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Possible Anticompetitive Barriers to E-Commerce: Contact Lenses

[1] *See, e.g.*, Keith Croes, *Contact Lens Market: Specialty Lenses and Favorable Demographics Are Driving Growth Worldwide*, OPTISTOCK MARKETWATCH, Nov. 2002 *available at* <http://www.optistock.com/mw/2002_11all.htm>; Joseph T. Barr, *The Contact Lens Spectrum Millennium Report*, CONTACT LENS SPECTRUM, Jan. 2000.

[2] *See* Health Products Research (VIS) – Annual 2000 Year-End Consumer Contact Lens Survey (*cited in* BAUSCH & LOMB, 2001 ANNUAL REPORT TO VISION CARE PROFESSIONALS: TRENDS IN CONTACT LENSES & LENS CARE 8), *available at* <http://www.optistock.com/trends_contact_lenses_2001_dec.pdf>.

[3] 16 C.F.R. Part 456.

[4] 16 C.F.R. §§ 456.1(c), 456.2(b).

[5] 16 C.F.R. § 456.2(d) (It is an unfair act or practice to "[p]lace on the prescription,

anticompetitive barriers to e-commerce in contact lenses and nine other industries.[10] 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.[11]

After extensive review, Commission staff have reached several conclusions regarding online contact lens sales:

- 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. States wishing to consider regulation of replacement lens sellers in addition to existing prescription requirements and general consumer protection laws should consider adopting simple registration requirements, as California recently did.

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[10] 67 Fed. Reg. 48,472 (2002). The other industries were: auctions; automobiles; caskets; cyber-charter schools; online legal services; real estate, mortgages, and financial services; retailing; wine; and telemedicine and online pharmaceutical sales. More information is available at the workshop's homepage, at <http://www.ftc.gov/opp/ecommerce/anticompetitive/index.htm.> The workshop's transcript is cited as "Tr.," and 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>.

[11] The following people testified at the workshop: Jonathan Coon, CEO, 1-800 Contacts, Inc. (the largest Internet contact lens retailer); Dr. J. Pat Cummings, Jr., O.D., President, American Optometric Association ("AOA"); Paul Halpern, National Association of Optometrists and Opticians ("NAOO"); Gerald M. Ostrov, Company Group Chairman, Johnson & Johnson Vision Care; and Morris Kleiner, Professor of Labor Policy, University of Minnesota and National Bureau of Economic Research.

The panelists also provided written submissions, as did James Saviola, O.D., Captain, U.S. Public Health Service, Chief, Vitreoretinal and Extraocular Implants Branch, Division of Ophthalmic and ENT Devices, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, and John Tennis, Assistant Attorney General, State of Maryland. Commission staff also gathered evidence from a wide variety of published sources, such as studies and court proceedings, and from other sources, such as state attorneys general and the Food and Drug Administration.

- The release of contact lens prescriptions by eye care providers facilitates consumer choice in replacement contact lens suppliers, and greater consumer choice increases consumer welfare. Adherence to the prescription requirement is important to consumer health, and online sales of contact lenses raise the question of what prescription verification procedure best protects consumers by ensuring compliance with the prescription requirement . The recently enacted Fairness to Contact Lens Consumers Act requires prescription release and provides that contact lenses must be sold in accordance with a prescription presented to a lens seller directly or by facsimile, or verified by direct communication with the prescriber. The Act permits passive verification of contact lens prescriptions, stating that a prescription is verified if, after direct communication by the seller, the prescriber confirms the prescription; corrects an inaccurate prescription; or fails to reply to the seller within eight business hours, or a similar time as defined by the Federal Trade Commission. Adherence by eye care practitioners to the Act's contact lens prescription release requirements and by contact lens sellers to the Act's prescription verification requirements should enhance consumer choice and protect consumer health.

- Private label lenses and short prescription lengths can promote consumer health and welfare but can also limit consumer choice and diminish consumer welfare. 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.

The report will first provide an overview of the current status of online contact lens sales and then examine in detail a number of issues relevant to online contact lens sales raised at the workshop and in other proceedings. The Fairness to Contact Lens Consumers Act, enacted after the workshop, resolved many of these issues – prescription release, prescription verification, and prescription length – but it did not resolve all issues, such as professional licensing for contact lens sellers. After discussing these issues, the report will offer recommendations.

II. Current status of online contact lens sales

Online contact lens sales primarily involve disposable replacement soft contact lenses. The FDA first approved a soft contact lens in 1971.[12] Beginning in the late 1980s, lens manufacturers began to market and sell "disposable" and "frequent replacement" soft lenses, designed to be replaced daily, weekly, or monthly.[13] Most soft lenses are now sold in

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[12] *See* 47 Fed. Reg. 53,411, 43,415 (1982).

[13] Many manufacturers only have FDA clearance to market a lens for daily wear. It would be an "off-label" use to prescribe a daily wear lens for extended wear. Comments of

James F. Saviola, O.D., FDA.

customer has already been fitted by an eye care professional.[17] Unlike traditional eye wear

[17] Testimony of Jonathan Coon, CEO, 1-800 Contacts, Inc., Tr. at 327 ("We don't have stores. We don't do eye exams. We don't have in-state locations. We only take orders over the Internet and by phone, with nearly half of our sales online.")

[18] *See supra* note 9.

[19] Connecticut Board of Examiners for Opticians, Declaratory Ruling Memorandum of Decision (June 24, 2003).

[20] *See* Request for Public Comments, 62 Fed. Reg. 15,865 (Apr. 3, 1997).

[21] *See* Fairness to Contact Lens Consumers Act (H.R. 2221), 108th Cong. (2003); Contact Lens Prescription Release Act of 2002, 107th Cong. 2d Sess. (2002).

[22] Fairness to Contact Lens Consumers Act (H.R. 3140), 108th Cong. (2003) (passed Nov. 20, 2003, signed into law Dec. 6, 2003).

[23]

[24] 15 U.S.C.A. § 7603(f).

[25] 15 U.S.C.A. § 7604.

[26] *See, e.g.*,

doctor's recommended wearing schedule, removing and replacing the lenses when recommended. Some individuals may develop eye problems even if they follow the doctor's advice; their eyes may develop problems simply in response to wearing lenses.[27] Contact lens wearers incur health risks if they forego regular eye exams that would allow the optometrist or ophthalmologist to spot emerging health problems in their early stages.[28] Consumers may thus endanger the health of their eyes if they obtain and wear replacement contact lenses without a valid prescription.

The AOA, while noting that consumers incur health risks if they skip regular eye exams, testified that the crux of the health issue in online sales is "[n]ot where the patient purchases replacement lenses, but that the validity of the prescription be properly verified by all sellers."[29] The primary means to ensure that contact lens wearers undergo periodic eye exams by qualified practitioners appear]TJ-0 12.iope .TDtly c eye e Tc-012 ofd eprope0.001 Tw(vali6(s bscription. [(FDA)8.7(a)-0

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[27] *Id.* ("Contact lens wear causes many changes to cells and tissues of the eye, and sometimes wearing contact lenses can damage the cornea (the clear window of the eye). *Even if you are currently experiencing no problems, the lenses may be causing damage to your eyes.* Regular check-ups will reduce the likelihood of damage going undetected.")

[28] Summary of testimony of J. Pat Cummings, Jr., O.D., President, American Optometric Ass'n.

[29] *Id.*

[30] 21 C.F.R. § 886.5925(b)(1) (2001). Class II devices are devices for which "general controls" are insufficient to provide a reasonable assurance of safety and effectiveness but for which there are existing methods to provide such assurances. 21 U.S.C. § 360c(a)(B). These methods may include special guidelines, performance standards, and postmarket monitoring. A prescription requirement is not explicitly mentioned.

[31] 21 C.F.R. §§ 886.5916 and 886.5925(b)(2). Class III is the most stringent regulatory category and applies to devices for which insufficient information exists to assure safety and effectiveness solely through general or special controls, but again the statute is silent regarding a prescription requirement. 21 U.S.C. § 360c(a)(C) .

[32] 21 U.S.C. § 360j(e)(1) ("The Secretary may by regulation require that a device be restricted to sale, distribution, or use – (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such a device, or (B) upon other such conditions

as the Secretary may prescribe in such regulation.").

[33] The FDA regulations for Ophthalmic Devices appear at 21 C.F.R. §§ 886.1 - 886.5928. None of these regulations specifies that contact lenses be restricted to sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use such a device. However, the Fairness to Contact Lens Consumers Act states

[37] Comments of James F. Saviola, O.D., Captain, U.S. Public Health Service, Chief, Vitreoretinal and Extraocular Implants Branch, Division of Ophthalmic and ENT Devices, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration.

[38] For example, each contact lens approved for marketing by the FDA has a generic name identifying the plastic polymer used to make it. The generic materials have different physical and optical characteristics, with the key differences being water content and oxygen permeability. Lens design elements are not considered in establishing a generic name and

lenses over the internet when they had never been fitted for lenses, or tried to purchase a lens different from the one prescribed by their doctor.")

[42] Testimony of J. Pat Cummings, Jr., O.D. Tr. at 323.

[43] Moreover, under the Preliminary Settlement Agreement, *In re: Disposable Contact Lens Antitrust Litigation*, (filed Apr. 23, 2001, approved Nov. 1, 2001) at 1, the American Optometric Association explicitly agreed that it:

> 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, 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 or pharmacy or drug stores.

[44] "Occupational Licensing and the Internet: Issues for Policy Makers," statement

[45] It is not clear whether the mail-order price includes shipping and handling. Survey takers were instructed to tell respondents to omit shipping and handling charges only if the respondent asked about the issue. In addition, some mail-order and Internet firms offer free shipping and handling.

[46] Susan Russell, *Nationwide Survey of Contact Lens Wearers*, SRI Consulting (1999).

[47] Testimony of Gerald Ostrov, Tr. at 332 ("We [J&J] also believe that the primary role of Internet in this category is convenience, not price.")

[48] Research indicates that individuals tend to assign a significant value to their transit time. The estimated value of transit time saved varies with the choice presented, trip purpose, income, and trip distance. *See, e.g.*, Small, Winston, and Yan, *Uncovering the Distribution of Motorists' Preferences*, at 3 UC Irvine Working Paper (2002); Calfee & Winston, *The Value of Automobile Travel Time: Implications for Congestion Policy*, 69 J. PUB. ECON. 83, 84 (1998). One review of many studies that focused on the value of travel time saved for

C. *Consumer protection for online sales*

As discussed previously, adherence to the prescription requirement is the most important consumer protection concern in connection with online contact lens sales. According to an FDA guide for consumers regarding the purchase of contact lenses over the Internet, however, a lens seller does not have to receive a written prescription to comply with the federal prescription device regulation.[49] The FDA guide suggests that if the company checks with the eye care provider in accordance with applicable state laws, the company has satisfied the prescription requirement.[50] Thus, the ability to check with the doctor orally or electronically satisfies the federal requirement that lenses be sonokT8.0oa'T 7(portTi5nSeralses beR6 8h4es)ssc4n beRabllydription. A wil

(including shopping) to range between 26 and 42 percent of the average wage, which falls within the range of estimates of business commute time values. David A. Hensher, *Uncovering the Distribution of Motorists' Preferences*, in THE FULL COSTS AND BENEFITS OF TRANSPORTATION (Green, Jones, and Delucchi eds. 1997). In addition, it appears that value of time varies directly, but not proportionally, with income. *See* Small, at 43. For instance, Calfee and Winston find the value of time saved more than doubles when comparing people with incomes of $7,500-$12,000 with those who earn $125,000-$175,000. *See* Calfee and Winston, at 93.

[49] *See* FDA Center for Devices and Radiological Health, *Buying Contact Lenses on the Internet, by Phone, or by Mail: Questions and Answers*, *supra* note 26..

[50] *Id.* ("Some Internet sites will allow you to fill out a chart with the ordering information about your contact lenses and ask you to fill in your doctor's name and phone number. The site may or may not ask for an actual copy of your prescription, but they should comply with applicable State law concerning contact lens prescription verification.")

[51] *See* 21 U.S.C. §§ 353(b)(1), 331(a) and 333.

[52] *See, e.g., Buying Contact Lenses on the Internet, by Phone or by Mail: Questions and Answers*, *supra* note 26. The Fairness to Contact Lens Consumers Act requires that, after completion of a contact lens fitting, the prescriber provide a patient with a contact lens prescription, and it lists certain information that must be included in a contact lens prescription. 15 U.S.C.A. §§ 7601, 7610.

[53] *Id.*

[54] Letter from Linda Gangloff, Policy Analyst, Executive Secretariat, FDA, to

return to an eye care practitioner for regular eye exams, regardless of where they purchase replacement lenses. To determine whether additional regulation of online lens sellers would enhance consumer welfare, it is necessary to consider what additional costs and benefits such regulation might generate. One possible additional regulation discussed in the workshop is requiring contact lens sellers to have state professional licenses, such as an optician's license. Panelists also considered possible registration requirements. Panelists discussed contact lens prescription release requirements and also debated whether requirements for verifying prescriptions impose different burdens on Internet sellers than on traditional contact lens sellers and whether health concerns justify such burdens. In addition, they explored the issues surrounding private label contact lenses.

A. *Professional licensing*

1. *Effect of licensing on costs*

Workshop 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. However, the idea that licensing requirements create additional costs for consumers is hardly novel or unique to replacement contact lenses.[58] Occupational licensing necessarily involves some restriction on the ability of individuals to enter an occupation, usually through a requirement of government permission and the demonstration of some minimum degree of competency. The stated motivation for licensing is the desire to maintain or increase the quality of service the regulated professionals provide. Members of the occupation often serve as members of the licensing boards.

Professor Kleiner testified about research on the economic costs and benefits of licensing on consumers and the impact of licensing on those in the occupation.[59] He observed that one of the benefits of the Internet is that it often makes intermediaries unnecessary because consumers and suppliers can more easily interact directly. Kleiner noted that provisions in state licensing laws may restrict such benefits by requiring the participation of an intermediary in the transaction. He further observed, "These state licensing provisions limit the ability of consumers to take advantage of the economic benefits of internet transactions. To the extent that other services such as dentistry, medical devices and pharmacy-related products have similar state occupational licensing-related restrictions, this may limit the ability of consumers to purchase

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[58] *See, e.g.,* Carolyn Cox and Susan Foster, *The Costs and Benefits of Occupational Regulation*, Federal Trade Commission (1990); Morris Kleiner and Robert Kudrle, *Does Regulation Affect Economic Outcomes?: The Case of Dentistry,* THE JOURNAL OF LAW AND ECONOMICS, Oct. 2000.

[59] "Occupational Licensing and the Internet: Issues for Policy Makers," statement of Morris Kleiner, University of Minnesota and the National Bureau of Economic Research.

products which have the lowest cost relative to quality."[60]

By restricting the supply of professionals into an occupation, licensing tends to raise their wages,[61]

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[60] *Id.* at 2.

[61] *Id.*

[62] *See, e.g.*, Kleiner and Kudrle, *supra* note 58, at 575; COMMITTEE TO STUDY THE ROLE OF ALLIED HEALTH PERSONNEL, INSTITUTE OF MEDICINE, ALLIED HEALTH SERVICES: AVOIDING CRISES 253 (1989) ("It appears that widespread licensure carries with it higher costs to consumers, reduced access to health care services, and reduced flexibility for managers. People in health care careers are inhibited from changing fields and from advancing within their fields by rigid requirements imposed by state regulatory mechanisms. Although these control mechanisms are designed and carried out in the stated interest of protecting the health and welfare of the public, their effectiveness in this regard has been mixed at best."); Arthur S. DeVany, *et al.*, *The Impact of Input Regulation: The Case of the U.S. Dental Industry*, THE JOURNAL OF LAW AND ECONOMICS, Oct. 1982 (finding that state legal restrictions on the use of paradentals decreased use of paradentals and raised dental fees for consumers).

For example, several states have considered measures that would require borrowers to hire attorneys to represent them in real estate loan closings, even in situations such as refinancings that involve little legal work on behalf of the borrower. Evidence submitted in these proceedings indicated that such requirements would increase prices to some borrowers by between $150 and $400. *See* Letter from Charles A. James and Timothy J. Muris to the Ethics Committee of the North Carolina Bar Re North Carolina State Bar Opinions Restricting Involvement of Non-Attorneys in Real Estate Closings and Refinancing Transactions (Dec. 14, 2001) <http://www.ftc.gov/be/V020006.htm>; Letter from Joel I. Klein and William J. Baer to the Supreme Court of Virginia Re Proposed UPL Opinion #183 (Jan. 3, 1997) <http://www.ftc.gov/be/v960015a.htm>.

[63] Cox and Foster, *supra* note 58, at 31; Kleiner and Kudrle, *supra* note 58, at 547-82.

[64] Cox and Foster, *supra* note 58, at 31. *But compare* a more recent study by Philip Parker (*'Sweet Lemons:' Illusory Quality, Self-Deceivers, Advertising, and Price*, JOURNAL OF MARKETING RESEARCH, Vol.32, Aug. 1995, at 291-307), suggesting that the results of some of

the earlier studies of the eye care market may be sensitive to alternative model specifications.

While the restriction of supply from professional licensing may lead to a higher average competence level for providers, the resulting higher prices or greater inconvenience can impair health by reducing consumer utilization. For contact lenses, higher prices or less convenient purchase options may influence how often consumers replace their contact lenses. Disposable lenses, especially when worn properly, are generally healthier than conventional daily wear lenses.[68] Doctors have reported that frequent replacement of lenses has yielded a significant decrease in eye infections and inflammation among their patients who wear disposables.[69] The AOA also confirmed that frequent replacement is in the patient's best interest.[70] To the extent that it raises costs for Internet sellers of replacement lenses that are passed along to consumers through higher prices or reduced convenience, licensing may actually increase the incidence of health problems associated with contact lens use. Several panelists confirmed that consumers, if they found it inconvenient or expensive to obtain replacement lenses, might wear their lenses for a longer period than recommended by their eye care providers.[71] Some commenters in the FTC Rule review also noted that fostering competition in contact lens sales can be expected to increase the quality of care rather than decrease it.[72]

Specifically, many consumers who wear disposable lenses over-wear their lenses, thus diminishing the health benefits of such lenses. One survey revealed that fewer than 50 percent of consumers comply with the recommended wearing schedule.[73] Fifty-seven percent of consumers stated they would replace their lenses more frequently if the lenses cost less,[74] and 30 percent specifically identified cost savings as the reason they over-wear their lenses, stating they

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[68] *See* Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 134-35 (citing studies).

[69] *Id.* at 135-36.

[70] Tr. at 359. ("I would support the concept that the more frequent the replacement of the lenses or whatever the replacement schedule is, if it's adhered to, that that is going to be in the patient's best interest." Testimony of Dr. Pat J. Cummings, Jr., O.D.)

[71] Tr. at 359-61.

[72] Comment from NAOO (#119), at 3-4, 12.

[73] McKinsey & Company, Consumer Fact Pack, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 92. *See also* BAUSCH & LOMB, 2001 ANNUAL REPORT TO VISION CARE PROFESSIONALS: TRENDS IN CONTACT LENSES & LENS CARE 14, *available at* <http://www.optistock.com/trends_contact_lenses_2001_dec.pdf> ("Among consumers prescribed lenses that are to be replaced monthly or more often, about a third do not do so. Conversely, many more consumers replace their lenses at intervals longer than one month when eyecare professionals have prescribed otherwise.")

[74] *Id.* at 97.

"try to save money by wearing [their] contact lenses for more days than [their] doctor recommends before disposing of them."[75] Twenty-two percent said they do not replace their lenses as often as they should because "purchasing them is inconvenient."[76] An Internet provider of replacement lenses testified that its sales data supports the position that consumers who find it more convenient or less expensive to obtain replacement lenses might be less likely to wear their lenses for a substantially longer period than that recommended by their eye care providers.[77] Not only will many disposable lens wearers over-wear their lenses in order to save money, but studies also suggest that more consumers would opt to switch from conventional lenses to the healthier disposable lenses if disposables cost less.[78]

Increasing the cost and inconvenience of obtaining disposable replacement lenses may induce more individuals to over-wear their replacement lenses; decreasing the cost and inconvenience may induce more individuals to comply with eye doctors' instructions. Imposing licensing requirements on stand-alone sellers of replacement lenses thus has the potential to increase health risks for consumers by raising the cost or inconvenience of purchasing replacement lenses.

3. *Forms of licensing and licensing alternatives*

Some licensing regimes are more onerous than others. For example, if a state requires that replacement lenses be sold through a licensed optical establishment, the establishment has to have a license, which may cost several hundred dollars a year, and may also have to be under the direct supervision of a licensed optician.[79] Obtaining a license as an optician involves a

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[75] *Id.*

[76] *Id.*

[77] Statement of Jonathan Coon, Tr. at 359 ("[O]ur data supports the Attorneys General position which is the industry average is about 28 lenses per year. Our average customer consumes about 40 lenses per year of the average disposable contact lenses.") The general recommendation for disposable lenses is that patients replace them every two weeks. Thus, a typical consumer who follows this recommended replacement schedule would use 52 lenses per year (26 lenses per eye).

[78] *See* Declaration of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 36 ("Some wearers of conventional contact lenses and eye glasses would also respond to the lower prices by switching over to these disposable and frequent replacement lenses.")

[79] *See, e.g.*, Conn. Gen. Stat. § 20-150 (2003), Conn. Gen. Stat. § 20-151.

[80] For example, in Connecticut a candidate for an optician's license must have four years of approved apprenticeship or an Associate's degree in ophthalmic dispensing from an approved school and have passed the American Board of Opticianry's National Opticianry Competency examination, the National Contact Lens Examination, and the Connecticut Practical Examination. *See* Conn. Gen. Stat. § 20-146. *See also* Connecticut Department of Health, Detailed Information for Optician Licensure, *available at* <http://www.ct-clic.com/detail.asp?code=1746.> Section 20-146 of the Connecticut statute also permits an optician licensed in another state to be eligible for a license in Connecticut without examination if the other state has licensing requirements similar to or higher than those of Connecticut.

[81] There is a question whether the Fairness to Contact Lens Consumers Act preempts some state laws regulating the sale of contact lenses. A federal enactment may preempt state law either through (1) express statutory preemption; (2) implied preemption where the intent of the federal law is to occupy the field exclusively ("field preemption"); or (3) implied preemption where state and federal law actually conflict ("conflict preemption"). *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 121 S. Ct. 2404, 2414 (2001); *Crosby v. National Foreign Trade Council. Reilly*

however. Some states make out-of-state contact lens sellers register with state boards and, as a condition of the registration, require the seller to have a professional license – such as a optometry or pharmacy license – in the seller's home state.[84] While this is less burdensome than requiring the seller to have a professional license from every state into which it sells, it still requires a substantial investment in professional licensing that may not otherwise be relevant to the seller's activities in supplying prepackaged replacement lenses.

4. *Benefits and costs of licensing*

One potential benefit of licensing out-of-state sellers is that the license may give a state additional leverage to protect consumers.[85] If an out-of-state seller fails to comply with prescription requirements or sends consumers the wrong lenses, then the State could prompt compliance by threatening to revoke the seller's license. If the seller still refuses to comply, the State could then revoke the license, thus protecting consumers from the health risks that seller poses. The Fairness to Contact Lens Consumers Act, which provides for federal enforcement of its requirement that contact lenses be sold pursuant to a prescription, obviates much of this concern about the difficulty of reaching out-of-state sellers.[86]

As discussed earlier,[87] however, existing regulatory requirements already address the primary health concerns at issue and, if enforced, ensure that appropriate safeguards will be maintained to protect consumers' health when purchasing replacement contact lenses online. The key question is whether there are benefits to consumers from additional, more restrictive

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[84] *See* Ariz. Rev. Stat. Ann. § 32-1773 (2004) (a nonresident dispenser may register with the board of optometry to dispense replacement soft contact lenses; registered dispensers shall maintain a valid pharmacy license in their state of domicile); N.H. RSA 327:31 (No person shall operate a business outside the state for the retail sale of contact lenses into the state unless the business has a permit issued by the board of pharmacy, if the business is a pharmacy, or by the board of registration in optometry, if the business is not a pharmacy).

[85] In comments submitted to the workshop, AOA stated that sales of contact lens without a valid prescription were frequent, and NAOO stated that it was difficult for state boards to reach out-of-state sellers who sold without a prescription. *See* Summary of Testimony of J. Pat Cummings, Jr., O.D., President, AOA ; Summary of the Position of the NAOO.

[86] Also, some states have pursued direct enforcement of their prescription requirements. For example, the Texas Optometry Board brought suit against a Florida mail order contact lens seller for violating the Texas statute requiring an unlicensed seller to obtain a complete physical copy of the patient's prescription before providing the lenses to the patient. The parties ultimately settled, with the seller agreeing to refrain from selling lenses without a proper prescription. *See Lens Express, Inc. v. Ewald*, 907 S.W.2d 64 (Ct. App. Tx. 1995) (describing history of proceedings).

[87] Section IV C *supra*.

regulations, such as licensing, that would outweigh the additional consumer costs. As noted above, online sellers of replacement lenses simply provide customers contact lenses that come from the manufacturer in sealed boxes labeled with the relevant specifications. Concerns about quality of care related to follow-up examinations can be addressed by enforcing contact lens prescription requirements, rather than by inhibiting sales by online providers. Requiring customers to return to an eye care professional to purchase replacement lenses does not reduce the individual's incentive or ability to wear lenses for too long and may even exacerbate them by increasing costs or inconvenience. Moreover, in the case of requiring an optometry license, state laws generally do not allow opticians to examine eyes or treat eye problems, so forcing consumers to purchase replacement lenses from an optician does not advance the health goal of more frequent eye exams.[88] Accordingly, it is doubtful that requiring an optician's license to sell replacement lenses is necessary to protect consumers.

If additional safeguards are desirable, there are safeguards that are less restrictive than professional licensing, such as a registration requirement. A registration system like California's, unlike licensing, would not require that individuals or firms that want to sell replacement lenses fulfill expensive and unnecessary training requirements to do so. Rather, replacement lens sellers would merely file their names and other required contact information with the state. The state would thereby know who is selling replacement lenses into the state and would have sufficient information in the event that a particular seller engages in practices that create health risks for consumers.

Registration that requires professional licensing in the seller's home state is a hybrid approach that imposes a lesser burden on Internet sellers than requiring a professional license from the state into which sales are made. Nevertheless, requiring any professional license for an Internet contact lens sellers seems unlikely to diminish any of the genuine health risks associated with contact lenses and is not necessary to ensure sellers follow prescriptions.

In sum, professional licensing for replacement lens sellers can increase the quality of care for consumers. Because it will almost certainly impose additional costs on Internet sellers of replacement lenses, however, it also can induce Internet sellers to charge higher prices or exit the market entirely, harming consumers. Moreover, the increase in price or reduction in convenience may lead some consumers to over-wear their lenses or forego replacement lenses altogether, reducing health benefits for consumers overall. Less burdensome regimes, such as simple registration requirements, are likely to provide consumer protections at a much lower cost.

B. *Prescription release and verification requirements*

1. *Prescription release*

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[88] *See, e.g.*, Conn. Gen. Stat. § 20-127(3) (defining the practice of optometry to include the examination of the human eye and eyelid for the purpose of diagnosis).

The FTC's Eyeglass Rule does not cover contact lens prescriptions. Instead, the Fairness to Contact Lens Consumers Act, which was enacted after the workshop, requires that upon the completion of a contact lens fitting a 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."[89] In addition, many states have similar requirements.[90]

The panelists seemed to agree about the desirability of prescription release. For example, the AOA testified, "The patient is entitled to choice. They are entitled to have that prescription, to purchase their replacement contact lenses where they choose . . . not just the private practitioner, but the big box retailers, mass merchandisers, the Internet and mail order."[91] The real point of disagreement among the panelists was whether consumers generally have had difficulty in obtaining a copy of their contact lens prescriptions. The AOA testified that "[s]ales figures for online sellers and studies on the release of contact lens prescriptions suggest the answer is no."[92] Similarly, the contact lens manufacturer stated that in the experience of his company's customers, prescription release has not been a problem,[93] and the NAOO testified that while prescription release was a pressing issue a few years ago, it is no longer an issue today.[94] By contrast, the online contact lens seller testified that before the state law was recently changed to require prescription release, the "most common complaint in California was refusal to release a contact lens prescription," and he provided numerous signed complaints from Texas consumers to the state optometry board regarding their eye care practitioners' refusal to release their lens prescription, despite a state law requiring release.[95]

Enactment of a federal prescription release requirement will help reduce any existing

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89 15 U.S.C.A. § 7601(a).

90 *E.g.*, 22 Tex. Adm. Code § 181.3 ("each physician who performs an eye examination and fits a patient for contact lenses shall, on request, prepare and give a contact lens prescription to the patient;") Conn. Gen. Stat. § 20-7c (requiring practitioners to release to a patient or his authorized representative a copy of the patient's health record, including "contact lens specifications.")

91 Tr. at 383.

92 Tr. at 324.

93 Tr. at 334-35.

94 Tr. at 342-43.

95 Tr. at 352, 369-70.

problems with prescription release, and officials should be vigilant for violations.

2. *Prescription verification*

According to the panelists, another issue – prescription verification – effectively eclipsed concerns about prescription release. Panelists had differing views on whether a valid prescription, communicated to the seller by the patient, can be presumed verified if the eye care practitioner is contacted and given sufficient opportunity to correct any errors, a practice known as passive verification. Active verification, by contrast, requires the seller to get an affirmative communication from the eye care practitioner confirming the validity of the prescription. Several panelists advocated a federal verification requirement but they differed on whether it should require active or passive verification.[96]

Existing state prescription verification regimes vary. For example, California has passive verification,[97] and New Mexico requires active verification.[98] Texas has an even stricter regime that requires the seller actually to possess the valid prescription either in writing or electronically and permits telephone verification only in an emergency.[99]

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[96] Testimony of J. Pat Cummings, O.D., Tr. at 324 ("AOA believes there's a simple answer: a Federal legislative requirement that providers must release and verify prescriptions and that sellers must obtain positive [*i.e.*, active] verification of the prescription before lenses are shipped to patients, with appropriate penalties for both for non-compliance."); testimony of Jonathan Coon, Tr. at 385 ("At the very least, contact lens wearers deserve a Federal right to their contact lens prescription like they've had for eyeglasses for over 20 years. In addition to that, we don't think that the competitors should be allowed to veto the consumer's choice to purchase from somewhere else by simply ignoring the request for a prescription.").

[97] CAL. BUS. & PROF. CODE § 2546.6(a), "A prescription shall be deemed confirmed upon the occurrence of one of the following: 1) The prescriber or the prescriber's agent confirms the prescription by communication with the seller. 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."

[98] N.M. STAT. ANN. § 61-2-10.5(M) & (N) (2003) (The statute specifies that verification takes place when "the prescribing licensed optometrist has orally or in writing verified the valid, unexpired prescription to a seller designated by the patient to act on his behalf," and that "[u]nder no circumstances shall a non-response to a verification request be deemed to authorize, validate or confirm any prescription.")

[99] Texas' Contact Lens Prescription Act provides that when contacts are dispensed by a party other than a physician or licensed optician, the party must be, "an employee of a physician, optometrist, therapeutic optometrist, or pharmacist who performs contact lens dispensing services only under the direct supervision and control of the physician, optometrist, therapeutic optometrist, or pharmacist." Tex Occ. Code Ann § 353.051. *See also* Tex. Adm.

Code. § 279.2 (The statute provides, at (e)(3), that valid prescriptions are issued by providing a signed original copy, sending an original signed prescription by facsimile, or "transmitting a complete prescription . . . by e-mail or other computerized electronic means," and it also specifies, at (e)(4), that if the eye care practitioner, "determines that the patient needs an emergency refill of the contact lens prescription, the prescription may be telephoned to a person authorized to fill the prescription.")

[100] Tr. at 367-68.

[101]

(d) VERIFICATION EVENTS – A prescription is verified under this Act 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 that the prescription is inaccurate and provides the accurate prescription.
>
> (3) The prescriber fails to communicate with the seller within 8 business hours, or a similar time as defined by the Federal Trade Commission, after receiving from the seller the information described in subsection (c) [patient information, prescription details, and contact information for the lens seller].

(e) INVALID PRESCRIPTION – If a prescriber informs a seller before the deadline under subsection (d)(3) 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 invalidity of the prescription. If the prescription communicated by the seller to the prescriber is inaccurate, the prescriber shall correct it. . . .

(g) DIRECT COMMUNICATION – As used in this section, the term "direct

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[105] 15 U.S.C.A. § 7603.

[106] The Act states that if the prescriber fails to communicate with the seller within "8 business hours, or a similar time as defined by the Federal Trade Commission," of the seller's direct communication with the prescriber the prescription is verified. 15 U.S.C.A. § 7603(d)(3) The Commission is conducting a rulemaking to define this time period under the Act. *See* n.8 *supra.*

[107] 15 U.S.C.A. § 7603(b).

[108] 15 U.S.C.A. § 7601(a).

[109] *See, e.g.*, GA. CODE ANN. § 31-12-12(e)(4) & (g) (2003), (requiring that the contact lens prescription explicitly state a brand name and stating that, "[a]t no time, without the direction of a prescriber, shall any changes or substitutions be made in the brand or type of lenses the prescription calls for with the exceptions of tint change if requested by the patient.") *But cf.* CAL. BUS & P

goods in general, which clearly increase consumer choices, and private labels in contact lenses, where the prescription locks the consumer into purchasing all replacement lenses from that practitioner.[112] The seller also emphasized that a consumer would have to pay for and undergo another eye exam to get a new prescription for a different brand of lens if the consumer wanted to purchase lenses from a different supplier.

Eye care practitioners offer similarly mixed views of private label lenses. In January 2002, Contact Lens Spectrum magazine ran an article in which eye care practitioners discussed how they use private label lenses.[113] Some of the practitioners stated that they use such lenses to help ensure that patients cannot buy lenses without a valid prescription, which might endanger their eyes. Other practitioners stressed, however, that they use private label lenses to prevent patients from buying their replacement lenses from other sellers, specifically Internet sellers.[114]

The Fairness to Contact Lens Consumers Act addresses the issue of private label lenses. Although it prohibits a seller from altering a contact lens prescription, the Act also provides that "if the same contact lens is manufactured by the same company and sold under multiple labels to individual providers, the seller may fill the prescription with a contact lens manufactured by that company under another label"[115] Thus, when a seller receives a prescription for a type of lens made by a single manufacturer but packaged under different names – for example, Dr. Jones lenses and Big Box lenses – the seller may fill the prescription for Dr. Jones lenses with Big Box lenses of the same type. This preserves the expanded consumer choice private label lenses may offer while preventing a prescriber from effectively evading the prescription release requirement by prescribing a private label lens only he or she sells.

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[112] Tr. at 383-84 ("There's a little difference between contact lenses and chocolate chip cookies in the sense that at least I'm not aware of anyone writing a prescription for chocolate chip cookies. . . . But once somebody writes a prescription, if they did, for chocolate chip cookies, it would be a shame if I couldn't go buy Chips Ahoy or Mrs. Field's Cookies somewhere else because I had been prescribed Sam's Choice of chocolate chip cookies.")

[113] *Using Private Label Lenses to Keep Patients in the Practice,* supplement to CONTACT LENS SPECTRUM, Jan. 2002.

[114] *Id.* ("Now when patients want to order a lens, they like the particular lens that we provide. It's a private label, so they can't get it anywhere else. It makes it a lot easier for them to come back to us. If they go down to Wal-Mart or Costco or someplace like that and ask, 'Do you have this lens?' Costco or Wal-Mart or 1-800 would say, 'Yes, we do, but it's a different name on the box.' That creates the problem within the patient's mind about whether or not it's the same lens. . . . I often don't give the 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.'")

[115] 15 U.S.C.A. § 7603(f).

2. *Prescription length*

Another way that eye care practitioners may constrain consumer choice is by writing prescriptions with very short expiration periods, thereby making it difficult for consumers to purchase replacement disposable lenses at the interval they would typically choose. For example, a consumer who buys two six-packs of lenses from his practitioner upon completion of the fitting and follows a recommended replacement schedule of every two weeks, would need to

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[116] McKinsey & Company, Consumer Fact Pack, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 90.

[117] 5 U.S.C.A. § 7604(a) & (b).

This provision protects consumer choice by ensuring that most consumers can purchase replacement disposable lenses at convenient intervals throughout the year. It also protects consumer health by permitting eye care practitioners to issue shorter prescriptions when medically justified, as long as the justification is documented in the patient's record.

VI. Recommendations

APPENDIX A

[1] This comment expresses the views of the Bureau of Consumer Protection and the Office of Policy Planning of the Federal Trade Commission. The comment does not necessarily represent the views of the Commission or of any individual Commissioner. The Commission

The staff of the FTC was designated an intervenor in accordance with Conn. Gen. Stat. ' 4-176(d) and Conn. Agencies Regs. ' 19a-9-27 by the Board of Examiners for Opticians on February 13, 2002.

The questions posed by the Board raise three issues: (1) the regulation of intrastate sellers, (2) the regulation of out-of-state sellers, and (3) the adherence of all sellers to prescription requirements. The questions are phrased in a general manner, apparently covering sellers of all types of contact lenses. However, we understand that the principal controversies concern the sale of disposable replacement lenses.[2] In any event, our comments address the three questions in the context of replacement lenses, the lion's share of which are sold as disposable replacement lenses.

Other parties to this proceeding, such as the Connecticut Attorney General, can be expected to address more fully the proper interpretation of Connecticut law. This comment will instead focus on the core concern of the Federal Trade Commission, which is how rules adopted in this proceeding will likely affect consumer welfare.

Executive Summary

To help ascertain the possible impact of the Board's decision on consumer welfare, this submission examines the likely costs and benefits to consumers of any incremental changes in regulation and barriers to entry that may result from this proceeding. Based on the Commission's significant expertise concerning regulation and competition, and considerable experience with the eye care industry in particular, FTC staff believe that an overly restrictive interpretation of the Connecticut statutes and regulations is likely to adversely affect consumer welfare by raising prices for at least some consumers without offsetting benefits in health or safety. To summarize our analysis:

1. Existing federal and state regulations already provide significant protections for the health and safety of contact lens wearers, even if the Board imposes no new requirements in this proceeding.

2. It is likely that mandatory licensing of stand-alone sellers of replacement contact lenses would both increase prices and reduce convenience for contact lens consumers and thus adversely affect consumer welfare. The critical inquiry is

[2] Replacement contact lenses means contact lenses that are sold to replace the contact lenses prescribed by the eye care professional after the initial fitting is complete.

3. The ways in which prescription requirements are interpreted and enforced may also have competitive consequences. The staff of the FTC believe that the Board can maximize consumer welfare by following the most procompetitive approach

[3] Federal Trade Commission Act, 15 U.S.C. § 45.

[4] *See, e.g.*, *Alaska Healthcare Network, Inc.*, Docket No. C-4007 (Apr. 25, 2001); *Colegio de Cirujanos Dentistas de Puerto Rico*, Docket No. C-3953 (June 12, 2000); *FTC v. Superior Court Trial Lawyers Ass'n*, 493 U.S. 411 (1990); *FTC v. Indiana Federation of Dentists*, 476 U.S. 447 (1986).

[5] 16 C.F.R. Part 456.

[6] Ophthalmic Practice Rules ("Eyeglasses II"), Statement of Basis and Purpose, 54 Fed. Reg. 10,285, 10,286 (Mar. 13, 1989).

restrictions on several types of commercial arrangements by eye care professionals.[7] The Commission has also taken action against anticompetitive restrictions on competition in the eye care industry through administrative litigation.[8]

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[7] The Court of Appeals ultimately vacated this "Eyeglasses II" rule on the ground that the Commission lacked the statutory authority to make rules declaring these state statutes unfair. However, the Commission's findings that the restrictions harmed consumers were not disturbed. *See California State Bd. of Optometry v. FTC*, 910 F.2d 976 (D.C. Cir. 1990).

[8] *See, e.g., Massachusetts Board of Registration in Optometry*, 110 F.T.C. 549 (1988) (challenging Board regulation that unreasonably restricted truthful advertising by optometrists; final order required Board to allow truthful advertising and to repeal regulation).

[9] 16 C.F.R. § 456; *see also* Ophthalmic Practice Rules, Final Trade Regulation Rule, 54 Fed. Reg. 10,285, 10,299, 10,303 (Mar. 13, 1989).

[10] 16 C.F.R. §§ 456.2(b), 456.1(c) .

[11] Advertising of Ophthalmic Goods and Services, Statement of Basis and Purpose and Final Trade Regulation Rule, 43 Fed. Reg. 23,992, 23,998 (June 2, 1978).

optometry boards, and consumers.[12] Those comments have contributed further to the Commission's expertise regarding the eye care marketplace.

II. Competition and innovation in eyewear markets have been enhanced by entry of nontraditional firms

The current proceeding stems from a decades-long evolution of the eyewear marketplace. A brief review of that evolution provides a useful context for understanding the larger policy issues involved.

The principal purpose of the Ophthalmic Practice Rules was to provide consumers a greater range of choices when buying ophthalmic goods and services. Prior to the Rule, prohibitions and restrictions on advertising of ophthalmic goods and services were commonplace; advertising of ophthalmic goods and services by either optometrists or opticians was prohibited or severely restricted by state or private regulation in every state but one.[13] Therefore, there was virtually no price competition and a general lack of consumer knowledge concerning purchasing eyeglasses and eye exams. Comparison shopping and obtaining

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[12] *See* Request for Public Comments, 62 Fed. Reg. 15,865 (Apr. 3, 1997).

[13] 1978 Statement of Basis and Purpose, *supra* note 11, 43 Fed. Reg. at 23,994.

[14] *Id.* at 23,995-96; 1989 Statement of Basis and Purpose, *supra* note 6, 54 Fed. Reg. at 10,288.

[15] 425 U.S. 748 (1976) (holding that the state's blanket ban on advertising prescription drug prices violated the First Amendment).

multiple types of eyewear, including eyeglasses, hard contacts, regular soft contacts, and disposable contacts.

The most recent step in the evolution of this market, and the one that brings us to the current controversy, is the development of stand-alone sellers of replacement contact lenses. Such firms tend to focus on the sale of replacement lenses. They do not sell eyeglasses. They do not fabricate lenses or fit them to the eye; they sell only replacement lenses for which the

[16] *In re: Disposable Contact Lens Antitrust Litigation*, No. MDL 1030, (complaints filed M.D. Fla. 1994).

apply to firms that sell only replacement lenses. We offer no opinion on how the laws and regulations should apply to contact lens providers who also sell eyeglasses, fabricate lenses, or fit them to the eye.

III. There are significant health issues concerning the sale of contact lenses

The sale of contact lenses raises significant health issues that many current federal and state laws and regulations are intended to address. This proceeding will determine whether some of Connecticut's regulations will be applied in a more or less restrictive fashion.

To ascertain whether a more restrictive interpretation would create incremental consumer benefits, one must first consider the health issues involved in contact lens sale and use. The Board will no doubt hear evidence from a number of medical experts in this proceeding. In the interest of making the record as complete as possible, we offer a brief summary of the pertinent medical evidence concerning health issues and contact lenses that FTC staff have encountered in the course of the Commission's Rule Review and the multidistrict antitrust litigation.

The primary health care concern with contact lenses appears to be ensuring that contact lens wearers return to their doctors regularly for eye examinations. Disposable contact lenses prevent oxygen from reaching the cornea, and lack of oxygen can lead to severe eye damage. Therefore, it can be important that a patient adhere to the doctor's recommended wearing schedule, removing and replacing the lenses when recommended. Some individuals may develop eye problems even if they follow the doctor's advice; their eyes may develop problems simply in response to wearing lenses. Customers incur health risks if they forego regular eye exams that would allow the optometrist or ophthalmologist to spot emerging health problems in their early stages.

The primary means by which federal and state regulators ensure that contact lens wearers undergo periodic eye exams by qualified practitioners is to require sale of contact lenses by prescription. In contrast to prescription drugs, virtually no consumer is likely to try to "self-prescribe" vision-correcting contact lenses. Unless a consumer is willing to bear the expense of

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[17] *See, e.g.*, Supplemental Report of Gerald E. Lowther, O.D., Ph.D., on behalf of The American Optometric Association, *et al.*, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 9 ("A contact lens prescription cannot be determined until a patient has worn a diagnostic lens for some time, usually days or weeks." This is because the fit may change based on various wearing factors. "Only after this time and process can a patient be given a contact lens prescription.") *See also* Conn. Gen. Stat. § 20-7c(b) (practitioners must release "contact lens specifications based on examinations *and* final contact lens fittings" (emphasis added)).

[18] There is anecdotal evidence that some customers who purchase lenses through these alternative channels developed eye problems. *See, e.g.*, Deposition of George Kenneth

Due to this difference, medical professionals do not always follow the same fitting and sales procedures with soft replacement lenses as they do with hard contacts. Several commenters have noted that medical practitioners do not examine the fit of each replacement

[23] Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation,* at 59-64.

[24] Preliminary Settlement Agreement, *In re: Disposable Contact Lens Antitrust Litigation,* (filed Apr. 23, 2001, approved Nov. 1, 2001) at 1.

[25] Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation,* at 131-34.

alternative channels. This is a disproportionately low percentage, since at least 5-10 percent of Vistakon lenses were sold though alternative channels in 1992.[26]

- Multiple optometrists who testified as witnesses were asked if they knew of any scientific studies showing that consumers face greater health risks if they purchase contact lenses from a mail order firm. No optometrist could cite such a study. Several said that the source from which the consumer purchases the lens should make no difference as long as the seller follows the prescription. One ophthalmologist was quoted as saying, "If the lens comes directly from the manufacturer in a sealed container, it should not matter where that lens is obtained by the patient."[27]

- In fact, Johnson & Johnson's own expert witness acknowledged that the "[s]teps which can be taken to minimize episodes of contact lens related complications include careful and appropriate lens selection and fitting, continuing patient education on proper lens care procedures, good hygiene, prompt reporting of symptoms by patients, and on-going monitoring and care of patients through regular aftercare visits."[28] Notably, none of these recommended steps involve obtaining replacement lenses directly from an optician or other eye care professional.

IV. Current federal and state regulations address contact lens health concerns

The Connecticut Board is not being asked to make its decisions in a regulatory vacuum. Existing regulatory requirements already address the primary health concerns at issue in this proceeding and ensure that appropriate safeguards will be maintained to protect consumers' health. The key question is whether there are benefits to consumers from additional, more restrictive regulations that would outweigh the substantial additional consumer costs.

A. FDA prescription requirements

Federal law on the prescription requirement for replacement contact lenses is complex and somewhat opaque. FDA regulations state that a soft contact lens is a Class II medical device if it is intended for daily wear.[29] Rigid gas permeable contact lenses and soft contact lenses

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[26] *Id.*

[27] *Id.* at 138.

[28] Contact Lenses: Fitting, Follow-up and Complications, Report of A. Christopher Snyder, O.D., M.S., for The American Optometric Association, *et al.*, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 48.

[29] 21 C.F.R. § 886.5925(b)(1) (2001). Class II devices are devices for which "general controls" are insufficient to provide a reasonable assurance of safety and effectiveness but for which there are existing methods to provide such assurances. 21 U.S.C. § 360c(a)(B).

intended for extended wear are Class III medical devices.[30] A provision in the Food, Drug & Cosmetics Act gives the FDA the authority to promulgate a regulation to require that a device be restricted to sale, distribution, or use only upon the written or oral authorization of a licensed practitioner.[31] Notably, there is no such regulation specifically requiring a prescription for contact lenses.[32]

Nevertheless, approval documents for individual lens products state that they must be sold by prescription. Additionally, there is a general regulation that covers prescription devices overall, which states that a device which "is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which 'adequate directions for use' cannot be prepared," will be exempt from the statutory labeling requirements if the device is "sold only to or on the prescription or other order of such practitioner."[33] Replacement contact lenses fall under this exemption.

The FDA also has strict labeling requirements. A device is considered misbranded if its labeling does not contain "adequate directions for use" and "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . . ."[34] Connecticut's Uniform Food, Drug, and Cosmetic Act has a similar provision.[35]

These methods may include special guidelines, performance standards, and postmarket monitoring, but a prescription requirement is not explicitly mentioned.

[30] 21 C.F.R. §§ 886.5916 and 886.5925(b)(2). Class III is the most stringent regulatory category and applies to devices for which insufficient information exists to assure safety and effectiveness solely through general or special controls, but again the statute is silent as to a prescription requirement. 21 U.S.C. § 360c(a)(C)

[31] 21 U.S.C. § 360j(e)(1) ("The Secretary may by regulation require that a device be restricted to sale, distribution, or use – (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such a device, or (B) upon other such conditions as the Secretary may prescribe in such regulation.").

[32] The FDA regulations for Ophthalmic Devices appear at 21 C.F.R. §§ 886.1 - 886.5928. None of these regulations specifies that contact lenses be restricted to sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use such a device.

[33] 21 C.F.R. § 801.109(a)(2).

[34] 21 U.S.C. § 352(f).

[35] Conn. Gen. Stat. § 21a-106(f).

Neither the Connecticut statute for optometry, the statute for opticians, nor the Uniform Food and Drug Act defines a prescription.[42] The Connecticut Pharmacy Practice Act defines a prescription as "a lawful order of a prescribing practitioner transmitted either orally, in writing or by electronic means for a drug or device for a specific patient."[43]

Connecticut law requires that a practitioner of the healing arts, including optometry, release to a patient or his authorized representative a copy of the patient's health record, including "contact lens specifications based on examinations and final contact lens fittings given within the preceding three months or such longer period of time as determined by the provider but no longer than six months," unless the provider "reasonably determines that the information is detrimental to the physical or mental health of the patient."[44] This strongly suggests that the legislature intended consumers to have the option to purchase lenses separately from the purchase of an eye examination.

If the Board determines that a prescription is required for the purchase of replacement lenses, it would then have a legal means of recourse against stand-alone firms that sell lenses without a prescription, even if those firms were not licensed in Connecticut. States have pursued direct enforcement of their prescription requirements in the recent past. For example, the Texas Optometry Board brought suit against a Florida mail order contact lens seller for violating the Texas statute requiring an unlicensed seller to obtain a complete physical copy of the patient's prescription before providing the lenses to the patient. The parties ultimately settled, with the seller agreeing to refrain from selling lenses without a proper prescription.[45]

C. Other consumer protection laws

A variety of other laws and regulations help protect contact lens consumers and ensure that customers purchasing contact lenses from sources other than doctors receive the lenses that are specified in the prescription.

Consumers have relatively easy recourse if an Internet or mail order firm fails to deliver the proper lenses. Unlike the situation with prescription drugs, consumers can easily determine if they have received the correct product by checking the box to ensure that it matches the prescription. In some instances, even if the consumer does not notice that he or she received the incorrect product, the customer may well discover the error when trying to wear the lenses. The

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[42] Conn. Gen. Stat. §§ 20-127 to 20-138d (optometry); §§ 2-139 to 20-162 (opticians); §§ 21a-91 to 21a-120 (Uniform Food, Drug and Cosmetic Act).

[43] Conn. Gen. Stat. § 20-571(23).

[44] Conn. Gen. Stat. § 20-7c(b) & (c).

[45] *See Lens Express, Inc. v. Lois Ewald, as Executive Director of Texas Optometry Board*, 907 S.W.2d 64 (Ct. App. Tx. 1995) (describing history of proceedings).

customer can then simply remove the incorrect lens. Obviously, this does not rise to the kind of serious risk of harm as would occur if a consumer took the wrong prescription drug.

The Federal Trade Commission has authority under Section 5 of the FTC Act to bring an enforcement action against a contact lens seller who makes false or misleading claims about the products or services it provides.[46] For example, the Commission has taken action pursuant to Section 5 against online pharmacies for making deceptive claims.[47] The Commission also has 0.00 1(we ighappbye iu TDvailn leaenefprohioe if a con5um)snorhioe i con5umSs.

[46] 15 U.S.C. § 45. In addition, Section 12 of the FTC Act prohibits the false advertisement of "food, drugs, devices, services, or cosmetics." 15 U.S.C. § 52.

[47] The Commission brought a complaint against operators of a group of online pharmacies that falsely claimed to be a full service clinic with a national network of physicians. *International Outsourcing Group, Inc.* (File No. 992 3245) (July 12, 2000). The Commission has also brought numerous cases challenging claims for medical devices. *See, e.g., London International Group, Inc.*, C-3800 (Apr. 7, 1998) (consent order) (challenging claims that Ramses condoms are 30% stronger than leading brand and break 30% less often); *United States v. Lifestyle Fascination, Inc.*, No. 97-1487 (CSF) (D.N.J. Mar. 27, 1997) (stipulated permanent injunction and $60,000 civil penalty) (challenging representations for pain relief device and other products).

[48] 15 U.S.C. § 45(n); *also see* Unfairness Policy Statement, appended to *International Harvester Co.*, 104 F.T.C. 949, 1070 (1984).

reproduced to personalized given formulas," this regulation means that contact lenses produced or reproduced to personalized given formulas must also be sold only by licensed opticians.

[55] *See, e.g.,*

an optical establishment permit and an optician's, optometric, or medical license would likely impose a potentially significant additional (and likely unnecessary) cost on these types of alternative sellers.

2. Similar licensing regulations in other professions often raise costs

We know of no study that directly assesses the impact of optical licensing on costs or prices of contact lenses in general or replacement lenses in particular. However, the idea that licensing requirements create additional costs for consumers is hardly novel or unique to replacement contact lenses. In assessing the impact of licensing in this area, it is helpful to consider the effects of licensing on consumer costs in other markets served by regulated professionals. We are more confident that licensing will raise prices for consumers of replacement lenses because we observe that professional licensing tends to raise prices in many other markets where it has been implemented. These price increases should be weighed against any consumer benefits created by occupational licensing to assess whether incremental increases in licensing improve consumer welfare.

Occupational licensing necessarily involves some restriction on the ability of individuals to enter an occupation. This is accomplished through the need for government permission and the demonstration of some minimum degree of competency. The stated motivation for licensing is the desire to maintain or increase the quality of service provided by the professionals being regulated. Business practice restrictions, such as limits on the commercial practice of optometry or restrictions on business relationships between optometrists and opticians, have similar rationales and effects as licensing.

By restricting the supply of professionals into an occupation, licensing tends to raise their wages, which in turn can lead to higher output prices. Licensing and various business practice restrictions can also lead to higher prices by limiting the availability of lower cost suppliers to consumers. Studies of the price effects of licensing are limited to those industries where a well-defined product can be identified. Studies of licensing in dentistry, perhaps the most analyzed of the professions, find price increases of from 4 percent to 15 percent.[58] Studies of the eye care market report price increases from 5 percent to 33 percent that are attributable to a variety of advertising and commercial practice restrictions.[59]

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licensed optician.

[58] Carolyn Cox and Susan Foster, *The Costs and Benefits of Occupational Regulation*, Federal Trade Commission (1990), at 31; Morris Kleiner and Robert Kudrle, *Does Regulation Affect Economic Outcomes?: The Case of Dentistry*, THE JOURNAL OF LAW AND ECONOMICS, Oct. 2000, at 547-82.

[59] Cox and Foster, *supra* note 58, at 31. *But compare* a more recent study by Philip Parker (*'Sweet Lemons:' Illusory Quality, Self-Deceivers, Advertising, and Price*, JOURNAL OF MARKETING RESEARCH, Vol.32, Aug. 1995, at 291-307), suggesting that the results of some of

the earlier studies of the eye care market may be sensitive to alternative model specifications.

There is a larger range of studies assessing the effects of licensing restrictions on wage rates, although the results tend to be mixed. Using a more sophisticated test for the stringency of licensing restrictions, Steven Tenn, finds that licensing is an effective barrier to entry into the legal profession and that it tends to increase the wages of lawyers appreciably. *See* Steven Tenn, Three Essays on the Relationship Between Migration and Occupational Licensing (2001) (unpublished Ph.D. dissertation, Univ. of Chicago).

[60] *See* Letter from Charles A. James and Timothy J. Muris to the Ethics Committee of the North Carolina Bar Re North Carolina State Bar Opinions Restricting Involvement of Non-Attorneys in Real Estate Closings and Refinancing Transactions (Dec. 14, 2001) <http://www.ftc.gov/be/V020006.htm>; Letter from Joel I. Klein and William J. Baer to the Supreme Court of Virginia Re Proposed UPL Opinion #183 (Jan. 3, 1997) <http://www.ftc.gov/be/v960015a.htm>.

[61] Morris Kleiner, *Occupational Licensing*

[68] Comment from NAOO (#119), at 11-12; Comment from State Attorneys General (#118), at 7.

[69] *See* Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 134-35 (citing studies).

[70] *Id.* at 135-36.

[71] McKinsey & Company, Consumer Fact Pack, filed in *In re: Disposable Contact Lens Antitrust Litigation,* at 92.

[72] *Id.* at 97.

[73] *Id.*

[74] *See* Report of Douglas F. Greer on Behalf of the Thirty-One Plaintiff States, filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 138 (citing study).ntah27.2 0dD0.325 2D0.0011 73

inconvenience may induce more individuals to comply with eye doctors' instructions. Imposing licensing requirements on stand-alone sellers of replacement lenses thus has the potential to increase health risks for consumers.

D. Licensing out-of-state sellers of replacement lenses

One potential additional benefit of licensing out-of-state sellers is that the license gives the state additional leverage to protect consumers. If an out-of-state seller fails to comply with prescription requirements, perhaps by sending consumers the wrong lenses or selling lenses without receiving a valid prescription, then the State could prompt compliance by threatening to revoke the seller's license. If the seller still refuses to comply, the State could revoke the license, thus protecting consumers from the health risks involved in dealing with that seller.

It is doubtful that licensing is necessary to protect consumers in this way. Even in the absence of licensing, both consumers and government have significant avenues of recourse if an out-of-state seller fails to comply with prescription requirements.[75] The Board could also suggest that the Connecticut legislature authorize it to adopt additional safeguards that would be less restrictive, such as registration. 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 contact information with the Board. The Board would thereby know who is selling replacement lenses in Connecticut and would have sufficient contact information in the event that a particular seller engages in practices that create health risks for consumers. For this reason, it is doubtful that out-of-state sellers present any unique consumer protection problems for which state licensing is a necessary solution. And, any theoretical increase in enforcement authority is almost certainly outweighed by the additional costs likely to be passed on to Connecticut consumers as a result of requiring replacement lens sellers to be licensed in Connecticut.

VI. The prescription requirement

The third question asks whether a contact lens seller that sells lenses to a Connecticut consumer without first receiving a prescription from a licensed physician or optometrist is in compliance with Connecticut law. The way in which the prescription requirement is interpreted and enforced could have a substantial impact on competition.

The real prescription issue in this proceeding is not whether a prescription should be required. The key question is what it means to say that the contact lens seller must *receive* this prescription from a licensed physician or optometrist. This question can be answered in a way that either restricts or promotes competition.

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[75] *See* Section IV above.

According to the FDA's guide for consumers regarding the purchase of contact lenses over the Internet, a lens seller does not have to receive a written prescription to comply with the federal prescription device regulation. The FDA indicates that if the company checks with the doctor, the company has satisfied the prescription requirement. The FDA guide notes that websites allow the purchaser to fill out a chart with the ordering information and supply contact information for the purchaser's doctor. Thus, the federal prescription requirement may be satisfied by the ability to check with the doctor orally. Connecticut's requirements are similar, since, by statute, a prescription can be transmitted either orally, in writing, or by electronic means.

It is clear that sales of lenses by alternate channels can easily satisfy federal and state prescription requirements. Consumers who wish to order lenses by phone, mail, or Internet can either mail in, call in, fax, or provide in electronic form their prescription information to the lens seller. The lens seller can contact the eye care provider in the same ways, if prescription verification is necessary. Likewise, a valid prescription, communicated to the seller by the patient, can be presumed verified if the doctor is contacted and given sufficient opportunity to correct any errors.

This multiplicity of ways to satisfy a prescription requirement is procompetitive in that it provides consumers with a number of ways in which to obtain their replacement lenses, thus allowing the market to respond to genuine consumer demand. The FTC staff believe it would be detrimental to competition and consumers to overly restrict the ways in which prescription information for replacement lenses may be transmitted.

Similarly, prescriptions that are narrowly drawn so as to favor one contact lens over another, absent sound medical justification, or that have unduly short expiration dates, may also raise significant anticompetitive problems. To the fullest extent consistent with necessary health standards, consumers should be allowed the widest latitude to receive replacement lenses from whichever providers they choose.

In neither the Rule review nor the multidistrict litigation has anyone suggested that consumers should be permitted, or that they are remotely likely to try, to obtain contact lenses without first being fitted for them by an eye care professional. Instead, the crucial question is whether consumers should be able to obtain replacement contact lenses using the prescription information they have from the box of lenses for which they were initially professionally fitted. Both industry representatives and government regulators have informed us that there is a strong consumer demand to obtain replacement contact lenses in this manner.

The position of the staff of the Commission is that strong consumer demands should not be thwarted lightly. The evidence suggests that the health concerns motivating the prescription requirement are satisfied if the contact lens seller receives a valid prescription, however that information is transmitted. If the Board disagrees with this assessment, we nevertheless urge the Board to carefully weigh the health effects of a more restrictive policy against the potential harm to competition and consumer choice.

VII. Conclusion

The staff of the Federal Trade Commission has extensive expertise in analyzing occupational regulation in general and eyewear issues in particular. When assessing the impact of a regulatory change, we typically examine the incremental costs and benefits that would be created by an increase or decrease in regulation.

Based on the evidence we have seen, we believe that requiring stand-alone sellers of replacement contact lenses to obtain Connecticut optician and optical establishment licenses would likely increase consumer costs while producing no offsetting health benefits. Indeed, such licensing could harm public health by raising the cost of replacement contact lenses, inducing consumers to replace the lenses less frequently than doctors recommend or to substitute other forms of contact lenses that pose greater health risks.

An overly narrow interpretation of Connecticut law on these issues will likely have two significant detrimental effects: (1) it will restrict the choices available to Connecticut consumers, raise their costs, and reduce their convenience unnecessarily, and (2) it will serve as a barrier to the expansion of Internet commerce in the State of Connecticut. Current federal and state prescription requirements and consumer protection laws are sufficient to address the health problems associated with contact lens use. Such requirements can be implemented in ways that are either procompetitive or anticompetitive, and the FTC staff urge the Board to implement the prescription requirement in a way that protects consumers health, promotes competition, and maximizes consumer choice.

Respectfully submitted,

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