

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

WASHINGTON, D.C. 20580

Office of Policy Planning Bureau of Consumer Protection Bureau of Economics

October 4, 2004

The Honorable Doug Matayo State of Arkansas House of Representatives 3110 Magnolia Place Springdale, Arkansas 72762-7416

Re: Arkansas HB 2286

Dear Representative Matayo:

The staff of the Federal Trade Commission's Office of Policy Planning, Bureau of Consumer Protection, and Bureau of Economics¹ are pleased to respond to your letter of June 23, 2004, asking us to comment on Arkansas HB 2286 ("HB 2286")² and the implementing draft regulation proposed by the Arkansas Board of Optometry (the "Board"). Your letter indicates that HB 2286 was enacted before the passage of the Fairness to Contact Lens Consumers Act (the "Act")³ and issuance of the Contact Lens Rule ("Contact Lens Rule"). You indicate that you are now conducting a review of HB 2286 in light of the passage of the Act and issuance of the Contact Lens Rule. Specifically, you asked us for assistance in determining the consistency of HB 2286 and the Board's draft regulation with federal law and their possible impacts on public health and consumers. We are pleased to provide such assistance with respect to HB 2286.⁴ In brief, we conclude that portions of Arkansas HB 2286 appear to be preempted in

⁴The Board of Optometry has informed us that it has not published an official draft regulation because it has been waiting for the Commission to issue the final Contact Lens Rule. Therefore, we would welcome another invitation to comment on such a regulation when it is finalized.

¹This letter expresses the views of the FTC's Office of Policy Planning, Bureau of Consumer Protection and Bureau of Economics. The letter does not necessarily represent the views of the Commission or of any individual Commissioner. The Commission has, however, voted to authorize us to submit these comments.

²HB 2286 amended Arkansas Code §§ 17-90-108; 17-90-109; 17-90-110. For purposes of this letter, we will refer to these amendments as HB 2286, even though the bill has been enacted into law. Your letter indicates that the Arkansas Legislature passed HB 2286 in the spring of 2003.

³15 U.S.C. §§ 7601-7610.

certain circumstances because they conflict with federal law. In addition, under the Board's interpretation of HB 2286, it appears that contact lenses can be legally sold to Arkansas residents only by Arkansas licensed optometrists and ophthalmologists. Thus, it appears that mail order, Internet, and other alternative providers must be licensed in Arkansas to provide contact lenses to Arkansas residents. Such an arrangement likely results in higher prices and reduced consumer choice, without substantially increasing health protections.

This letter briefly summarizes the Commission's interest and experience in the eye care industry and provides the staff's opinion regarding the consistency of HB 2286 with federal law and the possible impact of HB 2286 on consumers and competition. The Commission has been active in the eye care industry for almost thirty years. It enforces the Ophthalmic Practices Rules ("Eyeglass Rule")⁵ and recently issued the Contact Lens Rule⁶ as required by the Fairness to Contact Lens Consumers Act. As described in detail below, the agency has also recently issued a number of advocacy filings and reports regarding the contact lens market.

Based on our experience in the contact lens industry and our review of your letter and HB 2286, the FTC staff has reached the following conclusions:

- HB 2286 requires that contact lens prescriptions be released to the patient "upon request" and "upon payment." The "upon request" and "upon payment" restrictions on prescription release appear to be preempted because they conflict with the automatic prescription release standard imposed by the Act.
- HB 2286 contains an "active" verification requirement that appears to be preempted by the "passive" verification standard imposed by the Act and the Contact Lens Rule.
- It appears that mail order, Internet, and other alternative providers must be licensed in Arkansas to provide contact lenses to Arkansas residents. Although state licensing is not expressly covered by the Act or the Contact Lens Rule, such a requirement likely results in higher prices and reduced consumer choice. In turn, such effects may increase the incidence of health problems that are associated with contact lens use, such as the over-wearing of disposable lenses. Less restrictive alternatives to licensing, such as registration alone, may adequately protect consumers.

A brief summary of the Commission's history in the eye care industry and a detailed analysis in support of each of the FTC staff's conclusions is provided below.

⁵16 C.F.R. Part 456.

⁶69 Fed. Reg. 40481 (July 2, 2004) (to be codified at 16 C.F.R. Part 315). The Commission's press release regarding the issuance of the final Contact Lens Rule, including a link to the text of the Federal Register Notice, is available at http://www.ftc/gov/opa/2004/06/contactlens.htm.

I. Interest and Experience of the Federal Trade Commission

As noted above, the Commission has been active in the eye care industry for nearly three decades. It enforces the Eyeglass Rule, which requires an optometrist or ophthalmologist to provide a patient, at no extra cost, a copy of the patient's eyeglass prescription after completion of an eye exam.⁷ The Commission also recently issued the Contact Lens Rule, which requires a prescriber to provide the patient a copy of the contact lens prescription upon the completion of a contact lens fitting.⁸ The Contact Lens Rule also allows contact lenses to be sold if sellers obtain a copy of the consumer's prescription or verify the prescription with the prescriber.

In March 2002, the Commission staff filed a comment before the Connecticut Board of Examiners for Opticians in a declaratory ruling proceeding on the interpretation and applicability of various statutes and regulations concerning the sale of contact lenses. The comment addressed whether Connecticut state law requires that out-of-state sellers obtain a license to sell contact lenses to the state's residents. In that comment, Commission staff concluded that out-of-state sellers should not be subject to state licensing requirements because the possible benefit to consumers from increased state protection did not outweigh the likely negative effect from decreased competition. Ultimately, the Connecticut Board of Examiners decided that state law did not require out-of-state sellers to obtain a license to sell contact lenses to consumers. ¹⁰

In October 2002, the Commission held a public workshop entitled *Possible* Anticompetitive Efforts to Restrict Competition on the Internet to evaluate possible efforts to restrict competition in contact lenses and other industries.¹¹ Commission staff heard testimony about the contact lens issue from many perspectives, including eye care practitioners, a major contact lens manufacturer, an online seller, traditional bricks and mortar lens sellers, and an economics professor with expertise in occupational licensing issues. In March 2004, the

⁷16 C.F.R. Part 456.

⁸69 Fed. Reg. 40481 (July 2, 2004) (to be codified at 16 C.F.R. Part 315).

⁹FTC Staff Comment Before the Connecticut Board of Examiners for Opticians (Mar. 27, 2002), *available at* http://www.ftc/gov/be/v020007.htm.

¹⁰Connecticut Board of Examiners for Opticians, *In re: Petition for Declaratory Ruling Concerning Sales of Contact Lenses*, Declaratory Ruling Memorandum of Decision (June 24, 2003).

¹¹67 Fed. Reg. 48472 (2002). The workshop's transcript is available at http://www.ftc.gov/opp/ecommerce/anticompetitive/021008antitrans.pdf. All of the panelists' written statements are available at http://www.ftc/gov/opp/ecommerce/anticompetitive/agenda.htm.

Commission staff issued a report, *Possible Barriers to E-Commerce: Contact Lenses: A Report from the Staff of the Federal Trade Commission* ("Contact Lens Report"). 12

II. Federal Preemption

The Commission's Statement of Basis and Purpose (the "SBP") for the Contact Lens Rule addresses the issue of preemption. The SBP points out generally that a federal law may preempt state law through implied preemption where state and federal law actually conflict. The SBP notes that a conflict may arise where state law "stand[s] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." The SBP further states that "[t]he Act does not expressly state that it preempts any state laws. The language of the Act, however, appears to be inconsistent with the language of some state laws." Ultimately, the SBP concludes that "the Act preempts any State laws or regulations that restrict prescription release or require active verification, because they would undermine Congress's purpose of giving consumers greater freedom of choice in their choice of sellers from whom they purchase their contact lenses." 16

The Commission staff believes that the prescription release restrictions and the "active" verification standard contained in HB 2286 conflict with the language of the Act and would undermine the purpose that Congress intended to achieve: providing consumers with greater choice with respect to sellers of contact lenses. Consequently, such more restrictive and burdensome state laws and regulations conflict with the federal law and are therefore preempted. These issues are addressed more fully below.

¹²Possible Barriers to E-Commerce: Contact Lenses: A Report from the Staff of the Federal Trade Commission (Mar. 29, 2004), *available at* http://www.ftc.gov/os/2004/03/040329clreportfinal.pdf.

¹³69 Fed. Reg. at 40505, citing Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 121 S. Ct. 2404, 2414 (2001); Crosby v. National Foreign Trade Council, 530 U.S. 363, 372-73 (2000); English v. General Elec. Co., 496 U.S. 72, 78-79 (1990).

¹⁴69 Fed. Reg. at 40505, quoting Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995); Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

 $^{^{15}}$ *Id*.

¹⁶*Id.* at 40506.

A. <u>Prescription Release Restrictions</u>

The Commission has concluded that the Act preempts state laws or regulations restricting prescription release. Accordingly, Section 315.11 of the Contact Lens Rule provides that state laws and regulations "that restrict prescription release . . . are preempted." HB 2286 contains two restrictions on prescription release that appear to conflict with the Act and the Contact Lens Rule. Rule.

First, Section 1(a)(2)(A) of HB 2286 requires prescription release to occur "upon request of the patient" at the completion of the fitting. However, Section 2(a)(1) of the Act requires prescription release to occur at the completion of the contact lens fitting "whether or not the patient requests it." The "upon request" release standard set out in HB 2286 thus appears to be preempted because it conflicts with the automatic release standard imposed by the Act.

Second, Section 1(a)(2)(A) of HB 2286 requires release of the contact lens prescription "upon payment being made for the examination and the fitting." In contrast, Section 3 of the Act²⁰ allows a prescriber to require payment prior to the release of the contact lens prescription "only if the prescriber" also "requires immediate payment in the case of an examination that reveals no need for contact lenses or other ophthalmic goods." Because HB 2286 allows a prescriber to require payment prior to prescription release for contact lens patients even if the prescriber does not require immediate payment from patients whose exams reveal no need for ophthalmic goods, it conflicts with the Act and the Contact Lens Rule in certain circumstances. To the extent that HB 2286 conflicts with the Act and the Rule, it is preempted.

B. Positive Verification Systems

The Commission also has concluded that certain state laws regarding positive verification requirements appear to inhibit the accomplishment of the objectives of the Act. In particular, the SBP explains that the Act preempts state laws or regulations that "require active verification, because they would undermine Congress's purpose of giving consumers greater

¹⁷69 Fed. Reg. at 40506.

¹⁸In addition, Section 3 of the Act requires that "presentation of proof of insurance coverage for the service" be deemed a payment. 15 U.S.C. § 7602. HB 2286 does not expressly address the relationship between proof of insurance coverage and payment.

¹⁹15 U.S.C. § 7601(a)(1).

²⁰15 U.S.C. § 7602.

freedom in their choice of sellers from whom they purchase their contact lenses."²¹ Accordingly, the Commission added Section 315.11 to the Contact Lens Rule to clarify that state laws and regulations that "require active verification are preempted." Consequently, the active verification standard imposed by Section 1(a)(2)(B) of HB 2286, which requires out-of-state sellers to possess a "positively verified" prescription, appears to be preempted because it conflicts with the Act and the Contact Lens Rule.

III. State Registration and Licensing Issues

Section 2 of HB 2286 includes provisions for the registration of mail order, Internet, and other alternative providers of contact lenses to Arkansas residents. Your letter of June 23, 2004 indicates that the Board interprets existing law to mean that contact lenses can be legally sold to Arkansas residents only by Arkansas licensed optometrists and ophthalmologists.²² Thus, it appears that mail order, Internet, and other alternative providers must be licensed in Arkansas to provide contact lenses to Arkansas residents.

The Contact Lens Report considered the benefits and costs associated with licensing and concluded that "although there are significant health issues concerning the use and sale of contact lenses, requiring a professional license to sell replacement contact lenses over the Internet is likely to raise prices and/or reduce convenience to consumers without substantially increasing health protections." Accordingly, FTC staff recommended that policymakers and other officials "[r]escind, or refrain from adopting, requirements that an Internet seller have a

As prescribed by the Act, the Contact Lens Rule imposes requirements on sellers in connection with prescription verification: "the seller shall provide a reasonable opportunity for the prescriber to communication with the seller concerning the verification request" and a seller shall maintain a record of all direct communications. 16 C.F.R. § 315.5 (c)(3), (f). When seeking verification of a contact lens prescription, a seller shall also provide the prescriber with certain required information as set forth in the Contact Lens Rule. *Id.* at § 315.5 (b).

²¹69 Fed. Reg. at 40505, noting that legislative history supports the same conclusion: "The Committee believes that any state law with an active or positive contact lens prescription verification system would stand as an obstacle to the accomplishment of the full purposes and objectives of this Act. Practically, it would be impossible to comply with the terms of this Act and an active verification scheme. Therefore, it is the intent of the Committee that the passive verification system in section 4(d) preempt any conflicting state laws that use active or positive contact lens prescription verification systems." H. Rep. No. 108-318, at 9-10 (2003).

²²Existing Arkansas law specifies that "[t]he practice of optometry shall include but not be limited to: the prescribing and sale of eyeglasses and contact lenses. . . ." Ark. Code 17-90-101.

²³Contact Lens Report at 3.

professional license to sell replacement contact lenses. If states want to regulate such sellers beyond prescription requirements and general state and federal consumer protection laws, they should adopt a simple registration requirement."²⁴

An examination of the benefits and costs of licensing identified by the Contact Lens Report is helpful in evaluating the impact of Arkansas's licensing requirement on public health and consumers. The possible benefits include additional protections to consumer health and welfare. The costs include possible price increases, as well as reductions in convenience, which may also affect consumers' health.

The Contact Lens Report recognizes that the use and sale of contact lenses involves significant health issues. The primary health concern with contact lenses appears to be ensuring that contact lens wearers visit their doctors regularly for eye examinations.²⁵ Consumers may thus endanger the health of their eyes if they obtain and wear replacement contact lenses without a valid prescription.²⁶

Federal law currently requires that contact lenses only be sold to patients with valid prescriptions, which they receive after an eye examination. First, the Fairness to Contact Lens Consumers Act and the FTC's Contact Lens Rule prohibit sales of contact lenses unless the seller has a copy of the patient's prescription or has verified that prescription with the prescriber. Second, the Food and Drug Administration has strict labeling requirements for contact lenses, and it has the authority to take action against the sales of such a device without a valid prescription.²⁷

Some have argued that a potential benefit of requiring a state professional license for contact lens sellers is that the license may give the state additional leverage over out-of-state sellers.²⁸ If a seller fails to comply with prescription requirements, for example, then the state

 $^{^{24}}Id$, at 31.

²⁵See id. at 8. See, e.g., FDA Center for Devices and Radiological Health, Buying Contact Lenses on the Internet, by Phone, or by Mail: Questions and Answers (2002), available at http://www.fda.gov/cdrh/consumer/buycontactqa.html. Disposable contact lenses prevent oxygen from reaching the cornea, and lack of oxygen can lead to severe eye damage. Therefore, to lower their health risks, it is important that a patient adhere to the doctor's recommended wearing schedule, removing and replacing the lenses when recommended.

²⁶Contact Lens Report at 9.

²⁷See 21 U.S.C. §§ 331(a), 333, 352(f), and 353(b)(1).

²⁸For example, comments submitted to the FTC's E-commerce workshop argued that it was difficult for state boards to reach out-of-state sellers. *See* Summary of Testimony of J. Pat

could prompt compliance by threatening to revoke the seller's license. The Act, which provides for federal enforcement of its requirement that contact lenses be sold pursuant to a valid prescription, obviates much of the concern about the difficulty of reaching out-of-state sellers.²⁹

Although state licensing requirements can provide health and safety benefits, it is also important to examine the costs that a licensing requirement may impose on consumers. The Contact Lens Report found that requiring a professional license to sell replacement contact lenses over the Internet is likely to raise prices and/or reduce consumer choice.³⁰ In particular, the need to employ a state-licensed professional, such as an optometrist, an ophthalmologist or a dispensing optician, would likely be a costly proposition for an Internet or mail-order seller of replacement lenses.³¹ Because such firms may not sell eyeglasses or conduct contact lens fittings, they may not already have a state-licensed professional on staff.³² Because the Board's interpretation of Arkansas Code § 17-90-101 almost certainly imposes additional costs on standalone sellers of replacement lenses, however, requiring a state-licensed professional would likely induce such sellers to charge higher prices to consumers or – alternatively – to exit sales entirely, thereby harming consumers.³³

There seems to be consensus that disposable lenses, especially when worn properly,

Cummings, Jr., O.D., President, American Optometric Ass'n; Summary of the Position of the National Ass'n of Optometrists and Opticians, *available at* http://www.ftc.gov/os/2004/03/040329clreportfinal.pdf.

²⁹Contact Lens Report at 22. The Report did note that "[i]n comments submitted to the workshop, [the American Optometric Association] stated that sales of contact lens without a valid prescription were frequent, and [the National Association of Optometrists and Opticians] stated it was difficult for state boards to reach out-of-state sellers who sold without a prescription." *Id.* at 22, n.85. Nonetheless, staff concluded in the Contact Lens Report that concerns about quality of care issues can be addressed by enforcing contact lens prescription requirements. *Id.* at 23.

³⁰*Id.* at 6, 16-17, 21. The Contact Lens Report did state, however, that "[w]orkshop participants did not provide, and FTC staff does not know of, a study that directly assesses the impact of optical licensing on costs or prices of contact lenses in general or replacement lenses in particular." *Id.* at 16. While staff does not know of such a study, the report noted that "the idea that licensing requirements create additional costs for consumers is hardly novel or unique to replacement lenses" and referred to comments by Professor Kleiner on the potential impact licensing may have on costs. *Id.*

³¹*See id.* at 21.

³²See id.

³³See *id.* at 23.

generally promote better eye health than do conventional daily wear lenses.³⁴ Doctors have reported that frequent replacement of lenses has yielded a significant decrease in eye infections and inflammation among their patients who wear disposables.³⁵ However, it appears that while many consumers over-wear their disposable lenses, thus diminishing their health benefits, they might replace their lenses more frequently if the lenses cost less.³⁶

Thus, to the extent that licensing raises the cost or inconvenience of obtaining disposable replacement lenses, it may induce more individuals to over-wear their replacement contact lenses or exacerbate the practice by persons already doing so. Thus, licensing may increase the incidence of health problems associated with contact lens use.³⁷ In particular, to the extent that contact lens wearers choose to over-wear disposable contact lenses in response to a price increase, as a way to save money, they increase the risk of severe eye damage.

The key question, then, is whether there are incremental benefits to consumers from an additional, more restrictive regulation such as state licensing that outweigh its accompanying consumer costs. In this instance, it appears that the costs of such state licensing outweigh any possible benefits. The costs of a licensing requirement would be concentrated on customers who prefer stand-alone sellers of replacement lenses to other types of sellers. But such a requirement would not substantially increase the health protections already provided by existing law.

The Contact Lens Report recommends that if a state finds it necessary to regulate replacement lens sellers beyond already existing prescription requirements and general consumer protection laws, it should consider a simple registration requirement, which could provide additional consumer safeguards but would be less restrictive or burdensome than a state

³⁴See Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation*, No. MDL 1030 at 134-35 (complaints filed M.D. Fla. 1994) (citing studies); Contact Lens Report at 19.

³⁵Id. at 135-36. See also Contact Lens Report at 19.

³⁶For example, one survey has found that fewer than 50 percent of consumers comply with the recommended wearing schedule. McKinsey & Company, Consumer Fact Pack, filed in *In re: Disposable Contact Antitrust Litigation*, at 92. The same survey found that fifty-seven percent of consumers stated they would replace their lenses more frequently if the lenses cost less. *Id.* at 97. Thirty percent specifically identified cost savings as the reason they over-wear their lenses, stating they "try to save money by wearing [their] contact lenses for more days than [their] doctor recommends before disposing of them." *Id.* Twenty-two percent said they do not replace their lenses as often as they should because "purchasing them is inconvenient." *See also* Contact Lens Report at 19-20.

³⁷See Contact Lens Report at 19.

licensing requirement.³⁸ Specifically, a registration system, unlike licensing, would not require that individuals or firms that want to sell replacement lenses fulfill expensive and unnecessary requirements in order to do so. Rather, replacement lens sellers would merely file their names and other required information in Arkansas and would have sufficient contact information in the event that a particular seller engages in practices that create health risks for consumers.

IV. Conclusion

For these reasons, FTC staff believes that Arkansas HB 2286's release "upon request of the patient" and release "upon payment" requirements appear to be preempted in certain circumstances because they conflict with the Fairness to Contact Lens Consumer Act and the Contact Lens Rule. The active verification requirement also appears to be preempted because it conflicts with the Act and the Rule. In addition, the FTC staff recommends that if Arkansas finds it necessary to regulate replacement lens sellers beyond already existing regulations, it should consider a simple registration requirement instead of licensing.

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³⁸See id. at 20-23. For example, the Contact Lens Report notes that "California requires a non-resident contact lens seller to be authorized in its home state, to maintain records of lenses sold in California, and to provide a toll-free number where patients can ask questions or make complaints and a toll-free number or e-mail address where eye care practitioners can confirm their prescriptions." *Id.* at 21.

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