶ and 315.4²⁹⁷ is to prevent ECPs from engaging in coercive and unfair practices that limit prescription portability and effectively require consumers to purchase contact lenses from an ECP. Yet, in ECP chat rooms, ECPs have already discussed how to game the prescription release requirements in the Fairness Act to effectively coerce consumers into purchasing from an ECP.

According to typical ECP conversations, ECPs can coerce consumers into buying contact lenses from them by writing simple things, such as “diagnostic pairs only,” or “return for follow up” on the prescription. One ECP advises:

If patients want to get their lenses elsewhere, I will give them an Rx for a “Diagnostic Pair Only, Changes to Come” and write “Return for follow up” on the script. This way the seller is using his lens bank. If a seller wants to play the contact lens game, let them bear the whole burden just like I do!²⁹⁸

Unbelievably, some ECPs even go so far as giving patients the wrong prescription to ensure that they will come back:

I had a 19 year old female in 2 days ago who admitted to having gone 3 months with one pair of 2 week contact lenses. She was desperate for more, but only had enough \$ for her “CL exam” services. So I took the hint that I learned on this list recently, and sent her home under minused by half a diopter. She had, when she first arrived at the office, promised to return within the week with funds to purchase her contact lenses So thanks to whatever list member [sic] suggested underpowering those whom we feel we NEED back for a followup²⁹⁹

Perhaps the most widely suggested technique to coerce consumers into buying contact lenses from ECPs, despite the Fairness Act, is bundling examination fees, sample lenses, and/or initial lenses. Some ECPs are using the term “global fee” as a euphemism for bundling, and are recommending the following:

²⁹⁶ Proposed Section 315.3 mandates prescription release and prohibits enumerated anticompetitive behaviors designed to coerce consumers into purchasing contact lenses from an ECP. *See* 69 Fed. Reg. at 5449.

²⁹⁷ Proposed Section 315.4 permits ECPs to require payment for an eye examination/fitting prior to the release of a prescription only if the prescriber requires immediate payment when an eye examination reveals that the consumer does not need ophthalmic goods. *See id.*

²⁹⁸ Steve Sobel, *Opticom - Discount Contact Lenses/New CL Law*, ECP E-mail Forum, Nov. 21, 2003 (6:13 a.m.) (Att.152).

²⁹⁹ Mark R. Sukoening, O.D., *Opticom-Poll about “free” trial CLs*, ECP E-mail Forum, Mar. 13, 2004 (1:17 p.m.) (Att.153).

- It would be in our best interest to structure our CL fees so that at least the initial contact lenses are included in the initial contact lens fee.³⁰⁰
- If they don't like our global fee structure for new patients which include the initial lenses, then they are cordially invited to seek services elsewhere where the fitter is willing to put up with their warped sense of what the doctor-patient relationship is all about.³⁰¹
- Solutions: 1. New fits, patients who have never worn any contact lenses or this type of lens (for example: switching from soft to [rigid gas permeable]), will, henceforth, be required to obtain their initial minimum quantity [sic] lenses from the fitter as part of the global fee charged.³⁰²
- [T]he price [of the exam] includes all materials and lenses used in the fitting, the final pair of which they can keep at the end of the fitting if they want, but it's not required and whether they do or not does not change the price.³⁰³
- Some eyecare practitioners offer bundled packages of lenses and professional services.³⁰⁴
- So, in this particular scenario, the doctor/fitter has, in fact, charged the patient for the initial lenses, disguised as "fitting materials"; however, since there is no requirement by the doctor/fitter that the patient retain the lenses, the doctor/fitter is therefore in compliance with the law? Somehow, there is certainly the appearance that the patient was, in fact, "sold" the lenses ("fitting materials") as the patient does not get a refund for their return.³⁰⁵

Notably, the bundling strategy violates Section 2(b)(1) of the Fairness Act³⁰⁶ because it is essentially requiring the purchase of contact lenses prior to the release of the prescription. Bundling also undermines the objective of the Fairness Act because its purpose is to extract as much money as possible out of each consumer and to defeat prescription portability.

³⁰⁰ Henry Valentine, *Optcom - Discount Contact Lenses/New CL Law*, ECP E-mail Forum, Nov. 21, 2003 (4:38 p.m.) ([Att. 154](#)).

³⁰¹ Henry Valentine, *Optcom - Discount Contact Lenses/ New CL Law*, ECP E-mail Forum, Nov. 23, 2003 (7:54 p.m.) ([Att. 155](#)).

³⁰² Henry Valentine, *Optcom - Discount Contact Lenses/New CL Law*, ECP E-mail Forum, Nov. 23, 2003 (6:22 p.m.) ([Att. 156](#)).

³⁰³ Howard Ossen, *Optcom - FCLCA/FCLCA Scenario/FCLCA Charting*, ECP E-mail Forum, Jan. 31, 2004 (9:19 a.m.) ([Att. 157](#)).

³⁰⁴ Liz Segre, *Where's the Best Place to Buy Contact Lenses*, ECP Online Journal – All About Vision, <http://www.allaboutvision.com/buysmart/contacts/htm>, visited Mar. 23, 2004 ([Att. 158](#)).

³⁰⁵ Craig Steinberg, O.D., *Optcom - FCLCA/FCLCA Scenario/FCLCA Charting*, ECP E-mail Forum, Jan. 31, 2004 (11:00 a.m.) ([Att. 159](#)).

³⁰⁶ Fairness to Contact Lens Consumers Act, P.L. 108-164, § 2(b)(1), 117 Stat. 2024 (2003) ("A prescriber may not – (1) require purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription . . . or verification of a prescription . . .").

There is no legitimate interest behind this strategy given that ECPs generally do not have to pay for diagnostic lenses used during the fitting process. The manufacturers typically offer diagnostic lenses for free to ensure that their contact lenses are fitted, and therefore, prescribed.³⁰⁷ Accordingly, ECPs will not *lose* money if they do not charge for diagnostic or sample lenses.

It is imperative that the Fairness Act regulations, and the preamble thereto, make it clear that ECPs cannot game the Fairness Act and undermine prescription portability by bundling eye examinations and fittings with contact lens sales, or otherwise coercing consumers to purchase contact lenses from ECPs. The regulations should make it abundantly clear that there can be no commercial discussion prior to the release of the contact lens prescription.

To prevent this serious problem, consumers should be informed of their right to their prescriptions *before* the contact lens fitting process begins. 1-800 believes that ECPs should be required to give all consumers a form to educate consumers about the right to a contact lens prescription under the Fairness Act. The form should contain information about prescription rights under the Fairness Act only. It should not be used by ECPs as a marketing opportunity. The form should also contain a signature block for the consumer to acknowledge that he or she understands his or her rights. This education initiative is particularly important given the fact that 65.8% of consumers were not aware that they had a right to an eyeglass prescription in 1997, almost 20 years after the Eyeglass Prescription Release Rule was enacted.³⁰⁸ Similarly, in Texas, after the prescription release-upon-request provision was enacted, 57% of optometrists still would not release prescriptions unless the patients returned for follow-up visits.³⁰⁹

Requiring ECPs to give consumers a prescription rights information form prior to each eye examination or contact lens fitting would not be burdensome for ECPs. Indeed, in the past the AOA itself has encouraged member ECPs to distribute forms to consumers. For example, in response to the Fairness Act, an ECP trade article, entitled “CL Patient Information Form Now Available” provides an AOA recommended form to its ECP readers that contains a space to compare the ECP’s prices to leading Internet prices³¹⁰ and a signature block for the consumer to acknowledge that he or she has read the information carefully.³¹¹

Accordingly, the FTC should adopt the AOA’s concept of a signed consumer information form and add a new Subsection (a) to Section 315.3 regarding the prescription rights information form, which provides:

(a) Prescription Rights Information Form. Before a prescriber begins a contact lens fitting, the prescriber shall give the patient written notice of his or her prescription release right under the

³⁰⁷ See *supra*, discussion at Section II(A)(1).

³⁰⁸ 69 Fed. Reg. at 5452.

³⁰⁹ See, e.g., *The Eyes Don’t Have It Yet*, Consumers Union, Southwest Regional Office (Jan. 2001) (Att. 101).

³¹⁰ See *CL Patient Information Form Now Available*, Practice Strategies, 74 Optometry 792 (Dec. 2003) (Att. 160).

³¹¹ See *id.*

Fairness Act, and receive signed documentation that the patient understands his or her rights. The written notice shall not contain any commercial information. The written notice should stand alone on a form and state the following:

CONSUMERS HAVE A RIGHT TO THEIR CONTACT LENS PRESCRIPTIONS.

The Fairness to Contact Lens Consumers Act ("Fairness Act") requires a contact lens prescriber:

- (1) To automatically provide a consumer with a copy of his or her contact lens prescription, whether or not requested by the consumer, and*
- (2) To verify the prescription's accuracy, or make necessary corrections, to a contact lens seller or any person designated by the consumer.*

The Fairness Act prohibits a prescriber from:

- (1) Requiring the purchase of contact lenses as a condition of releasing the prescription,*
- (2) Charging an additional fee for a copy of the prescription,*
- (3) Requiring a patient to sign a waiver to obtain a prescription,*
- (4) Attempting to sell contact lenses to any person before the contact lens fitting process is complete and the prescription has been released to the consumer, or*
- (5) Otherwise coercing a consumer to purchase contact lenses from the prescriber.*

I understand that I have a right to my contact lens prescription and that no purchase is necessary.

Patient Signature _____

Subsection 315.3(a) in the proposed rule would become Subsection (b), and Subsection 315.3(b) in the proposed rule would become Subsection (c). ECPs should also be required to maintain signed copies of their customers' prescription rights information forms, and Subsection 315.3(d) should be added to that effect, to read:

(d) Recordkeeping requirement. A prescriber shall maintain a record of all prescription rights information forms referred to in paragraph 315.3(a) of this section for not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

The prescription rights information form and the recordkeeping requirement would simplify enforcement for the FTC and protect ECPs. Without such a form and the corresponding recordkeeping requirement, it would be virtually impossible for the FTC to identify non-compliant ECPs, unless the FTC had the resources for regular secret shopping, and it would be virtually impossible for an ECP to defend himself against an allegation.

In addition, Section 2(a)(1) of the Fairness Act guarantees a patient the right to receive automatically a copy of the contact lens prescription once “a prescriber completes a contact lens fitting.”³¹² The statute provides no interval prior to the release of a contact lens prescription for the ECP to engage in the process of selling lenses to the patient. This makes sense inasmuch as having a consumer receive his or her prescription *after* the ECP has already initiated the sale of lenses undermines the purposes of prescription release, may limit the patient's sense of choice, and can be seen by the patient as coercive.

To assure the statute is carried out as written and the purposes of prescription release are honored, the FTC should make clear that ECPs may not discuss with a patient the purchasing of lenses until after the patient has received a copy of his or her contact lens prescription. Specifically, provisions (4) and (9) should be added to new Subsection (c) as follows:

Limitations. A prescriber shall³¹³ not . . . (4) Attempt to sell contact lenses to any person until the contact lens fitting process has been completed and the prescription has been released to the consumer, or . . . (9) Otherwise coerce the consumer to purchase contact lenses from the prescriber.

ii. FTC Regulations Must Provide Countermeasures Against Other ECP Anticompetitive Practices

The FTC's regulations must also provide countermeasures against the anticompetitive practices that ECPs are currently engaging in, and similar practices that are likely to emerge in the future as the traditional practices are prohibited. As mentioned, in Section III(A)(4) herein, regarding “direct communication,” the FTC's regulations should prohibit ECPs from attempting to avoid the obligation to verify prescriptions by avoiding communication with sellers. Accordingly, paragraph (5) should be added to Section 315.3(c) as follows:

Limitations. A prescriber shall³¹⁴ not: . . . (5) Fail to keep an open line of communication or otherwise avoid seller attempts to verify a prescription.³¹⁵

³¹² Fairness to Contact Lens Consumers Act, P.L. 108-164, § 2, 117 Stat. 2024 (2003).

³¹³ 1-800 proposes that FTC use the word “shall,” rather than the word “may” because “shall” connotes that the provision is mandatory, whereas “may” connotes that the provision is permissive.

³¹⁴ *See id.*

³¹⁵ A prohibition against prescribers otherwise avoiding seller attempts to verify prescription information would include, for example, misrepresenting the applicability of HIPAA. *See infra*, discussion at Section III(B)(3)(c).

In addition, as mentioned in Sections II(B)(3)(a) and III(A)(1), several ECP articles recommend that ECPs use the prescription verification call from alternative sellers to interfere with alternative sellers' sales, and 1-800 has evidence that ECPs have already begun to do just that.³¹⁶ Accordingly, the FTC should add paragraph (6) to Section 315.3(c) as follows:

Limitations. A prescriber shall³¹⁷ not: . . . (6) Use a seller's prescription verification request to interfere with a contact lens sale.

Moreover, as noted in Section II(B), ECPs have long been playing the avoid-prescription-release game, and tactics have included activities, such as removing prescription information from contact lens packaging. This practice interferes with consumers' ability to rely on prescription information from contact lens packaging when they lose their actual prescriptions. Therefore, 1-800 recommends adding paragraph (7) to Section 315.3(c) as follows:

Limitations. A prescriber shall³¹⁸ not: . . . (7) Remove, conceal, or otherwise interfere with the visibility of prescription information present on the packaging or labeling of contact lenses provided to patients.

Finally, as mentioned in Section III(A)(1)(b), the definition of "business hours" should permit sellers to verify an ECP office's actual business hours. However, given the anticompetitive practices that ECPs have engaged in previously, 1-800 is concerned that ECPs could undermine the verified business hour system by providing sellers with false information. Accordingly, 1-800 recommends adding paragraph (8) to Section 315.3(c) as follows:

Limitations. A prescriber shall³¹⁹ not: . . . (8) Provide false information to sellers regarding actual business hours of the prescriber's office, or avoid providing information regarding actual business hours of the prescriber's office to sellers.

2. Limits on Requiring Immediate Payment

Section 315.4 of the proposed Contact Lens Rule limits the circumstances under which a prescriber may require immediate payment for fees for an eye examination, fitting, and evaluation prior to releasing a contact lens prescription, providing:

A prescriber may require payment of fees for an eye examination, fitting, and evaluation before the release of a contact lens prescription, but only if the

³¹⁶ Ronald P. Snyder, O.D., F.A.A.O., *Winning the War Against Mail-Order Contact Lenses*, *Optometry Today* (Jan./Feb. 1993) (Att. 62); see also Gary Gerber, O.D., *Patient "Cheapskate" and The New Law*, *Review of Contact Lenses* (Jan. 2004) (Att. 86); Michelle Boyles, *Cole to Give Exams to 1-800 Customers*, 140 *Review of Optometry* 4 (Aug. 15, 2003) (Att. 84); Joseph Barr, O.D., M.S., F.A.A.O., *Annual Report: 2003*, *Contact Lens Spectrum* (Jan. 2004) (Att. 87); see also 1-800 Sales Interference Responses (Att. 132).

³¹⁷ 1-800 proposes that FTC use the word "shall," rather than the word "may" because "shall" connotes that the provision is mandatory, whereas "may" connotes that the provision is permissive.

³¹⁸ See *id.*

³¹⁹ See *id.*

prescriber requires immediate payment in the case of an examination that reveals no requirement for ophthalmic goods. For purposes of the preceding sentence, presentation of proof of insurance coverage for that service shall be deemed to be a payment.³²⁰

In its proposed rule, the FTC questions whether this provision sufficiently clear.³²¹

The objective of Section 315.4 in the proposed rule is to prevent prescribers from engaging in coercive and unfair practices at the time of the eye exam that limit prescription portability and effectively require consumers to purchase contact lenses from the prescriber. Notably, however, the last sentence in Section 315.4 of the proposed rule, regarding the presentation of proof of insurance coverage, may frustrate this objective. For example, some insurance policies, such as the VSP contact lens plan, memorialize anticompetitive practices by giving ECPs a decided advantage. Under the VSP plan, patients are eligible for 20% discounts – *i.e.* VSP Member Preferred Pricing – “as long as they purchase the lenses from the *same doctor who provided the exam.*”³²²

To prevent this limitation on portability, 1-800 recommends that a sentence be added to Section 315.4 that reads: “*No insurance or pricing policy shall require a patient to purchase contact lenses from a prescriber in order to enjoy the benefits of the policy.*” At minimum, the FTC should examine the issue of whether insurance company policies unlawfully limit prescription portability and frustrate consumers’ opportunity to choose among retailers as part of the study and report required by Section 10 of the Fairness Act.³²³

3. Seller Duties: Prescriber Verification

a. Prescription Requirement

Section 315.5(a) of the FTC’s proposed Contact Lens Rule establishes the circumstances under which contact lens sellers may sell contact lenses to a patient, providing:

- (a) Prescription requirement. A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is:
 - (1) Presented to the seller by the patient or prescriber directly or by facsimile; or
 - (2) Verified by direct communication.³²⁴

³²⁰ 69 Fed. Reg. at 5449.

³²¹ *See id.* at 5447.

³²² *See* 2003 WellVision Plan Manual, VSP Member Contact Lens Program (Att. 161).

³²³ Fairness to Contact Lens Consumers Act, P.L. 108-164, § 10, 117 Stat. 2026-27 (2003).

³²⁴ 69 Fed. Reg. at 5449.

The FTC, in its proposed rule, questions: “(a) Is this provision sufficiently clear, and, if not, what should be clarified? (b) Should the Commission specify, for purposes of paragraph (a)(1), that either the original or a copy of a prescription will suffice? [and] (c) Are there additional requirements the Commission should consider imposing, and what would be the impact, including costs and benefits, of such additional requirements?”³²⁵

1-800 is troubled by the fact that a seller may sell contact lenses only if the seller receives the prescription from the patient or the prescriber “directly or by facsimile.” The term “directly” should explicitly permit the information to be provided by telephone, e-mail, or by some equivalent future technology. 1-800 recommends that the words “directly or by facsimile” be replaced, such that the provision states: “A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is: (1) Presented to the seller by the patient or prescriber *in person, or by telephone, facsimile, electronic mail, or a substantially equivalent communication technology . . .*”

b. Information for Verification

Section 315.5(b) of the proposed Contact Lens Rule establishes the information a contact lens seller must provide to a prescriber when the seller seeks verification of a contact lens prescription, providing:

- (b) Information for verification. When seeking verification of a contact lens prescription, a seller shall provide the prescriber with the following information through direct communication:
 - (1) The patient’s full name and address;
 - (2) The contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate;
 - (3) The quantity of lenses ordered;
 - (4) The date of patient request;
 - (5) The date and time of verification request; and
 - (6) The name of a contact person at the seller’s company, including facsimile and telephone numbers.³²⁶

At this time, 1-800 has no comments on this language.

³²⁵ *Id.* at 5447.

³²⁶ *Id.* at 5449.

c. Verification Events – Affirmative and Default Verification

Section 315.5(c) of the proposed rule establishes the circumstances under which a contact lens prescription is deemed verified, providing:

- (c) Verification events. A prescription is verified under paragraph (a)(2) of this section only if one of the following occurs:
 - (1) The prescriber confirms the prescription is accurate by direct communication with the seller;
 - (2) The prescriber informs the seller through direct communication that the prescription is inaccurate and provides the accurate prescription; or
 - (3) The prescriber fails to communicate with the seller within eight (8) business hours after receiving from the seller the information described in paragraph (b) of this section.³²⁷

The FTC, in its proposed rule, questions: “(a) Is this provision sufficiently clear? (b) What is the impact, including costs and benefits, of this provision? (c) Is there a different time period that is similar to eight business hours, as set forth in section 315.5(c)(3), that would give prescribers an adequate period of time during normal office hours to act upon a prescription verification request and still allow sellers to fill customer orders expeditiously? (d) What would be the impact, including costs and benefits, of such other time period? [and] (e) Does the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) limit or otherwise affect prescribers’ ability to respond to a verification request pursuant to section 315.5(c) and/or section 315.5(d)?”³²⁸

The two primary issues implicated by this section are: (1) the length of the waiting period for presumed verification, and (2) the application of HIPAA to prescription verification. As noted 1-800 believes that 8 business hours is too long of a waiting period for presumed verification and that 5 business hours is more than sufficient, unless a live agent of the seller communicates with a live agent of the ECP via telephone, in which case, 2 business hours is sufficient. This issue is of paramount importance, and is discussed in depth in Section III(A)(1) herein. Based on that discussion, 1-800 proposed that the final Section 315.5(c)(3) read:

The prescriber fails to communicate with the seller within five (5) business hours after receiving from the seller the information described in paragraph (b) of this section, or if a live agent for the seller communicates with a live agent for the prescriber via telephone (or a substantially equivalent technology that permits immediate communication between the seller and the prescriber), and the prescriber fails to verify the prescription within two (2) business hours after receiving from the seller the information described in paragraph (b) of this section.

³²⁷ *Id.* at 5449.

³²⁸ *Id.* at 5447.

With regard to HIPAA, the Standards for Privacy of Individually Identifiable Health Information³²⁹ (the “HIPAA Privacy Regulation”) does not limit or otherwise affect an ECP’s ability to respond to a prescription verification request. The HIPAA Privacy Rule does *not* require ECPs to obtain a written, signed patient authorization before verifying prescription information to contact lens sellers. The HIPAA Privacy Regulation, as modified in April 2002, permits the disclosure of individually identifiable health information for *treatment purposes* without obtaining any consent or authorization from patients.³³⁰

The HIPAA Privacy Rule specifically allows a covered health care provider to “disclose protected health information for treatment activities of a health care provider.”³³¹ Alternative contact lens sellers are health care providers for this purpose.³³² Verifying a contact lens prescription (which is a disclosure of protected health information)³³³ is treatment within the definitions of the regulation.³³⁴ Therefore, prescription verification is permitted under the Privacy Rule.

³²⁹ See 45 C.F.R. pts. 160 and 164 (2003).

³³⁰ *Id.* at § 164.502(a)(1)(ii).

³³¹ *Id.* at § 164.506(c)(2).

³³² The regulation defines a “health care provider” broadly to include any “person or organization who furnishes, bills, or is paid for health care in the normal course of business.” *Id.* at § 160.501. Health care is defined to include:

Preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual that affects the structure or function of the body; and . . . [s]ale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Id. Because alternative contact lens sellers sell and/or dispense contacts in accordance with a prescription, they are “health care providers” under the HIPAA regulations.

³³³ The verification is a disclosure, even though the alternative sellers already “know” the prescription information. A disclosure is “the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.” *Id.* at § 164.501. A verification process is a disclosure because it reveals the validity of the protected health information to the party seeking the verification. It is an exchange of information.

³³⁴ The final rule defines treatment as:

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

Id. at § 164.501. Filling a contact prescription meets this definition.

ECPs hoping to undermine the Fairness Act may argue that a patient must affirmatively agree to the disclosure before it can be made.³³⁵ This statement, however, is false. The HIPAA Privacy Rule does not require ECPs (*i.e.*, covered health care providers) to obtain consents. According to HHS:

A health care provider that has a direct treatment relationship with an individual [*i.e.*, an ECP] is not required by the Privacy Rule to obtain an individual's consent prior to using and disclosing information about him or her for treatment, payment, and health care operations. They, like other covered entities, have regulatory permission for such uses and disclosures.³³⁶

Moreover, in public questions and answers, HHS has explicitly stated that the HIPAA Privacy Rule does not limit or otherwise affect an ECP's ability to verify a prescription to an alternative seller:

Question: Does the HIPAA Privacy Rule permit an eye doctor to confirm a contact [lens] prescription received by a mail order contact [lens] company?

Answer: Yes. The disclosure of protected health information by an eye doctor to a distributor of contact lenses for the purpose of confirming a contact lens prescription is a treatment disclosure, and is permitted under the Privacy Rule at 45 C.F.R. 164.506.³³⁷

Notably, the language prescribed in Section III(B)(1)(b)(ii) herein, for Section 315.3(c)(5) of the regulations, which prohibits "otherwise avoid[ing] attempts to verify a prescription," would prohibit ECPs from misrepresenting the applicability of HIPAA in an attempt to undermine the prescription verification obligation.

d. Invalid Prescription

Section 315.5(d) of the proposed Contact Lens Rule prohibits a contact lens seller from filling the prescription if the prescriber provides timely notice to the seller that the prescription is inaccurate, expired, or otherwise invalid, unless the prescriber has corrected the inaccuracy. Specifically, that Section provides:

- (d) Invalid prescription. If a prescriber informs a seller before the deadline under paragraph (c)(3) of this section that the contact lens prescription is inaccurate, expired, or otherwise invalid, the seller shall not fill the prescription. The prescriber shall specify the basis for the inaccuracy or

³³⁵ Indeed, ECPs have used HIPAA as an excuse to refuse prescription release in the past. *See, e.g.*, Letter from R. Joe Zeidner, General Counsel, 1-800 to Robinsue Frohboese, Acting OCR Director, Department of Health and Human Services, dated Apr. 25, 2002 ([Att. 162](#)).

³³⁶ 67 Fed. Reg. 53182, 53211 (Aug. 14, 2002). Even though patient permission is *not* needed, one prominent ECP noted that with an alternative seller, the transaction is initiated by the patient, so there is implied permission. *See* Craig Steinberg, *Optcom – HIPAA & New CL Law*, Nov. 26, 2003 (10:10 a.m.) ([Att. 163](#)).

³³⁷ HHS, Questions & Answers, Category: Privacy of Health Information/HIPAA, Answer ID 270, updated July 18, 2003, http://answers.hhs.gov/cgi-bin/hhs.cfg/php/enduser/prmt_adp.php?p_faqid=270&p_created=040317858&p_sid=aN4zja4h ([Att. 164](#)).

invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it, and the prescription shall then be deemed verified under paragraph (c)(2) of this section.³³⁸

The FTC, in its proposed rule, questions: “(a) Is this provision sufficiently clear? (b) Should the Commission specifically define inaccurate, invalid, and expired prescriptions, and, if so, what should those definitions include? [and] (c) What is the impact, including the costs and benefits, of this provision?”³³⁹

Section 315.5(c)(2) and Section 315.5(d), which require ECPs to specify the basis for the inaccuracy or invalidity of a prescription and to correct inaccurate information, generally ensures that ECPs will actually: (1) consult their records, and (2) correct the prescription information where necessary.

However, 1-800 is concerned that ECPs will be able to use the language in these provisions to argue that they can simply write “expired” on a prescription, without giving sellers – at a minimum – the exam date and issue date, which reflect whether or not the prescription is in fact expired. If ECPs are not required to provide such information, they may simply write “expired” on a prescription to avoid complying with the prescription verification provisions, the minimum prescription expiration period, or other requirements of the Fairness Act.³⁴⁰ Accordingly, Section 315.5(d) should explicitly require ECPs to give sellers the exam date and issue date of the prescription when they report that a prescription is expired, as is required by the Sections 2 and 11(3) of the Fairness Act³⁴¹ and Sections 315.2 and 315.3 of the proposed rule.³⁴²

Moreover, ECPs have already begun to undermine the prescription verification requirement in the Fairness Act by suggesting that ECPs can reject prescription information as inaccurate even if the information provided by the seller is materially complete. In an ECP chat room, one ECP advised that under the Fairness Act:

[I]f [sellers] give WRONG prescription information you must provide the CORRECT information, but if they don't give ALL the required items below, you need only inform them of which section is invalid or missing (e.g., “I am unable to verify this prescription because the request is invalid in that it does not comply

³³⁸ 69 Fed. Reg. at 5449.

³³⁹ *Id.* at 5447.

³⁴⁰ *See* Responses to 1-800 Prescription Verification Requests – So-Called “Expired” Prescriptions. Writing “expired” on prescriptions, in the past, has been an easy way for ECPs to avoid verification requirements because, without more information, there is no way to prove that the prescription is actually expired (Att. 165).

³⁴¹ Fairness to Contact Lens Consumers Act, P.L. 108-164, §§ 2, 11(3), 117 Stat. 2024, 2027 (2003).

³⁴² 69 Fed. Reg. at 5449. *See supra*, at Section III(A)(5) (discussing the importance of using the issue date to trigger the 1 year minimum expiration date, which provides an incentive for ECPs to actually issue the prescription when the exam is complete).

with [the Fairness Act]” [If you want to be a real stickler, if the full 9 digit zip code is missing, go for it . . .].³⁴³

To prevent unscrupulous ECPs from gaming this system, 1-800 proposes that the language in Section 315.5(d) be changed to make it explicit that prescription verification information is not invalid, so long as the ECP is provided with enough information to locate the consumer’s records. Section 315.5(d) should also explicitly require ECPs, in those circumstances, to provide the seller with all of the prescription information listed in Section 315.5(b) that is in their records.

In addition, 1-800 is concerned that ECPs will tell sellers that prescriptions are expired or otherwise invalid, only to turn around and sell to the consumer without performing another exam and issuing a new prescription. This behavior is not far removed from the current ECP practice of using the prescription verification process to interfere with alternative sellers’ sales. Notably, this behavior is the equivalent of selling contact lenses without a prescription because ECPs, as sellers, cannot self-verify an otherwise invalid prescription. Accordingly, Section 315.5(d) should expressly articulate this parity - if sellers cannot fill a prescription, ECPs cannot fill it either without another eye exam.

Based on these considerations, 1-800 recommends adding language to Section 315.5(d) as follows:

Invalid Prescriptions. If a prescriber informs a seller before the deadline under paragraph (c)(3) of this section that the contact lens prescription is inaccurate, expired, or otherwise invalid, *neither the prescriber nor the seller shall fill the prescription. The prescriber shall specify the basis for the inaccuracy or invalidity of the prescription (e.g., the prescriber shall provide the issue date and expiration date for any verification request as part of the prescription, and the prescriber shall provide the issue date and expiration date for any expired prescription as the basis for the prescription’s invalidity).*³⁴⁴ If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it, and the prescription shall then be deemed verified under paragraph (c)(2) of this section. *If the prescription information in paragraph (b) of this section communicated by the seller to the prescriber is materially complete, such that the prescriber can locate the patient’s records, the prescriber shall provide the seller with any additional information listed in paragraph (b) that is in his or her possession, and the prescription shall then be deemed verified under paragraph (c)(2) of this section.*

In addition, in accordance with Section III(A)(1)(b) herein, discussing the definition of “business hour,” the following sentence should be added to the end of Section 315.5(d):

³⁴³ Craig Steinberg, O.D., *Optcom – HR 3140 – Fairness to Contact Lens Consumer Act*, ECP E-mail Forum, Dec. 11, 2003 (10:48 p.m.) ([Att. 166](#)); *see also* Craig Steinberg, *Optcom-Contact Lens Rx*, ECP E-mail Forum, Dec. 13, 2003 (11:06 p.m.) (inappropriately suggesting that ECPs should reject prescriptions as invalid if consumers order a large number of lenses a month before their prescription expires) ([Att. 167](#)).

³⁴⁴ Notably, any time a prescriber verifies a valid prescription, the prescriber is still *required* to give the seller the issue date as well as the expiration date. *See* Fairness to Contact Lens Consumers Act, P.L. 108-164, § 2, (11)(3), 117 Stat. 2024, 2027 (2003); *see also* Sections 315.2 and 315.3 of the proposed regulations, requiring the prescriber to give the issue date and expiration date to the seller as part of the prescription. *See* 69 Fed. Reg. at 5449. The FTC should make it clear in the preamble that the prescriber must give the seller the issue date and the expiration date on all requests, regardless of whether the prescription is valid or invalid.

Sellers that receive notification from a prescriber outside of the verification period that a prescription is inaccurate, must notify the patient, and permit the patient to return any unused resaleable product.

c. No Alteration of Prescription/ Private Label Substitution

Section 315.5(e) prohibits sellers from altering contact lens prescriptions, but allows them to substitute identical contact lenses from the same manufacturer for private label lenses specified on a prescription.³⁴⁵ 1-800 agrees with the FTC that this provision is necessary to check anticompetitive uses of private label lenses, and that this provision is an important first step.

However, as noted in Section III(A)(3) herein, it is important to recognize that even with private label substitution, the private label ruse *still does work*. The Fairness Act assumes that alternative sellers can easily obtain equivalent national brands for private label lenses. This is absolutely not the case. Private label manufacturers have stepped up their efforts to cut off those who supply alternative sellers with private label lenses or their equivalents. 1-800 goes to great lengths to obtain products equivalent to private label lenses, often paying grossly inflated prices. In some cases, 1-800 cannot get all the lenses it needs. Thus, despite Congress' clear intent to remedy the private label problem, private label substitution is really just a first step to eliminating the problem.

1-800 believes that the FTC also should require ECPs that prescribe private label lenses to include the name of a brand *sold directly to alternative sellers* in the prescription. These recommendations are detailed in Section III(A)(3) herein.

In addition, 1-800 believes that private label lenses should be equally available to all sellers, and that the issue should be reviewed as part of the study and report required by Section 10 of the Fairness Act.³⁴⁶ Finally, as mentioned, 1-800 believes that the FTC regulations should provide a countermeasure for anticompetitive uses of "doctor exclusive contact lenses." 1-800's recommendations are in Section III(A)(3) herein.

f. Recordkeeping Requirements

Section 315.5(f) of the proposed Contact Lens Rule requires contact lens sellers to maintain for 3 years records of prescriptions received, direct communications with prescribers to verify prescriptions, and responses from prescribers to these requests for verification.³⁴⁷

ECP attempts to game this provision warrant mention because they are designed to undermine the procompetitive goals of the Fairness Act. ECPs in chat rooms have advised each other to inundate alternative sellers with requests for verification that the prescriptions were sold:

- I have an idea. When 1-800 faxes us a confirmation for the Rx and we send it back. Why don't we wait 24 hours and then fax a request for verification of the contact lens prescription

³⁴⁵ See 69 Fed. Reg. at 5449.

³⁴⁶ Fairness to Contact Lens Consumers Act, P.L. 108-164, § 10, 117 Stat. 2026-27 (2003).

³⁴⁷ See 69 Fed. Reg. at 5449.

that was sold? We have a right to make sure that the Rx was duplicated correctly, and it would give the 1-800 contact lens verification people something to do with their free time.³⁴⁸

- I ABSOLUTELY LOVE THIS IDEA! IF EVERY DOC DID THIS WE WOULD FLOOD THEM AND SHUT DOWN THEIR FAX SYSTEM.³⁴⁹
- The FTC rule states “the seller must maintain copies of all [. . .] rx verification responses from prescribers.” If we do as Dr. Abdella indicates, this would seemingly increase their cost of operations which would presumably increase their CL pricing. I’m sure this could be looked on as ill-spirited by them, but I actually like the idea³⁵⁰

C. Expiration of Contact Lens Prescriptions

Section 315.6 of the proposed Contact Lens Rule establishes a minimum contact lens prescription expiration date of one year, subject to an exception based on the medical judgment of a prescriber. Specifically, Section 315.6 provides:

- (a) In general. A contact lens prescription shall expire:
 - (1) On the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;
 - (2) Not less than one year after the issue date of the prescription if such State law specifies no date or specifies a date that is less than one year after the issue date of the prescription; or
 - (3) Notwithstanding paragraphs (a)(1) and (2) of this section, on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.
- (b) Special rules for prescriptions of less than one year.
 - (1) If a prescription expires in less than one year, the specific reasons for the medical judgment referred to in paragraph (a)(3) of this section shall be documented in the patient’s medical record with sufficient detail to allow for review by a qualified professional in the field.
 - (2) The documentation described in paragraph (b)(1) of this section shall be maintained for a period of not less than three years, and it must be available

³⁴⁸ John Abdella, O.D., *Optcom – 1-800 contacts*, ECP E-mail Forum, Feb. 19, 2004 ([Att. 168](#)).

³⁴⁹ DRM, *Optcom – 1-800 contacts*, ECP E-mail Forum, Feb. 19, 2004 (10:33 a.m.) ([Att. 169](#)).

³⁵⁰ Keith Poindexter, *Optcom – 1-800 contacts*, ECP E-mail Forum, Feb. 19, 2004 (10:34 a.m.) ([Att. 170](#)).

for inspection by the Federal Trade Commission, its employees, or its representatives.

- (3) No prescriber shall include an expiration date on a prescription that is less than the period of time that he or she recommends for a reexamination of the patient that is medically necessary.³⁵¹

The FTC, in its proposed rule, questions: (a) Is Section 315.6(a) sufficiently clear? (b) What is the impact, including the costs and benefits, of Section 315.6(a)? (c) Is Section 315.6(b) sufficiently clear? (d) What is the impact, including the costs and benefits, of Section 315.6(b)? (e) In what circumstances would there be legitimate medical reasons for setting a contact lens prescription expiration date of less than one year? (f) How can the Commission minimize the burden on prescribers imposed by the documentation requirement and the three-year time period for retention? and (g) For how long do prescribers currently retain medical records for their contact lens patients?³⁵²

As stated in Section III(A)(5) regarding the definition of “issue date,” 1-800 strongly agrees that the “issue date” should be the date on which the consumer, or the consumer’s agent, receives the prescription and that the expiration date should be triggered by the “issue date.” However, 1-800 believes that there should be additional clarity regarding the expiration date provisions to ensure that ECPs do not circumvent the law and, once again, practice anticompetitive behaviors.

Specifically, the FTC should: (1) provide a countermeasure to prevent ECPs from artificially expiring prescriptions early by attempting to limit the number of contact lenses that may be purchased under the prescription, and (2) recognize in the preamble to the final rule that using the special rules to shorten the length of a prescription to less than one year should be used in only the rarest of circumstances.

1. The Fairness Act Does Not Permit ECPs to Limit the Number of Lenses On A Prescription to Artificially Expire the Prescription

The Fairness Act clearly establishes a *minimum* expiration date of one year for contact lens prescriptions.³⁵³ The minimum expiration date prevents ECPs from limiting prescription portability by writing artificially short expiration dates.³⁵⁴ Even the chat room ECPs understand as much:

- Come on guys (and gals), read the law. It’s pretty clear. . . . the Rx can’t expire for at least one year (unless medically necessary. So no messing around with 1 week expirations and other dub [sic] things doctors have tried doing to defeat meal [sic] order³⁵⁵

³⁵¹ 69 Fed. Reg. at 5449-50.

³⁵² *Id.* at 5448.

³⁵³ Fairness to Contact Lens Consumers Act, P.L. 108-164, § 5, 117 Stat. 2025-26 (2003).

³⁵⁴ *Tracking Patient Retention*, ECP Journal – Contact Lens Spectrum Insert (Jan. 2002) (“the prescription expiration provides a retention tool”) (Att. 171).

However, ECPs are circumventing expiration date requirements by attempting to limit the number of lenses that may be sold under a prescription. For example, one ECP recommended shortening a two year expiration date, as follows:

- We can try to specify the amount of boxes (or lenses) that make up a one year supply and specify no refills. Even though the Rx expires in two years, it would have to be renewed yearly.³⁵⁶

Similarly, another ECP noted that quantity control “put[s] a crimp in the internet trade of medical devices.”³⁵⁷

There is no statutory basis or valid health reason to limit the number of contact lenses that can be issued under a prescription. Importantly, limiting the number of lenses just limits how frequently consumers can replace their dirty lenses. As mentioned, increasing consumer access to contact lenses increases consumer safety because consumers can change their lenses more frequently.³⁵⁸

Notably, contact lenses are not subject to abuse like controlled drugs – they cannot be abused if dispensed in large quantities. One prominent ECP noted:

- Quantity is pretty much irrelevant with contact lenses – you can’t overdose on them. Assuming that every patient is able to wear every lens for it’s full expected lifespan, then, yes, quantity would be the BEST way to limit the prescription. But lenses are lost, tear, etc. Perhaps the 7 day lens only lasts 5 days for a given patient, and on and on. Because of this, and because the ISSUE with contact lenses is not the risk of overuse, but the risk of going too long without being checked for complications, an expiration date is more appropriate.³⁵⁹

Indeed, unlike a drug, where a patient must take a set number of doses a day, the frequency with which consumers change their contact lenses varies greatly. Over 50% of contact lens wearers use 1 to 2 week disposable contact lens products, but others use 30-day extended wear, and still others change their contact lenses daily.³⁶⁰ Accordingly, without accounting for lost contacts or torn contacts, a typical consumer could need anywhere from 12 to 365 pairs of contact lenses a year.

Moreover, consumers are not hoarding lenses. As one ECP recently noted:

³⁵⁵ Craig Steinberg, O.D., *Optcom – Discount Contact Lenses/ New CL Law*, ECP E-mail Forum, Nov. 22, 2003 (11:50 a.m.) ([Att. 150](#)).

³⁵⁶ Michael Davis, *Optcom Rx Expiration Quantity*, Feb. 7, 2004 (11:56 a.m.) ([Att. 172](#)).

³⁵⁷ Jeffrey Kiener, *New Rx Release Law*, *Optometric Journal – Review of Optometry*, <http://www.revoptom.com/index.asp?show=content&idx=3289> ([Att. 173](#)).

³⁵⁸ See FTC Comments of the AGs, at 7 ([Att. 6](#)); see also Letter to FDA Docket No. 2003P 0291, from 1-800, dated Jan. 13, 2004 (with attachments) ([Att. 11](#)); Hubbard Testimony, Sept. 9, 2003, at 5 ([Att. 5](#)).

³⁵⁹ Craig Steinberg, *Optcom-Contact Lens Rx*, ECP E-mail Forum, Dec. 13, 2003 (11:06 p.m.) ([Att. 167](#)).

³⁶⁰ See, AOA website: <http://www.aoanet.org/eweb/DynamicPage.aspx?site=AOAStage&WebCode=CLLactsStars> ([Att. 31](#)); see, e.g., Joseph Barr, O.D., M.S., F.A.A.O., *Annual Report: 2003*, *Contact Lens Spectrum* (Jan. 2004) ([Att. 87](#)).

- I don't think I've ever known any patients who actually "stockpile" lenses. . . . I think most people do not like to invest in contacts unless they have to because they would rather spend their money . . . on cars, jewelry, boats, and bigscreen TVs. . . . [M]ost people live paycheck to paycheck.³⁶¹

Indeed, most of 1-800's consumers reasonably buy a four months supply of contact lenses at a time. To the extent that a consumer orders more contact lenses than he or she needs before his or her prescription changes, he or she may return their unused contact lenses to 1-800. 1-800's return policy also alleviates any concern about consumers purchasing a full year supply of contact lenses 11 months after a prescription has been issued, if the prescription is only valid for a year. Notably, however, permitting consumers to buy a full year supply of contact lenses, literally in the 11th hour, is an accepted industry-wide practice, as reflected by the Questions and Answers in the VSP Member Contact Lens Program.³⁶²

Notably, the practice of limiting the portability of prescriptions by placing quantity limits in prescriptions is not isolated to a few ECPs. Indeed, some ECP influenced state laws, such as the law in Texas, *require* quantity limits in prescriptions.³⁶³ The anticompetitive effect of this state law is not lost on consumers. Recently, the Consumers Union testified before Congress and complained that under the Texas law "[i]f a consumer tears a lens or loses a box, then the prescription can 'run out' long before the year is up and the [ECP] can require a new exam before writing it out again."³⁶⁴

Artificially expiring the prescription earlier than one year by limiting the number of contact lenses that may be dispensed undermines the Fairness Act's objectives of promoting competition, prescription portability, and consumer choice. The FTC should make it clear to all ECPs that they cannot use quantity limits to circumvent the expiration date provisions in the Fairness Act.

2. Expiration of a Prescription Prior to One Year Should Be Used Only in the Rarest of Occasions

The Fairness Act provides that, if medically necessary, the prescription may expire prior to one year as specified by the prescriber. 1-800 believes that this provision should be used only on the rarest of occasions. Congress set the minimum expiration period at one year, rather than longer, out of an abundance of caution. Even ECPs concede that:

- As we have established through discussion over the last few months, there does not seem to be a great deal of evidence to support our claims of "significant health risk" associated with exam intervals longer than a year.³⁶⁵

³⁶¹ Keith Watson, *Optcom- Discount Contact Lenses/ New CL Law*, ECP E-mail Forum, Nov. 23, 2003 (2:48 a.m.) ([Att. 174](#)).

³⁶² See 2003 WellVision Plan Manual, VSP Member Contact Lens Program ([Att. 161](#)).

³⁶³ See Texas Contact Lens Prescription Act, § 353.103 ([Att. 16](#)).

³⁶⁴ See Gadhia Testimony ([Att. 7](#)).

³⁶⁵ Christopher Feahr, *Optcom- Fairness to CL Patients Law*, ECP E-mail Forum, Dec. 13, 2003 (5:31 p.m.) ([Att. 175](#)).

- I am not so sure that 2 years is too long. . . I say this because during the time that I practiced, I saw thousands of contact lens patients. . . [I]n summary: I never saw ONE patient who used the lenses as they were intended to be used EVER have a problem, EVEN if they obtained lenses from “alternative sources” for years on end.³⁶⁶

Moreover, for the majority of contact lens wearers, most of whom are between the ages of 18-44 years old,³⁶⁷ the AOA recommends an eye exam once every two years. Specifically, the AOA recommends that eye exams should be scheduled, as follows³⁶⁸:

<u>Eye Exam</u>	<u>Age Range</u>
Every 2-3 years	Between age 18 and 40
Every 2 years	Between age 41 and 60
Every year	61 and older

Further, the majority of states that cover regular refractive eye exams under their Medicaid programs allow adult Medicaid recipients to receive one eye exam every two years.³⁶⁹

1-800 fully supports the enhancement of, and believes its retail services contribute to, ocular health. The notion that sellers contribute to ocular health problems is a chimera created by anticompetitive ECPs.³⁷⁰

³⁶⁶ Ken Elder, *SeniorDocs - Between a Rock and a Hard Place*, Feb. 14, 2004 (5:51 p.m.) (quoting Paul Farkas) (Att. 176).

³⁶⁷ See, AOA website: <http://www.aonet.org/eweb/DynamicPage.aspx?site=AOAStage&WebCode=CLFactsStats> (Att. 31).

³⁶⁸ The Great American Eye Test, AOA, www.aonet.org (Att. 177).

³⁶⁹ See Survey of 50 States, District of Columbia and Territories released jointly by Kaiser Commission on Medicaid and Uninsured with the National Conference of State Legislatures, Jan. 2003 (Att. 116); see also Alabama Medicaid Agency Administrative Code, Ch. 560-X-17.30 (authorizes Medicaid recipients over the age of 21 to receive one complete eye exam each 2 calendar years; recipients under 21 are authorized one complete eye exam each calendar year) (Att. 117).

³⁷⁰ The available information indicates that complications associated with contact lenses, regardless of origin, are extremely low. For example, although approximately 882.26 million individual contact lenses were sold in 2002, FDA’s medical device adverse event database indicates that approximately 85 adverse events involving contact lenses were reported in 2002 – without reference to lens retailer origin. (Adverse event data for contact lenses was obtained from the FDA’s Center for Devices and Radiological Health (“CDRH”) website, MAUDE database. See <http://www.fda.gov/cdrh/maude.html>. These 85 events are limited to events involving the contact lenses alone – they do not include events regarding contact lens solution, care products, etc.). The Association of Regulatory Boards of Optometry (“ARBO”) recently issued a report for 2003 identifying 116 reports of complications involving contact lenses that were purportedly issued without a prescription. See ARBO, *2003 Report on Complication(s) Due to Contact Lenses Dispensed Without a Valid Prescription*, Feb. 18, 2004 (Att. 55). This report is self-serving and wholly anecdotal in nature, and has no scientific validity whatsoever. There is no comparison to a baseline of complications that occurred when the contact lenses were dispensed under a prescription, or any comparison to an overall background rate of eye complications. Indeed, ECPs have repeatedly avoided looking at this issue in a serious scientific manner, as noted in Section II(B). Moreover, if ECPs comply with the Fairness Act’s requirements regarding prescription release and verification, and the Fairness Act is properly implemented, the Fairness Act would ensure that consumers are dispensed lenses consistent with their prescription parameters, making the notion that somehow alternative sellers contribute to ocular health problems nonsensical. (Note – the estimate regarding the number of contact lenses sold in 2002 is based on the fact that, in 2002, 1-800 sold approximately 49.4 million individual lenses. Alternate sellers represent 8% of the overall contact lens market, and 1-800’s contact lens sales represent 70% of the alternate contact lens sales market. Therefore, 1-800’s sales represent 5.6% of the entire contact lens market (70% of 8% of the market = 5.6% overall). Therefore, based on 1-800 sales data, approximately 882.26 million individual lenses were sold market-wide in 2002 (5.6% of 882.26 million = 49.4 million).

Indeed, a study conducted in the United Kingdom demonstrated that the most common reasons for discontinuing contact lens use are minor – e.g., discomfort and, particularly, dryness-related discomfort.³⁷¹ According to that study, contact lens failure is product or practitioner-related, and the overwhelming majority of contact lens wearers, who had discontinued use at one time, could successfully wear contact lenses again. The short-term success rate (based upon continuous wear of lenses rather than any health problems associated with the lenses) for these contact lens wearers was 76% overall, 91% for bi-weekly or monthly lenses, and 89% for daily disposable lenses.

Accordingly, the FTC should clearly articulate in the preamble of the final rule that early expiration of the contact lens prescriptions should occur only in exceptional circumstances where the ECP fully documents the medical need for early expiration and provides that information with the prescription or verification response.

D. Content of Advertisements and Other Representations

Section 315.7 of the proposed Contact Lens Rule prohibits the representation that contact lenses may be obtained without a prescription.³⁷² At this time, 1-800 has no comments on this provision.

E. Prohibition of Certain Waivers

Section 315.8 of the proposed Contact Lens Rule prohibits prescribers from waiving liability or responsibility for the accuracy of the eye examination.³⁷³ 1-800 has no comments on this provision.³⁷⁴

F. Enforcement

Section 315.9 of the proposed Contact Lens Rule explains how the Commission will treat violations of the Contact Lens Rule and defines the scope of the agency's enforcement power and jurisdiction, providing:

Any violation of this part shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices, and the Commission will enforce this part in the same manner, by the same means, and with the same jurisdiction, powers, and duties as

³⁷¹ See G. Young, *et al.*, *A multi-centre study of lapsed contact lens wearers*, 22 *Ophthal. Physiol. Opt.*, 516 (2002) (Att. 37).

³⁷² See 69 Fed. Reg. at 5450.

³⁷³ See *id.*

³⁷⁴ Notably, the AOA advises that an ECP who issues and correctly verifies a valid prescription is not liable if another seller dispenses the prescribed ophthalmic goods or services incorrectly. See *Hot Topics: Fairness to Contact Lens Consumers Act Takes Effect February 4, 2004*, AOA Website (2004) (Att. 178). The AOA is correct that under the text of the Fairness Act itself and under common law definitions of negligence, an ECP will not be liable for the acts of a seller, as long as the ECP has met his or her own required standard of care in diagnosing patients and issuing and verifying the prescription. See *Fairness to Contact Lens Consumers Act*, P.L. 108-164, § 7, 117 Stat. 2026 (2003); see, e.g., W. PA KEEFON, *ET AL.*, *PROSSER AND KEATON ON THE LAW OF TORTS*, § 30 (5th ed. 1984 & Supp. 1988) (Att. 179).

are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 et seq.³⁷⁵

The FTC, in its proposed rule questions: “(a) Is this provision sufficiently clear? [and] (b) What is the impact, including the costs and benefits, of this provision?”³⁷⁶

1-800 has no comments on the language in this provision at this time. However, as detailed more fully below, 1-800 would like to take this opportunity to emphasize the overwhelming importance of enforcement of the Fairness Act.

Based on their experiences with the Eyeglass Prescription Release Rule, ECPs have been cavalier about their obligation to comply with the Fairness Act. As one ECP recently noted in an ECP chat room:

- Doesn't current federal law mandate an eyeglass Rx be given after every exam? How many ODs have gotten in trouble for not giving their patient an eyeglass Rx.³⁷⁷

The long history of ECP activities to thwart consumers and competition mandates that the FTC demonstrate clearly that it is serious about enforcement of this law.

IV. Education and Enforcement Are Critical

Congress enacted the Fairness Act to ensure meaningful contact lens prescription portability, which will in turn increase competition and consumer choice in the contact lens market and make contact lenses cheaper and more accessible. As noted, to achieve this objective, it is critical that the FTC educate the eye care industry and consumers regarding the Fairness Act, and enforce its provisions.

Failure to invest in education and enforcement will significantly limit the efficacy of the Fairness Act. Indeed, lack of education and enforcement of the Eyeglass Prescription Release Rule has limited that rule's efficacy. As mentioned, the FTC itself recently reported that 1997 surveys showed that – after almost 20 years of the Eyeglass Prescription Release Rule being in effect - 65.8% of consumers were not aware that they had a right to their eyeglass prescription; 29.3% of consumers did not automatically receive their prescriptions; and 10.1% of consumers did not receive their prescriptions even when they asked.³⁷⁸ The FTC also reported that anecdotal evidence in the Eyeglass Prescription Release Rule record indicates that the overwhelming majority of ECPs who dispense eyewear do not automatically release eyeglass prescriptions.³⁷⁹ Moreover, as mentioned in Section III(F) regarding enforcement, based on their experiences with the enforcement of the

³⁷⁵ 69 Fed. Reg. at 5450.

³⁷⁶ *Id.* at 5448.

³⁷⁷ Joseph Hegyi, *Optcom - FCLCA*, ECP E-mail Forum, Jan. 30, 2004 (8:09 p.m.). (Att. 180).

³⁷⁸ 69 Fed. Reg. at 5452.

³⁷⁹ *See id.*

Eyeglass Prescription Release Rule, ECPs have questioned whether they really need to comply with the contact lens prescription release rule.³⁸⁰

Notably, a Consumers Union survey demonstrated that a similar lack of education and enforcement in Texas, after the prescription release-upon-request provision was enacted, limited the efficacy of that provision. The survey showed that 57% of optometrists still would not release prescriptions unless the patients returned for follow-up visits.³⁸¹

In addition, the FTC cannot leave ECP and consumer education up to optometric associations. As recently as March 15, 2004, the Texas Optometric Association Inc. was disseminating false information about prescription release rights. According to its website, a consumer can get a copy of his or her prescription only if he or she “request[s] a contact lens prescription.”³⁸² The website further states that “[t]he only time your optometrist might not give you a copy upon request is if there is an eye health reason not to, if the fitting has not been complete, or if monies are owed to the doctor.”³⁸³

The information on the website is false. Under the Fairness Act, which became effective on February 4, 2004, all consumers are entitled to *automatic* prescription release. No request for the prescription is necessary. Moreover, an ECP cannot withhold a prescription for any purported eye health reason and can only require payment of fees for an eye examination or fitting prior to prescription release in limited circumstances.³⁸⁴

In sum, 1-800 urges the FTC to send a notice summarizing the requirements of the Fairness Act to the major optometry and ophthalmology trade associations and the state optometry boards, asking them to disseminate the notice to the regulated community. Moreover, we ask that the FTC bring enforcement actions against prominent non-compliant ECPs soon after the final regulations take effect, to show ECPs that the FTC is serious about enforcement.

V. Conclusion

1-800 urges the FTC to ensure that the final Fairness Act regulations eliminate anticompetitive behaviors in the contact lens industry, by promoting meaningful prescription portability and defeating the powerful conflict of interest presented by optometrists selling what they prescribe. Toward that end, the FTC should prohibit the well-documented misdeeds of the past, such as the use of private label and doctor exclusive contact lenses to coerce consumers to purchase contact lenses from the prescribing ECP and the use of the prescription verification process to interfere

³⁸⁰ See, e.g., Joseph Hegyi, *Optcom - FCLCA*, ECP E-mail Forum, Jan. 30, 2004 (8:09 p.m.). ([Att. 180](#)); Cliff Courtenay, *Optcom - FCLCA Question*, ECP E-mail Forum, Feb. 5, 2004 (7:18 p.m.) ([Att. 181](#)).

³⁸¹ See, e.g., *The Eyes Don't Have It Yet*, Consumers Union, Southwest Regional Office (Jan. 2001) ([Att. 101](#)).

³⁸² Texas Optometric Association Inc., <http://texas.optometry.net/public/patientrights/index.asp> ([Att. 72](#)).

³⁸³ See *id.*

³⁸⁴ See Fairness to Contact Lens Consumers Act, P.L. 108-164, §§ 2, 3, 117 Stat. 2024 (2003).

with the sales of alternative sellers. Moreover, the FTC should anticipate and prohibit similar behaviors that are likely to emerge in the future.

The FTC should take care not to enshrine ECP conflicts and undue advantages – such as the 8-Hours-Plus-One-Day waiting period for alternative sellers in the proposed rule - into the final regulations. As fully discussed in Section III(A)(1) herein, the proposed definition of “business hour” and its accompanying examples, which would establish an 8-Hours-Plus-One-Day waiting period for consumers purchasing lenses from alternative sellers, threaten to take the Fairness Act, which was intended to make the industry more competitive, and turn it on its head. The 8-Hours-Plus-One-Day waiting period in practice would force consumers purchasing contact lenses from alternative sellers to wait an additional 24 hours beyond the time period intended by Congress. This could potentially drive alternative sellers out of business and leave consumers with fewer choices and less convenience. Thus, the Fairness Act would ultimately make the contact lens industry less, rather than more, competitive.

It is critical that the final regulations actually achieve the purpose of the Fairness Act – meaningful prescription portability – such that consumers have a true choice of whether to purchase their contact lenses from ECPs or alternative sellers. This would set an important example for other industries where entrenched interests have tried to defeat new modes of competition that benefit consumers.

For the reasons set forth, 1-800 respectfully requests that the FTC revise the proposed rule in accordance with the proposals herein, and that the FTC take vigorous action to enforce the Fairness Act, and consumers’ unfettered right to obtain their prescription.

Respectfully submitted,



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