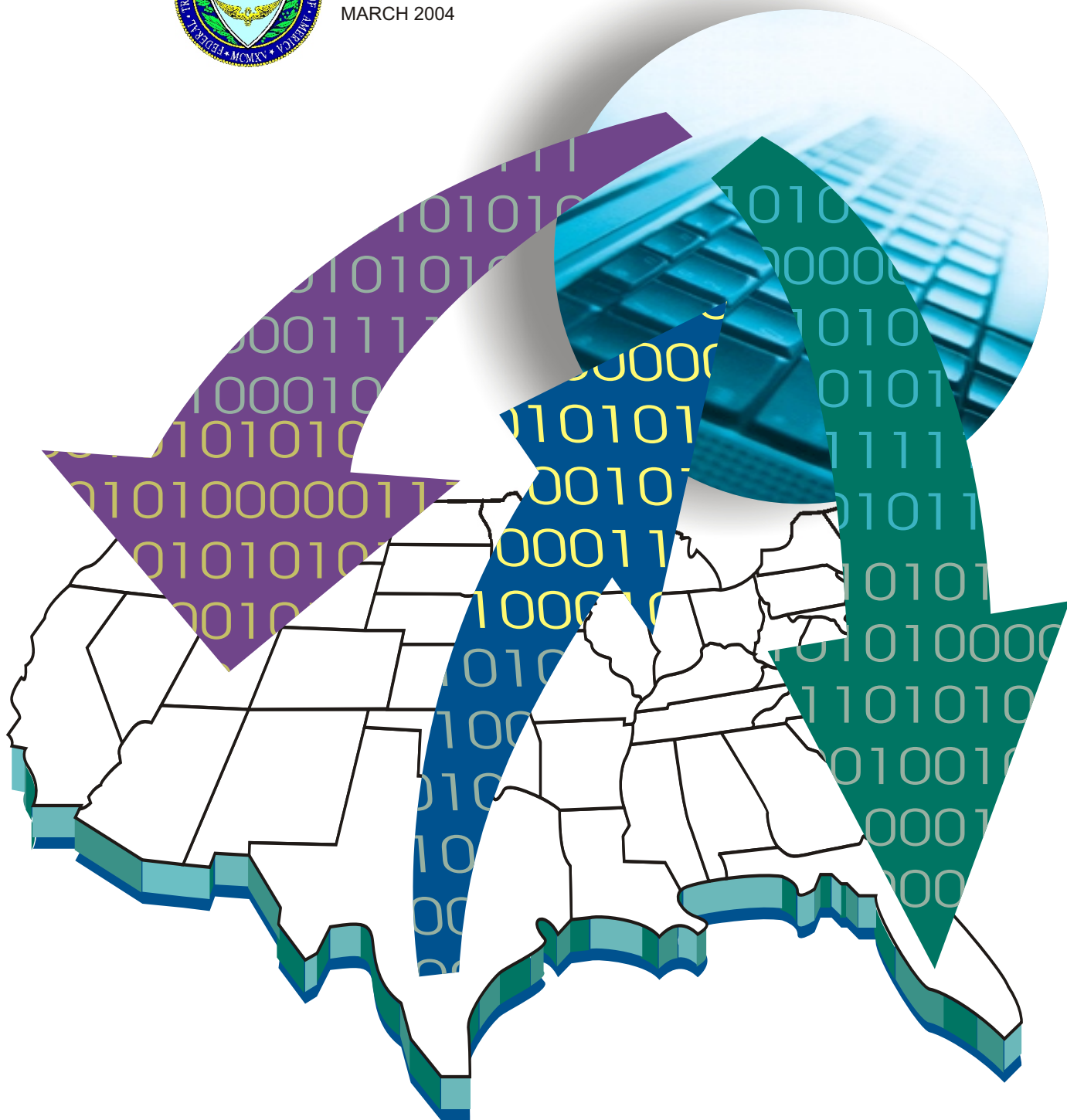


Possible Anticompetitive Barriers to E-Commerce: Contact Lenses



A Report from the Staff of the Federal Trade Commission

MARCH 2004



Federal Trade Commission*

TIMOTHY J. MURIS	Chairman
MOZELLE W. THOMPSON	Commissioner
ORSON SWINDLE	Commissioner
THOMAS B. LEARY	Commissioner
PAMELA JONES HARBOUR	Commissioner
Susan A. Creighton	Director, Bureau of Competition
J. Howard Beales, III	Director, Bureau of Consumer Protection
Luke Froeb	Director, Bureau of Economics
William E. Kovacic	General Counsel
Todd J. Zywicki	Director, Office of Policy Planning
Rosemarie Straight	Executive Director

Report Contributors

Maureen K. Ohlhausen, Deputy Director, Office of Policy Planning
John Delacourt, Chief Antitrust Counsel, Office of Policy Planning
Asheesh Agarwal, Assistant Director, Office of Policy Planning
James Cooper, Office of Policy Planning
C. Lee Peeler, Deputy Director, Bureau of Consumer Protection
Thomas B. Pahl, Assistant Director, Division of Advertising Practices, Bureau of Consumer Protection
Kial Young, Division of Advertising Practices, Bureau of Consumer Protection
Paul A. Pautler, Deputy Director for Consumer Protection, Bureau of Economics
Dennis Breen, Assistant Director, Economic Policy Analysis, Bureau of Economics
Joseph Mulholland, Bureau of Economics
Debra Holt, Bureau of Economics
Patricia Galvan, Bureau of Competition
Anant Raud, Bureau of Competition
Theodore A. Gebhard, Bureau of Competition
Rachel Hertzman, Bureau of Competition

Inquiries

Please direct inquiries concerning this report to:
Maureen Ohlhausen, (202) 326-2632, or mohlhausen@ftc.gov,
Asheesh Agarwal, (202) 326-3558, or aagarwal@ftc.gov.

Acknowledgment

R. Ted Cruz, the former Director of the Office of Policy Planning, and Jerry Ellig, the former Deputy Director of the Office of Policy Planning, oversaw much of this report prior to leaving the FTC.

* This report represents the views of the staffs of the Office of Policy Planning, Bureau of Competition, Bureau of Consumer Protection, and Bureau of Economics. It does not necessarily represent the views of the Commission or any individual Commissioner. The Commission has, however, voted to authorize the staff to publish this report.

TABLE OF CONTENTS

	<u>Page</u>
I. Introduction	1
II. Current Status of Online Contact Lens Sales	4
III. Issues Related to Online Contact Lens Sales	6
A. State Licensing	6
B. Prescription Release and Verification	6
C. Other Issues	8
IV. Consumer Risks and Benefits from Online Contact Lens Sales	8
A. The Sale of Contact Lens Raises Significant Health Issues	8
B. Cost and Convenience Benefits from Online Contact Lens Sales	12
C. Consumer Protection for Online Sales	14
V. Policies Affecting Online Contact Lens Sales	16
A. Professional Licensing	16
1. Effect of Licensing on Costs	16
2. Effect of Licensing on Quality	18
3. Forms of Licensing and Licensing Alternatives	21
4. Benefits and Costs of Licensing	22
B. Prescription Release and Verification Requirements	24
1. Prescription Release	24
2. Prescription Verification	25
C. Other Issues	28
1. Private Label Contact Lens	28

2.	Prescription Length	30
VI.	Recommendations	31
Appendix A	FTC Staff Comment Before the Connecticut Board of Examiners for Opticians (Mar. 27, 2002)	

Possible Anticompetitive Barriers to E-Commerce: Contact Lenses

I. Introduction

Sales of contact lenses in the United States are well over a billion dollars a year.¹ Recent data indicate that nearly 36 million people - almost 13% of all Americans - wear contact lenses.² There are numerous manufacturers of contact lenses (*e.g.*, Johnson & Johnson, Bausch & Lomb, and CIBA Vision) and many different channels of distribution, including eye care practitioners (ophthalmologists and optometrists), national and regional optical chains, mass merchants, and mail order and Internet firms.

In the past, contact lenses were designed to be worn for long periods of time, required daily removal, and involved extensive cleaning regimens. Consumers generally purchased these lenses from their eye care providers after an eye exam and lens fitting and replaced them infrequently. The advent of disposable soft contact lenses – which consumers wear for only a few weeks and throw away – followed by the growth of non-practitioner lens sellers, such as Internet-based contact lens retailers, have changed the market dynamics. While eye care providers still control the prescription process, consumers now not only purchase more lenses with greater frequency but they also have a greater choice of lens suppliers and modes of delivery. These changes have caused tension among eye care practitioners, bricks-and-mortar lens sellers, contact lens manufacturers, Internet lens sellers, and state officials over issues such as licensing contact lens sellers, contact lens prescription release requirements, and methods of verifying prescriptions. These tensions have led to state board proceedings, the adoption of new state and federal legislation, and litigation.

The Commission has been active in the eye care industry for nearly three decades. It enforces the Ophthalmic Practice Rules (“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.³ The Rule also prohibits optometrists and ophthalmologists from conditioning the availability of an eye examination on a requirement that

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.

the patient agree to purchase ophthalmic goods (which the Rule defines as eyeglasses and contact lenses) from the practitioner⁴ and from placing on the prescription, or delivering to the patient, certain disclaimers or waivers of liability.⁵ In adopting the Eyeglass Rule, the Commission found that many consumers were deterred from comparison shopping for eyeglasses because eye care practitioners refused to release prescriptions, even when asked to do so, or charged an additional fee for release of a prescription.⁶ The Rule currently does not require an optometrist or ophthalmologist to release a contact lens prescription to a patient after an eye exam.⁷ Recently enacted federal legislation, the Fairness to Contact Lens Consumers Act, however, requires that when a prescriber completes a contact lens fitting, the prescriber must provide the patient a copy of the contact lens prescription.⁸

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.⁹ The staff comment examined the issues surrounding the online sale of contact lenses while addressing whether the Board should interpret state law to require out-of-state sellers of contact lenses to have a Connecticut opticians license.

In October 2002, the Commission held a public workshop to evaluate possible

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, or require the patient to sign, or deliver to the patient a form or notice waiving or disclaiming the liability or responsibility of the ophthalmologist or optometrist for the accuracy of the eye examination or the accuracy of the ophthalmic goods and services dispensed by another seller.”)

⁶ 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).

⁷ 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).

⁸ 15 U.S.C.A. §§ 7601-7610. The Commission issued a Notice of Proposed Rulemaking seeking comment on a proposed “Contact Lens Rule” to implement the Fairness to Contact Lens Consumers Act. *See* 69 Fed Reg. 5440 (Feb. 4, 2004). The Commission also issued a notice regarding the completion of the regulatory review of the Eyeglass Rule. 69 Fed Reg. 5451 (Feb. 4, 2004).

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

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.

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

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

multipacks, with disposable lenses typically sold in packs of six. When first developed, soft contact lenses were not manufactured in a way that always accurately reproduced the same fit on a patient's eye. In the past 20 years, however, manufacturers have developed production methods for soft contact lenses that have eliminated these standardization problems.¹⁴ Now, the replacement soft contact lenses that a patient receives pursuant to a prescription specifying brand and power will be identical, regardless of whether the patient gets the lenses from an eye care professional or from a non-traditional seller.¹⁵

In light of these factors, after the prescription has been finalized through the fitting process, eye care practitioners do not examine the fit of each replacement lens on the patient's eye. In fact, some lens manufacturers provide direct shipment of replacement lenses to consumers, and some eye care practitioners mail replacement contact lenses to patients without an office visit during the span of the patient's prescription.¹⁶

The most recent step in the evolution of the market for contact lenses is the development of stand-alone sellers, such as Internet sellers or pharmacies, who do not sell eyeglasses, fabricate contact lenses, or fit them to the eye but only offer replacement lenses for which the

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

¹⁴ See, e.g., Summary of views of Gerald M. Ostrov, Company Group Chairman, Johnson & Johnson Vision Care, Inc. ("It is true that disposable lens technology has eliminated the need to have each individual replacement disposable lens fitted on the patient's eye by an eye care practitioner."); Summary of testimony of Jonathan Coon, Chief Executive Officer, 1-800 Contacts, Inc. ("Technological advances led to the introduction of 'soft' disposable contacts in the late 1980s. Disposable soft lenses are standardized, mass-produced commodities.") See also comments filed in the Rule review by the American Academy of Ophthalmology and the California Optometric Association stating that while fabrication errors might present a problem with respect to hard contact lenses, soft lenses, such as disposables, are relatively standard and can be easily reproduced. Comment from COA, #112 at 8; Comment from AAO, #97 at 1-2. The comments from the FTC's Rule review are on file on the Commission's public record as Document Nos. B21940700001, *et seq.* The comments are cited herein by the name of the commenter, a shortened version of the comment number (the last one to three digits), and the relevant page(s) or attachments of the comment.

¹⁵ See Summary of testimony of J. Pat Cummings, Jr., O.D., President, American Optometric Ass'n.

¹⁶ See Summary of views of Gerald M. Ostrov, Company Group Chairman, Johnson & Johnson Vision Care, Inc. (stating that consumers "have the option of purchasing from eye care professionals who participate in Johnson & Johnson's Acuvue® Patient Delivery Program, which offers shipment of lenses to the patient at the doctor's direction.")

customer has already been fitted by an eye care professional.¹⁷ Unlike traditional eye wear sellers, their business consists simply of providing customers contact lenses that come from the manufacturer in sealed boxes labeled with the relevant specifications.

III. Issues related to online contact lens sales

A. State licensing

In its March 2002 comment to the Connecticut Board of Examiners for Opticians, Commission staff argued against the board issuing a declaratory ruling that Internet sellers of replacement contact lenses must have a Connecticut optician's license, even though such sellers merely mail out prepackaged lenses pursuant to an eye doctor's prescription.¹⁸ The staff concluded that such a requirement would increase consumer costs while producing no offsetting health benefits and would be a barrier to the expansion of Internet commerce. 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. The staff noted that current federal and state prescription requirements and consumer protection laws are sufficient to address the health problems associated with contact lens use and urged the Board to implement the prescription requirement in a way that protects consumers' health, promotes competition, and maximizes consumer choice. On June 24, 2003, the Connecticut Board of Examiners for Opticians ruled that, under state law, out-of-state contact lens sellers do not have to have a Connecticut opticians license, although in-state sellers must have such a license.¹⁹ The Board also ruled that a contact lens seller, whether in or outside the state, may only sell the lenses pursuant to a lawfully issued prescription.

B. Prescription release and verification

The principal purpose of the FTC's Eyeglass Rule is to provide consumers a greater range of choices when buying ophthalmic goods and services. As noted above, the Rule's prescription release requirement applies only to eyeglass prescriptions, not contact lens prescriptions. The Commission was considering whether to extend the prescription release requirement to contact lenses during its review of the Eyeglass Rule, which was part of its systematic review of its Rules and Guides to determine their effectiveness and impact. The Commission requested public comment about the overall costs and benefits of the Rule and

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).

related questions, and it received comments from numerous parties, including associations representing various segments of the industry and professions, state attorneys general, state optometry boards, and consumers.²⁰ Given the passage of the Fairness to Contact Lens Consumers Act, the Commission has ended this review.

A number of states have statutes requiring eye care providers to release contact lens prescriptions to patients. Congress considered several bills to impose a federal prescription release and prescription verification requirements for contact lenses,²¹ and eventually passed the Fairness to Contact Lens Consumers Act in November 2003.²² Whether verification must be active – meaning that the eye care provider must affirmatively respond before the seller can provide the lenses – or passive – meaning that the seller can provide the lenses unless the eye care provider notifies him that the prescription is invalid – was a hotly contested issue with important implications for consumer protection and competition in this market. Some contact lens sellers were concerned that, under an active verification regime, eye care providers would prevent their patients from patronizing a competing lens seller by not responding to the verification request. Eye care providers were concerned that, under a passive verification regime, patients would too easily receive lenses with expired or incorrect prescriptions. As discussed below, the Fairness to Contact Lens Consumers Act addresses prescription release and prescription verification requirements.

Tensions between online/mail order lens sellers, their more traditional competitors, and contact lens manufacturers also led to litigation. In *In re: Disposable Contact Lens Antitrust Litigation*,²³ a multidistrict litigation, the Attorneys General of 31 states and a certified class alleged that eye care professionals engaged in an organized effort to prevent or hinder consumers from obtaining their contact lens prescriptions. The complaints alleged two conspiracies: (1) that the practitioners and their trade associations conspired to prevent the release of contact lens prescriptions to consumers, and (2) that the manufacturers, practitioners, and trade associations, including the American Optometric Association, conspired to eliminate sales of contact lenses by pharmacies, mail order, and other alternative sellers. According to the complaints, the conspiracy severely restricted the supply of contact lenses available to alternative sellers, which has hampered the growth of such sellers, decreased the supply of lenses to consumers, and increased the price of lenses. The parties reached settlements, the last of which the court approved in November 2001. As part of the settlement, defendant manufacturers agreed to sell

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

lenses to alternative distribution channels.

C. Other issues

Panelists at the workshop touched on additional issues involving online contact lens sales. One of these issues is the practice of eye care practitioners writing prescriptions for lenses that are not available from other lens sellers. For example, Dr. Jones may write a prescription for Dr. Jones Brand lenses, which Dr. Jones contracts with a lens manufacturer to produce, or merely to label, for him. These are called private label lenses. Dr. Jones' patients who receive these prescriptions typically cannot purchase their lenses elsewhere since only Dr. Jones carries these lenses and most contact lens prescriptions do not allow substitution. Another issue was the length of contact lens prescriptions. Unless limited by state law, eye care practitioners could write prescriptions of any length, including theoretically a period so brief as to impair a patient's ability to purchase replacement lenses elsewhere.

Passage of the Fairness to Contact Lens Consumers Act also affects these issues. The Act permits a contact lens seller to substitute the same lens made by the same manufacturer as the lens prescribed if it is sold under a different label.²⁴ As for the length of prescriptions, the Act specifies that contact lens prescriptions expire not less than one year after their issuance, unless the prescriber specifies a shorter length based on the prescriber's medical judgment with respect to the health of an individual patient.²⁵

IV. Consumer risks and benefits from online contact lens sales

A. The sale of contact lenses raises significant health issues

To ascertain whether restrictions on Internet contact lens sales benefit or harm consumers, one must first consider the health issues involved in contact lens sale and use. Panelists and those who submitted comments to the workshop discussed this issue in detail. FTC staff have also received pertinent medical information during the Commission's Rule Review and the declaratory ruling proceeding in Connecticut.

The primary health care concern with contact lenses appears to be ensuring that contact lens wearers return to their doctors regularly for eye examinations.²⁶ Like other soft contact lenses, 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

²⁴ 15 U.S.C.A. § 7603(f).

²⁵ 15 U.S.C.A. § 7604.

²⁶ 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>>.

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 appears to be the requirement that contact lenses be sold by prescription.

FDA regulations state that a soft contact lens is a Class II medical device if it is intended for daily wear.³⁰ Rigid gas permeable contact lenses and soft contact lenses intended for extended wear are Class III medical devices.³¹ The Food, Drug & Cosmetics Act gives the FDA the authority to promulgate regulations to require that such a device be restricted to sale, distribution, or use only upon the written or oral authorization of a licensed practitioner.³² There

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

is no such blanket regulation specifically requiring a prescription for contact lenses.³³

Instead, the FDA indirectly controls whether contact lenses are sold pursuant to a prescription through its regulation of labeling for individual devices. The FDA has strict labeling requirements, and it deems a device misbranded if its labeling does not contain, among other things, adequate directions for use.³⁴ When the FDA approves a device for sale by prescription,³⁵ however, the device is exempt from the requirement that its label contain adequate directions for use.³⁶ The FDA treats devices, including contact lenses, sold without a prescription and without adequate directions for use on the label as “misbranded” in violation of the Food, Drug & Cosmetics Act.

Prescriptions for eyeglasses and prescriptions for contact lenses differ in several respects. In addition to the information about the degree of vision correction that is present in both types of prescriptions, contact lens prescriptions include information regarding the fit of the lens on the surface of the eye, which is determined by the base curve (shape) and diameter of the lens. Also, unlike the case for eyeglass prescriptions, eye care practitioners generally denote the brand name

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 “A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is (1) presented by the patient or prescriber directly or by facsimile; or (2) verified by direct communication.” 15 U.S.C.A. § 7603(a).

³⁴ 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” 21 U.S.C. § 352(f).

³⁵ *See, e.g.*, Summary of views of Gerald M. Ostrov, Company Group Chairman. Johnson & Johnson Vision Care, Inc. (“Every letter of FDA approval that Johnson & Johnson has received for its lenses recites that contact lenses are prescription devices and warns that, if lenses are sold in a manner inconsistent with the conditions under which they [have] been approved, the FDA may withdraw its approval.”)

³⁶ A general regulation for all prescription devices 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.” 21 C.F.R. § 801.109(a)(2).

of the contact lens in the prescription.³⁷ Due to differences in manufacturing methods, lenses with the same base curve and diameter made by different manufacturers may suit a patient's eyes differently.³⁸ Lens fit affects corneal tolerance and patient comfort, and thus substituting one manufacturer's lens for another manufacturer's lens even of the same generic material may result in a different fit to the patient's eyes and in a difference in oxygen transferability to the cornea.³⁹

Consumers are generally unlikely to try to "self-prescribe" vision-correcting contact lenses. Unless he or she is willing to bear the expense of purchasing and trying on numerous brands, types, and powers of contact lenses, it is difficult for a consumer to find out what to order in the absence of an eye care practitioner's assistance, especially because an eyeglass prescription does not supply all the information necessary to choose suitable contact lenses. It is thus reasonable to assume that a large majority of contact lens wearers have received a prescription for those lenses at some time.⁴⁰ Panelists did note, however, that some people do use or purchase lenses based on someone else's prescription or before their doctor has completed the fitting process.⁴¹ Also, in a recent development, manufacturers have begun to offer cosmetic

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 manufacturers may use the same generic material but different lens design. These differences in lens design may result in different amounts of oxygen being provided to the cornea from lenses created by different manufacturers using the same generic material. Comments of James F. Saviola, O.D., FDA.

³⁹ *Id.*

⁴⁰ *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.")

⁴¹ *See, e.g.,* Summary of Views of Gerald M. Ostrov, Company Group Chairman, Johnson & Johnson Vision Care, Inc. (relating case of woman who sustained severe eye injury after purchasing and wearing lenses not prescribed for her); Summary of position of the National Association of Optometrists and Opticians ("Many NAOO customers have attempted to buy

plano contact lenses, which do not correct vision but merely alter the appearance of the eye for cosmetic purposes. This development may affect the number of consumers who might attempt to buy lenses without a prescription.

It is important to note that the medical purpose of the prescription requirement (aside from describing the proper lenses) is to induce the customer to have regular eye exams – *not* to control where the customer may purchase replacement lenses with a valid prescription.⁴² The workshop, the Commission’s Rule review, the multidistrict litigation, and the Commission staff’s own consultations with industry experts have revealed no systematic evidence that sales through alternative channels, such as Internet or mail order, pose any additional health risk as long as the retailer sells in accordance with a valid prescription.⁴³

B. *Cost and convenience benefits from online contact lens sales*

Professor Morris Kleiner testified that the economic advantages of the Internet are well documented. It gives consumers the ability to gather more easily information on prices, quality, and availability, and this reduction in search costs leads to more efficient transactions and reduced transaction costs.⁴⁴

Non-traditional contact lens sellers, such as Internet and mail order providers, represent a unique alternative distribution channel and offer some consumers a combination of price and convenience that they value highly. While data on price differences between non-traditional sellers and bricks-and-mortar sellers of replacement lenses are sparse, a nationwide survey commissioned by the state attorneys general as part of the Florida multidistrict litigation revealed that, in 1998, the average price of a six-lens multipack purchased via mail order was \$19.90,

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 of Morris Kleiner, University of Minnesota and the National Bureau of Economic Research.

compared to an average of \$23.76 for lenses purchased from ophthalmologists, optometrists, and optical chains – a 19 percent difference.⁴⁵ The survey data also suggested, however, that consumers who purchase their lenses from traditional suppliers could achieve equivalent savings at a mass merchant discounter, such as Wal-Mart, Costco, or BJ's; the average price at such retailers was \$19.98.⁴⁶

This survey data indicates that consumers can often achieve significant savings by purchasing replacement lenses from sellers other than their eye care providers, especially consumers who use independent eye care providers who are not associated with commercial chains and mass merchandisers. While the survey also indicates that there is not a significant difference in price between mass merchandisers and Internet lens sellers, online sales may have a significant convenience advantage for some consumers.⁴⁷ To enjoy the price savings at a mass merchandiser, a consumer has to make a trip to the store and often wait in a line. Multiple trips may be necessary if the store does not have the particular lenses in stock and must order them. Consumers who opt for an Internet seller, on the other hand, can have replacement lenses delivered simply by visiting a web site. The convenience of shopping online for replacement contact lenses could be substantial for consumers who attach high value to their time, must make a special trip to the store just to obtain replacement lenses, or live in areas distant from mass merchandisers.⁴⁸

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 business commutes concludes that “a reasonable average value of time for a journey to work is 50 percent of the gross wage rate,” while recognizing that it varies among different industrialized cities from perhaps 20 to 100 percent of the gross wage rate, and among population subgroups by even more. Kenneth Small, *URBAN TRANSP. ECON.* 44 (1992). To the extent that shopping may take place during leisure time, the value of time saved during a business commute may overstate or understate the value of time savings from online purchases. For example, a recent empirical study of commuters in Sydney, Australia, finds the value of transit time savings for leisure

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 sold pursuant to a prescription to avoid being mislabeled. Allowing a seller to provide lenses without possessing a written prescription is also plainly contemplated by the Fairness to Contact Lens Consumers Act, which provides detailed methods for verifying prescriptions – including by telephone, facsimile, or email – if the seller does not have a written copy of the prescription.

The FDA has the authority to take action against the dispensing of a prescription device without a valid prescription.⁵¹ State law determines what is included in a valid prescription,⁵² however, and the FDA generally defers to the states on enforcement concerning the dispensing of a prescription device without a valid prescription. Its guide for purchasers of contact lenses

(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.

over the Internet states that, “[s]ince individual states have different licensing requirements for optical dispensers, enforcement of prescription device sales has usually been left to State authorities.”⁵³ However, the FDA is not powerless. In a 1998 letter, the FDA noted that it had received complaints about sales of contact lenses by mail without a prescription and confirmed that “FDA is itself investigating alleged violations of Federal law as a basis for possible action.”⁵⁴

A variety of other laws and regulations help protect contact lens consumers and ensure that customers purchasing contact lenses from sources other than eye care practitioners receive the lenses that are specified in the prescription. The 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.⁵⁵ For example, the Commission has taken action pursuant to Section 5 against online pharmacies for making deceptive claims.⁵⁶ The Commission also has authority under its unfairness jurisdiction to regulate marketing practices that cause or are likely to cause substantial consumer injury, which is not reasonably avoidable by consumers and is not outweighed by countervailing benefits to consumers or to competition.⁵⁷ States also have consumer protection statutes.

V. Policies affecting online contact lens sales

As discussed above, the prescription requirement helps ensure that contact lens wearers

⁵³ *Id.*

⁵⁴ Letter from Linda Gangloff, Policy Analyst, Executive Secretariat, FDA, to Thomas W. King, Jr., Executive Secretary, Office of the State Board for Optometry, New York (Oct. 21, 1998).

⁵⁵ 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.

⁵⁶ The Commission entered a settlement with operators of a group of online pharmacies that falsely claimed to be a full service clinic with a national network of physicians. The settlement prohibited such false claims and required them to disclose the name and location of the dispensing pharmacies and 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).

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

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

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 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.⁶² Studies of the price effects of licensing are limited to industries for which 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.⁶³ 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.⁶⁴

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 parentals decreased use of parentals 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

2. Effect of licensing on quality

The effect of licensing on service quality is ambiguous as an *a priori* matter.⁶⁵ A license requirement may limit the market to providers who are initially more qualified but the reduced competition faced by these providers may allow them to offer less innovative service without losing their customers to new, more up-to-date entrants. Moreover, while the restriction of supply from licensing typically leads to a higher average competence level for the professionals allowed to practice, the higher price for their services can lead to less utilization by consumers. Thus, while outcomes for an individual consumer who can still afford the service may be improved, beneficial outcomes for consumers overall may be lower.⁶⁶ This indeterminacy is reflected in the empirical research, where no clear link between licensing and service quality has been demonstrated.⁶⁷

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 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).

⁶⁵ *See, e.g.,* Morris Kleiner, *Occupational Licensing*, JOURNAL OF ECONOMIC PERSPECTIVES, Vol. 14, No. 4, Autumn 2000, at 198. Economic theory also cautions that increased quality does not always benefit consumers. Higher quality by licensed professionals may not be worth the extra cost to certain individuals, who would prefer lower quality for a lower price.

⁶⁶ *See* Sidney L. Carroll and Robert J. Gaston, *Occupational Licensing and the Quality of Service*, LAW AND HUMAN BEHAVIOR, Vol. 7, Nos. 2/3 at p.145 (1983) (“The evidence available indicates that licensing tends to enhance the capabilities of the licensed professionals, resulting in better delivered quality. Often, however, this is not reflected in better quality received in the society as a whole.”)

⁶⁷ Of the 11 studies surveyed by Cox and Foster, *supra* note 58, at 26-27, only two reported a positive association between the strength of restrictions on practitioners and quality. More recent studies are no more supportive of the purported tendency of licensing to improve service quality. In a study of dental licensing, Kleiner and Kudrle, *supra* note 58, found that more stringent licensing did not result in improved dental outcomes among a sample of 464 new Air Force recruits. Similarly, Gary Colbert and Dennis Murray, (*State Accountancy Regulations, Audit Firm Size, and Auditor Quality: An Empirical Investigation*, 16(3) JOURNAL OF REGULATORY ECONOMICS, Nov. 1999, at 267-85) found no association between audit quality and variations in the strictness of state accountancy regulations. Defining quality can be very difficult, and typically it is studied for those outcomes where empirical definitions are feasible. There thus remains a large number of situations that have not been investigated.

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

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

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.

substantial amount of education and training.⁸⁰ If licensing regulations such as these are applied to Internet sellers of replacement lenses, such sellers must pay for a permit and arrange for a licensed optician to supervise their operations. The need to employ an optician would likely be a costly proposition for an Internet seller of replacement lenses. Because such firms do not sell eyeglasses or conduct contact lens fittings, they may not already have an optician on staff. Some states apply even more burdensome requirements.⁸¹ For example, Georgia specifies only an optometrist, ophthalmologist, or optician in a face-to-face transaction can sell contact lenses.⁸²

Some states impose a registration requirement on Internet contact lens sellers rather than a license requirement. For example, California requires a non-resident contact lens seller to be authorized in its home state, to maintain records of lenses sold into 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.⁸³

Not all registration requirements completely supplant professional license requirements,

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*, 530 U.S. 363, 372-73 (2000); *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990). Determining whether the Act preempts a particular state law is beyond the scope of this report.

⁸² GA. CODE ANN. § 31-12-12(h) (2003) ("No person, other than persons licensed and regulated by Chapter 29, 30, or 34 of Title 43 [regulating optometrists, ophthalmologists, and opticians], shall sell, dispense, or serve as a conduit for the sale or dispensing of contact lenses to the ultimate user of such contact lenses in this state through the mail or any other means other than direct, in-person delivery to such ultimate user by such person after having personally ascertained by reliable means the identity of the deliverer.")

⁸³ CAL. BUS. & PROF. CODE § 2546.5 (2004).

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

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*

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

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

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.

A leading Internet seller of contact lenses strongly supported passive verification. The seller testified that 1-800 Contacts, Inc. requires a doctor's name and telephone number on every order, uses a database to verify that the number belongs to a doctor's office, and contacts the doctor's office by telephone or facsimile to request confirmation of the prescription.¹⁰⁰ If the doctor gives notice within a reasonable period that the prescription is expired or invalid, the seller stated it will not fill the order.¹⁰¹

The NAOO expressed concern that a passive verification system allowed contacts to be shipped even if the customer lacked a valid prescription.¹⁰² A major contact lens manufacturer asserted that passive verification "opens the door for people who don't really want to comply to wink at the system and it will give a competitive advantage to people who want to be efficient . . . but who don't think that the consumer health is at risk or don't care about the consumer health . . ." ¹⁰³ The AOA testified that active verification is in the patient's best interest because some consumers will attempt to get contact lenses without a prescription or with an expired prescription.¹⁰⁴

The Fairness to Contact Lens Consumers Act, which was enacted after the workshop, adopted a federal passive verification regime:

(a) PRESCRIPTION REQUIREMENT– A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is –

- (1) presented to the seller by the patient or prescriber directly or by facsimile; or
- (2) verified by direct communication. . . .

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 *Id.*

¹⁰² *Id.* at 371-372.

¹⁰³ *Id.* at 374-75.

¹⁰⁴ *Id.* at 378.

(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 communication” includes communication by telephone, facsimile, or electronic mail.¹⁰⁵

Some panelists argued that active verification for prescriptions is necessary to ensure that consumers are not harmed by obtaining contact lenses without a valid prescription, and others countered that strict active verification requirements also have risks for consumers, both in terms of possible anticompetitive abuses by competitors and possible negative effects on patient adherence to lens replacement schedules. The Fairness to Contact Lens Consumers Act seeks to protect consumer choice and promote competition, while also reducing health risks for consumers, by imposing obligations both on lens sellers and eye care providers. A lens seller can only sell contact lenses pursuant to a prescription received directly or verified by direct communication with a prescriber. When verifying a prescription by direct communication with a prescriber, the seller must wait 8 business hours after the communication for the prescriber to respond before selling the lenses.¹⁰⁶ In addition, a lens seller must maintain records of all such direct communications.¹⁰⁷ An eye care practitioner who prescribes lenses must release the contact lens prescription to the patient and, as directed by the patient or any person designated to

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).

act on the patient’s behalf, “provide or verify the contact lens prescription by electronic or other means.”¹⁰⁸ To protect consumer choice, promote competition, and reduce health risks for consumers, enforcement officials should ensure that contact lens sellers and eye care practitioners comply with contact lens prescription release and verification requirements.

C. *Other issues*

1. *Private label contact lenses*

Most contact lens prescriptions, unlike eyeglass prescriptions, specify a particular brand of lens. Some states require this and prohibit a dispenser from substituting a different brand.¹⁰⁹ Some eye care practitioners – including individual practitioners and those associated with chain optical stores and big box retailers – prescribe private label lenses that are available for purchase only through that practitioner or associated retailer. Panelists debated whether these private label lenses promoted or impeded consumer choice.

A leading contact lens manufacturer explained that, although it does not manufacture private label lenses, the practice is a competitive part of the market, which spurs the branded manufacturers to continue to innovate.¹¹⁰ The NAOO stated that consumers are very aware of the branded products and that “they can and they do ask about the differences in cost and quality between the branded product and private label product that they can choose between at the time of the prescription process . . . in concert with a medical professional who is not entirely unbiased, but is a necessary intermediary for the health and safety of the process.”¹¹¹ The Internet contact lens seller, however, drew a distinction between private labels in consumer

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 & PROF. CODE § 2541.2(e) (“When a provider prescribes a private label contact lens for a patient, the prescription shall include the name of the manufacturer, the trade name of the private label brand, and, if applicable, the trade name of the equivalent national brand.”)

¹¹⁰ Tr. at 379-381 (“They offer sometimes lower prices, sometimes not lower prices. But it’s a competitive aspect of the marketplace. . . . So, as long as we do a good job . . . and keep ahead of the competition, we’ll do [fine] against private label. If we stop innovating, they eat into our market share, and that’s the way it is.”)

¹¹¹ Tr. at 381-82.

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.

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 purchase replacement lenses approximately three months later. If his practitioner wrote a prescription with a 60-day expiration period, the consumer may have to obtain a new prescription to purchase replacement lenses, unless he purchases additional lenses before the end of two months, which is at least a month before he exhausts his initial supply. Some evidence suggests that most consumers prefer to purchase replacement disposable contact lenses less frequently, however, with the greatest percentage of consumers purchasing three to four times a year or less.¹¹⁶

The workshop panelists did not discuss the practice of writing short prescriptions. The Fairness to Contact Lens Consumers Act, however, addresses the issue:

- (a) In General – A contact lens prescription shall expire –
- (1) on the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;
 - (2) not less than one year after the issue date of the prescription if such State law specifies no date or a date that is less than one year after the issue date of the prescription; or
 - (3) notwithstanding paragraphs (1) and (2), on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.
- (b) Special rules for prescriptions of less than 1 Year – If a prescription expires in less than 1 year, the reasons for the judgment referred to in the subsection (a)(3) shall be documented in the patient’s medical record. In no circumstances shall the prescription expiration date be less than the period of time recommended by the prescriber for a reexamination of the patient that is medically necessary.¹¹⁷

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

Consumer health and consumer choice are closely intertwined in the issues surrounding Internet contact lens sales. The FTC staff recommends that policymakers and other officials can advance both of these interests if they:

- Rescind, or refrain from adopting, requirements that an Internet seller have a professional license to sell replacement contact lenses. If states want to regulate such sellers beyond prescription requirements and general state and federal consumer protection laws, they should adopt a simple registration requirement.
- Enforce prescription release requirements and prescription verification requirements to ensure that both consumers' health and consumers' economic interests are protected, especially given that consumers are more likely to adhere to recommended replacement schedules if lenses are less expensive and/or more conveniently available.
- Enforce statutory provisions regarding private label lenses and prescription length to ensure that contact lens seller and contact lens prescriber practices generally promote consumer health and welfare and do not hamper consumer choice in a way that ultimately harms consumers.

APPENDIX A

**STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH
CONNECTICUT BOARD OF EXAMINERS FOR OPTICIANS**

IN RE: DECLARATORY RULING)
PROCEEDING ON THE)
INTERPRETATION AND)
APPLICABILITY OF VARIOUS)
STATUTES AND REGULATIONS)
CONCERNING THE SALE OF)
CONTACT LENSES)

March 27, 2002

COMMENTS OF
THE STAFF OF THE FEDERAL TRADE COMMISSION,
INTERVENOR

The staff of the Office of Policy Planning and the Bureau of Consumer Protection of the Federal Trade Commission (hereinafter, the “FTC”) welcome the opportunity to submit this comment as an intervenor in the above-captioned proceeding.¹ The Notice of Declaratory Ruling Proceeding, as published in the CONNECTICUT LAW JOURNAL on November 20, 2001, stated that the Board of Examiners for Opticians would hold a declaratory ruling proceeding on the following issues:

1. Is a contact lens seller located in Connecticut in compliance with state law if it sells lenses to Connecticut residents without a Connecticut optician license and optical establishment permit, or an optometric or medical license;
2. Is a contact lens seller located outside Connecticut in compliance with state law if it sells lenses to Connecticut residents and does not hold a Connecticut optician license and optical establishment permit, or an optometric or medical license; and
3. Is a contact lens seller, whether located in or out of Connecticut, that sells lenses to a Connecticut consumer without first receiving a prescription from a licensed physician or optometrist in compliance with Connecticut law?

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 has, however, voted to authorize the Office of Policy Planning and the Bureau of Consumer Protection to submit this comment.

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 whether requiring Connecticut licenses for firms who sell only replacement lenses will create sufficient new benefits for contact lens wearers to offset these adverse effects.

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 consistent with the protection of consumers' health. In other words, it is desirable to accomplish regulatory objectives in a way that is least restrictive of innovative distribution methods.

I. Interest and experience of the FTC

In answering the questions at issue in this proceeding, the Board will no doubt wish to consider a variety of factors. One significant factor that needs to be taken into account is the impact of the Board's decisions on competition and consumer welfare. The FTC's primary expertise is in competition and consumer protection policy, and we offer these comments to assist the Board in assessing how its decisions may affect competition and consumer welfare.

The FTC's statutory mission is to protect consumers. The FTC is charged by statute with enforcing those laws that prohibit unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce.³ Pursuant to this statutory mandate, the Commission encourages competition in the licensed professions to the maximum extent compatible with other state and federal goals. The Commission has extensive experience assessing the impact of regulation and business practices on competition in many regulated professions.⁴

The Commission also has significant expertise concerning competition in the eye care industry in particular and has been active in this area for nearly three decades. The Commission enforces the Ophthalmic Practice Rule ("Prescription Release Rule"), originally promulgated in 1978, 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.⁵ In another rulemaking proceeding during the 1980s, the Commission examined other kinds of restraints on the business practices of eye care professionals and concluded that restrictions on commercial practices have caused significant injury to consumers, resulting in both monetary losses and less frequent vision care, without offsetting consumer benefits.⁶ Based on the evidence assembled in that rulemaking proceeding, the Commission adopted a rule that prohibits state-imposed

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

The Prescription Release Rule requires an optometrist or ophthalmologist to provide a patient, at no extra cost, a copy of the patient's eyeglass prescription immediately after the eye examination is completed. The Rule also prohibits optometrists and ophthalmologists from conditioning the availability of an eye examination on a requirement that the patient agree to purchase ophthalmic goods from the optometrist or ophthalmologist and from placing on the prescription, or delivering to the patient, certain disclaimers or waivers of liability. The Rule currently does not require an optometrist or ophthalmologist to release a contact lens prescription to a patient after an eye exam.⁹ However, the Rule does state that it is an unfair practice for an ophthalmologist or optometrist to condition the availability of an eye exam on a requirement that the patient agree to purchase any ophthalmic goods, including contact lenses, from the ophthalmologist or optometrist.¹⁰ In adopting the original Prescription Release Rule, the Commission found that many consumers were deterred from comparison shopping for eyeglasses because eye care practitioners refused to release prescriptions, even when asked to do so, or charged an additional fee for release of a prescription.¹¹

The Commission is conducting a review of the Prescription Release Rule, as part of its systematic review of its Rules and Guides to determine their effectiveness and impact. The Commission requested public comment about the overall costs and benefits of the Rule and related questions and received comments from numerous parties, including associations representing various segments of the industry and professions, state attorneys general, state

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 information about goods and services offered in the ophthalmic market was difficult or impossible.¹⁴

In contrast, competition has increased dramatically in the eye care marketplace since the 1970s. In the wake of *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*,¹⁵ and other commercial speech cases, advertising of ophthalmic goods and services is now common. Chain firms have become a fixture in the optical industry marketplace, and the market share of "alternative" retail sources of contact lenses, including mail order, pharmacy and mass merchants (such as Costco and Wal-Mart), grew significantly during the 1990s. Many of these entities advertise heavily and widely, in publications, direct mail coupon packs, on television, and on the Internet.

Many significant innovations in the sale of eyewear came from the entry of nontraditional players. In some cases, the innovators offer the services of both optometrists and opticians, by employing or entering various kinds of contractual agreements with both types of professionals. In other cases, new entrants have focused on selling eyewear, relying on the customer to first obtain a prescription from an optometrist or ophthalmologist. Both types of firms typically offer

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 customer has already been fitted by an eye care professional. Unlike other eyewear sellers, their business consists simply of shipping to customers lenses that come from the manufacturer in sealed boxes labeled with the relevant specifications. Many of these businesses are located in a single state but ship orders to customers nationwide. Some of the largest are located outside the state of Connecticut.

Disagreements between these firms, their more traditional competitors, and contact lens manufacturers came to a head in *In re: Disposable Contact Lens Antitrust Litigation*.¹⁶ In that multidistrict litigation, the Attorneys General of 31 states and a certified class alleged that eye care professionals engaged in an organized effort to prevent or hinder consumers from obtaining their contact lens prescriptions. The complaints alleged two conspiracies: (1) that the practitioners and their trade associations conspired to prevent the release of contact lens prescriptions to consumers, and (2) that the manufacturers, practitioners, and trade associations, including the American Optometric Association, conspired to eliminate sales of contact lenses by pharmacies, mail order, and other alternative sellers. According to the complaints, the conspiracy severely restricted the supply of contact lenses available to alternative sellers, which has hampered the growth of such sellers, decreased the supply of lenses to consumers, and increased the price of lenses. The parties reached settlements, the last of which the court approved in November 2001.

As part of the settlement, Johnson & Johnson agreed to sell its lenses to alternative distribution channels, as long as those firms sell lenses to customers in accordance with a valid prescription and in compliance with all federal and state laws and regulations. Johnson & Johnson petitioned the Board for this proceeding in order to clarify Connecticut's regulations, to aid Johnson & Johnson in ascertaining whether alternative lens sellers are in compliance with all Connecticut laws and regulations.

The three questions in this proceeding are phrased in a way that implies that each question has a single answer that applies to all sellers of contact lenses. However, it is clear from the historical context that the real issue is how the Connecticut laws and regulations apply to a particular type of seller: the stand-alone seller of replacement lenses that merely sells lenses and does not fabricate lenses or fit them to the eye. For this reason, we will focus on the relevant factors that should be considered in determining how the Connecticut laws and regulation should

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 purchasing and trying on countless brands, types, and powers of contact lenses, it is impossible for the consumer to find out what to order in the absence of an optometrist's or ophthalmologist's assistance. It is thus reasonable to assume that every contact lens wearer has received a prescription for those lenses at some time.¹⁷

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)).

For the purposes of this proceeding, it is important to note that the medical purpose of the prescription requirement (aside from describing the proper lenses) is to induce the customer to have regular eye exams – *not* to control where the customer may purchase replacement lenses with a valid prescription. The Commission’s Rule review, the multidistrict litigation, and Commission staff’s own consultations with industry experts have revealed no systematic evidence that sales through alternative channels, such as Internet or mail order, pose any additional health risk as long as the retailer sells in accordance with a valid prescription.¹⁸

The FDA first approved a soft contact lens in 1971.¹⁹ Beginning in the late 1980s, lens manufacturers began to market and sell “disposable” and “frequent replacement” soft lenses, which are designed to be replaced daily, weekly, or monthly. Most soft lenses are now sold in multipacks, with disposable lenses typically sold in multipacks of six lenses. When first developed, soft contact lenses were not manufactured in a way that always accurately reproduced the same prescription.²⁰ In the past 20 years, however, manufacturers have developed production methods for soft contact lenses that have eliminated these standardization problems.²¹ According to commenters during the Rule review, the soft contact lenses that a patient receives will be identical regardless of whether the patient gets the lenses from an eye care professional or from a non-traditional seller. In comments filed in the FTC’s review of the Rule, the American Academy of Ophthalmology and the California Optometric Association both stated that while fabrication errors might present a problem with respect to hard contact lenses, soft lenses, such as disposables, are relatively standard and can be easily reproduced.²²

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 Johnson, O.D., filed in *In re: Disposable Contact Lens Antitrust Litigation*, at 102-3, 168. These patients, however, purchased lenses using invalid or incorrect prescriptions. We are aware of no systematic study demonstrating that lens wearers who purchase replacement lenses through alternative channels in accordance with a valid prescription show any greater incidence of eye health problems.

¹⁹ *See* 47 Fed. Reg. 53,411, 43,415 (1982).

²⁰ *See* 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 18-20.

²¹ *Id.*

²² Comment from COA, #112 at 8; Comment from AAO, #97 at 1-2. The comments from the FTC’s Rule review are on file on the Commission’s public record as Document Nos. B21940700001, *et seq.* The comments are cited herein by the name of the commenter, a shortened version of the comment number (the last one to three digits), and the relevant page(s) or attachments of the comment.

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 lens on the patient's eye after the prescription has been finalized through the fitting process.

In fact, some lens manufacturers provide direct shipment of replacement lenses to consumers, and some eye care practitioners mail replacement contact lenses to patients without an office visit during the span of the patient's prescription.²³ Thus, the practice, *even among some traditional eyecare professionals*, suggests that replacement lenses can be marketed and delivered somewhat differently from other lenses, without adverse health effects.

Under the terms of the settlement agreement of the multidistrict litigation, 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.”²⁴

Not surprisingly, this aspect of the settlement agreement is precisely consistent with medical evidence presented in the multidistrict litigation:

- The Wisconsin Optometric Association in 1988 repeatedly urged members to notify the association of any health problems that occurred when patients took their prescriptions and ordered lenses from a source other than the doctor. As of 1998, the association still had not received any documented reports of such health problems.²⁵
- In 1992, Vistakon (a subsidiary of Johnson & Johnson) tracked complaint calls and sorted them into various categories. Only three phone calls – 0.8 percent of the total – involved any type of link between health problems and purchases of lenses from

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 through 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

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).

The FDA has the authority to take action against the dispensing of a prescription device without a valid prescription.³⁶ The FDA generally defers to the states on these enforcement issues. Its guide for purchasers of contact lenses over the Internet states that, “[s]ince individual states have different licensing requirements for optical dispensers, enforcement of prescription device sales has usually been left to the state in which the company selling the contact lens is located.”³⁷ However, that does not mean the FDA is either passive or powerless. In a 1998 letter, the FDA noted that it had received complaints about sales of contact lenses by mail without a prescription and confirmed that “FDA is itself investigating alleged violations of Federal law as a basis for possible action.”³⁸ In 2000, the agency reportedly launched an investigation of 1-800 Contacts, as well as 96 other companies suspected of selling by mail various types of prescription devices without first obtaining prescriptions.³⁹

Even with a prescription requirement for replacement contact lenses, it is important to note that federal law does not require that the prescription be written, nor does it define what constitutes a valid contact lens prescription. Instead, state law determines what is included in a valid prescription.

B. Connecticut prescription and prescription release requirements

Connecticut law does not explicitly require that replacement contact lenses be sold pursuant to a prescription.⁴⁰ In fact, the main provision covering where optical goods may be sold, while requiring the supervision of an optician for production or reproduction of optical glasses or kindred products to personalized given formulas, does not require that this be done pursuant to a prescription.⁴¹

³⁶ See 21 U.S.C. §§ 353(b)(1), 331(a) and 333.

³⁷ *Buying Contact Lenses on the Internet, by Phone or by Mail: Questions and Answers*, available at <<http://www.fda.gov/cdrh/consumer/buycontactqa.html>>.

³⁸ Letter from Linda Gangloff, Policy Analyst, Executive Secretariat, FDA, to Thomas W. King, Jr., Executive Secretary, Office of the State Board for Optometry, New York (Oct. 21, 1998).

³⁹ Hank Greenberg, *1-800 Contacts in FDA's Sights*, TheStreet.com (4/11/00).

⁴⁰ Conn. Gen. Stat. § 20-139, entitled Purpose and legislative policy, states in general terms that regulation is required of optical appliances, eyeglasses, lenses, and all aids to human vision sold, dispensed, or supplied in the state and that persons “filling prescriptions having to do with optical glasses from given formulas, and kindred products” shall have the education, skill, and ability to properly fill any such formulas and shall be licensed. This section imposes no specific licensing or prescription requirements, however.

⁴¹ Conn. Gen. Stat. § 20-150.

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

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 authority under its unfairness jurisdiction to regulate marketing practices that cause or are likely to cause substantial consumer injury, which is not reasonably avoidable by consumers and is not outweighed by countervailing benefits to consumers or to competition.⁴⁸

V. The costs and benefits of licensing stand-alone sellers of replacement lenses

Federal and state regulations already seek to ensure that lens wearers receive the lenses prescribed by their doctors. As long as these regulations are enforced, prescription requirements ensure that lens wearers return to the doctor for regular eye exams, regardless of where the customer purchases replacement lenses. To determine whether additional incremental regulation of stand-alone replacement lens sellers beyond the prescription requirement would enhance consumer welfare, it is necessary to consider what additional costs and benefits the additional regulation might create.

A. Costs of licensing stand-alone replacement lens sellers could be substantial

1. Connecticut requirements

Connecticut law, Conn. Gen. Stat. § 20-150, provides “[n]o optical glasses or kindred products or other instruments to aid vision which are produced or reproduced to personalized given formulas, shall be sold at retail except under the supervision of a licensed optician and in a

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).

registered optical establishment, office or store. An optical establishment, office or store is defined as meaning one the owner of which has had issued to him an optical license selling permit.”⁴⁹

To obtain a license as an optical establishment, the retail seller of optical glasses or kindred products produced or reproduced to a personalized given formula must be under the direct supervision of a licensed optician.⁵⁰ These permits cost \$250 and are generally valid for one year, although they are terminated immediately if the licensed optician of record disassociates himself from the establishment. Holders of such permits are permitted to use the term “optician.”⁵¹

The statute defines a licensed optician as “[o]ne having a knowledge of optics and skilled in the technique of producing and reproducing ophthalmic lenses and kindred products and mounting the same to supporting materials and the fitting of the same to the eyes.”⁵² To obtain a license as an optician, a candidate 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.⁵³

The Connecticut statute and regulations apply when a retail seller of ophthalmic lenses and kindred products is himself producing or reproducing lenses to “personalized given formulas.”⁵⁴ Connecticut’s regulatory regime for opticians thus focuses on the producing and

⁴⁹ When citing this law in its petition for declaratory ruling, Johnson & Johnson omitted the crucial limitation on this provision, namely that it covers only sales of optical devices that *are produced or reproduced to personalized given formulas*.

⁵⁰ Conn. Gen. Stat. § 20-151.

⁵¹ Conn. Gen. Stat. § 20-153.

⁵² Conn. Gen. Stat. § 20-145.

⁵³ Conn. Gen. Stat. § 20-146. *See also* Connecticut Department of Health, Detailed Information for Optician Licensure, <<http://www.ct-clic.com/detail.asp?code=1746>>. Section 20-146 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.

⁵⁴ A regulation by the Board of Opticians defines contact lenses and says that the “sale of contact lenses in the state of Connecticut is an inclusion under the provision that optical glasses, instruments and kindred products to aid vision may be sold only by licensed opticians . . .” Conn. Agencies Regs. § 20-141-10. Assuming that this regulation refers to § 20-150, based on the statute’s specific limitation to optical glasses and kindred products “produced or

reproducing of lenses.⁵⁵ However, once a patient has been fitted with contact lenses by an optometrist or ophthalmologist, the patient merely purchases replacement contact lenses that come prepackaged from the manufacturer and which are not produced or reproduced to a personalized given formula by the seller.⁵⁶ Providing replacement lenses in sealed packages from manufacturers does not involve producing or reproducing lenses and clearly does not require the seller to produce or reproduce lenses to “personalized given formulas”– which is the practice, under the statute, that must be licensed.

If these licensing regulations nevertheless are applied to stand-alone sellers of replacement lenses, such sellers would have to arrange for a licensed optician to supervise their operations and pay a \$250 fee. The need to employ an optician would likely be a costly proposition for a stand-alone seller of replacement lenses. Because such firms do not sell eyeglasses or conduct contact lens fittings, they may not already have an optician on staff. Alternatively, a large operation may not have a sufficient number of opticians to satisfy the state’s “supervision” requirement.⁵⁷ Therefore, a requirement that all contact lens sellers obtain

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., Conn. Agencies Regs. §§ 20-141-1, Experience in the producing and mounting of ophthalmic lenses, and 20-141-2, Experience in the fitting of ophthalmic lenses to the eyes by mechanical manipulation. Both of these regulations discuss the grinding, polishing, and forming of lenses and the fitting of ophthalmic lenses to the individual wearer. In fact, the provision on mechanical manipulation specifies that it covers “the casting or fitting of contact lenses;” it does not discuss supplying prepackaged lenses to a customer who has already been fitted for them by an eye care professional.

⁵⁶ It is instructive to compare the statute’s wording with the Food and Drug Act’s definition of a custom device. See 21 U.S.C. § 360j(b) (a custom device is one that is generally not available in finished form for purchase or dispensing upon prescription). In *Contact Lens Mfrs. Ass’n v. FDA*, 766 F.2d 592, 599 (D.C. Cir. 1985), the manufacturers argued that lenses were custom devices but the court upheld the FDA’s conclusion that contact lenses for “all but the most pathological eyes” are not custom devices because they are replicated again and again and are generally available.

⁵⁷ Connecticut appears to have construed section 20-153’s supervision requirement stringently in the past. For example, the Board of Examiners for Opticians successfully brought a proceeding against a chain of optical shops on the basis that the shops were open without having a licensed optician on the premises at all times, even if the shops were not engaging in the activities that must be performed under the direct supervision of a licensed optician when the optician was absent. *U.S. Vision, Inc. v. Board of Examiners for Opticians*, 545 A.2d 565 (Ct. App. Ct. 1988). This raises the possibility that a stand-alone seller of replacement lenses would be required to have a Connecticut optician supervise operations at all times, even while the seller was not engaging in the activities that, according to Connecticut law, must be performed by a

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

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

Laws, regulations, or other rules that unnecessarily require firms or customers to employ members of the regulated professions for specified tasks can also raise consumer prices. Several states, for example, 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. Based on evidence from several states, the Federal Trade Commission and U.S. Department of Justice have concluded that such requirements would typically increase prices to borrowers by between \$150 and \$400.⁶⁰

Licensing can either increase or decrease service quality.⁶¹ While the restriction of supply from licensing typically leads to a higher average competence level for the professionals allowed to practice, the higher price for their services can lead to less utilization by consumers. This indeterminacy is reflected in the empirical research, where no clear link between licensing and service quality has been demonstrated.⁶²

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*, JOURNAL OF ECONOMIC PERSPECTIVES, Fall 2000, at 198. Economic theory also cautions that increased quality does not always make consumers better off. The slightly higher quality of licensed professionals may not be worth the significant extra cost to certain individuals, who would rather trade off some minimal reduction in quality for a lower price.

⁶² Of the 11 studies surveyed by Cox and Foster, *supra* note 58, at 26-27, only two reported a positive association between the strength of restrictions on practitioners and quality. More recent studies are no more supportive of the purported tendency of licensing to improve service quality. In a study of dental licensing, Kleiner and Kudrle, *supra* note 58, found that more stringent licensing did not result in improved dental outcomes among a sample of 464 new Air Force recruits. Similarly, Gary Colbert and Dennis Murray, *(State Accountancy Regulations, Audit Firm Size, and Auditor Quality: An Empirical Investigation)*, 16(3) JOURNAL OF REGULATORY ECONOMICS, Nov. 1999, at 267-85) found no association between audit quality

3. Adverse effects would be concentrated on customers who prefer stand-alone sellers of replacement lenses

Most stand-alone sellers represent unique alternative distribution channels: Internet and mail order. Internet and mail order offer some consumers a combination of price and convenience that they value highly. Because licensing may impose additional costs on stand-alone sellers of replacement lenses, it has the potential to curtail these consumer benefits by inducing mail-order firms to charge higher prices or exit the Connecticut market entirely.

Data on price differences between mail order and other sellers of replacement lenses are sparse. The most recent data are from a nationwide survey by SRI commissioned by the state attorneys general as part of the multidistrict litigation. In 1998, the average price of a six-lens multipack purchased via mail order was \$19.90, compared to an average of \$23.76 for lenses purchased from ophthalmologists, optometrists, and optical chains – a 19 percent difference.⁶³ The survey also reported that price differences matter for most consumers, even if they were not currently mail-order customers. Of the survey respondents who had not purchased their most recent set of contact lenses via mail order, 62 percent said they would do so if the mail-order price were 15 percent less than the last price they paid, and 78 percent said they would do so if the mail-order price were 25 percent less. The SRI data also suggest, however, that consumers who purchase their lenses from traditional suppliers could achieve equivalent savings at a mass merchant discounter, such as Wal-Mart, Costco, or BJ's; the average price at such retailers was \$19.98.⁶⁴

The principal difference between the mail-order firms and the mass merchandisers thus appears to be the delivery mode, not the price. The two delivery modes involve significantly different convenience costs for consumers. To enjoy the price savings at a mass merchandiser, the consumer has to make a trip to the store and often endure a wait in a line. Multiple trips may be necessary if the store does not have the particular lenses in stock and must order them. Consumers who opt for mail order, on the other hand, can have replacement lenses delivered simply by calling a toll-free phone number or visiting a web site. The inconvenience of visiting a mass merchandiser is likely unimportant for consumers who attach a low value to their time or who were going to the store to purchase other items anyway. It could be substantial, however,

and variations in the strictness of state accountancy regulations. Defining quality can be very difficult, and typically it is studied for those outcomes where empirical definitions are feasible. There thus remains a large number of situations that have not been investigated.

⁶³ 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 firms offer free shipping and handling.

⁶⁴ Susan Russell, *Nationwide Survey of Contact Lens Wearers* (1999).

for consumers who attach high value to their time, make a special trip to the store just to obtain replacement lenses, or live in areas distant from mass merchandisers.

How much value might some customers place on the convenience of mail order? Research in transportation economics suggests that individuals value urban travel time by automobile and public transit at between 75 and 178 percent of their wage rate.⁶⁵ At the average private hourly wage of \$14.61 (December 2001), an hour-long trip to Wal-Mart to buy replacement lenses has an implicit time cost of between \$10.96 and \$26.00.⁶⁶ That figure represents a markup of between 50 and 130 percent over the price of a multipack. Therefore, the convenience cost of policies that impede entry by mail-order replacement lens sellers could be substantial.

B. Licensing stand-alone replacement lens sellers offers no additional consumer protection

Licensing stand-alone replacement contact lens sellers is unlikely to diminish any of the genuine health risks associated with contact lenses. Licensing the lens seller will not induce individuals to comply with the wearing or disposal schedules recommended by the doctor. Licensing the lens seller will also not induce individuals to have more frequent eye exams.

Licensing is not necessary to ensure sellers follow prescriptions. Concerns about quality of care related to follow-up examinations can be addressed by enforcing contact lens prescriptions, rather than by inhibiting sales by non-traditional 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. Moreover, Connecticut law does 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.⁶⁷

C. Licensing may produce unintended consequences harmful to consumers

⁶⁵ Clifford Winston, *Conceptual Developments in the Economics of Transportation: An Interpretive Survey*, 23 JOURNAL OF ECON. LIT., 1985, at 77.

⁶⁶ Average wage is from Council of Economic Advisers, *Economic Report of the President* (2002), at Table B-47.

⁶⁷ See 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).

Several commenters in the FTC Rule review noted that fostering competition in contact lens sales can be expected to increase the quality of care rather than decrease it.⁶⁸ To the extent that it raises costs for stand-alone sellers of replacement lenses, licensing of opticians and optical establishments may actually increase the incidence of health problems associated with contact lens use.

Stand-alone sellers of replacement lenses derive the bulk of their revenue from the sale of disposable lenses. As a threshold matter, there seems to be consensus that disposable lenses, especially when worn properly, are generally healthier than conventional daily wear lenses.⁶⁹ Doctors have reported that frequent replacement of lenses has yielded a significant decrease in eye infections and inflammation among their patients who wear disposables.⁷⁰

However, many consumers who wear disposable lenses over-wear their lenses, which diminishes the health benefits of such lenses. One survey revealed that fewer than 50 percent of consumers comply with the recommended wearing schedule.⁷¹

Importantly, fifty-seven percent of consumers stated they would replace their lenses more frequently if the lenses cost less.⁷² Moreover, 30 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.”⁷³ Twenty-two percent said they do not replace their lenses as often as they should because “purchasing them is inconvenient.” 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.⁷⁴

Increasing the cost and inconvenience of obtaining disposable replacement lenses may induce more individuals to over-wear their replacement lenses; decreasing the cost and

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).

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.

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,

J. HOWARD BEALES, III
Director, Bureau of Consumer Protection

R. TED CRUZ
Director, Office of Policy Planning

JERRY ELLIG
Deputy Director, Office of Policy Planning

MAUREEN K. OHLHAUSEN
Attorney

KIAL S. YOUNG
Attorney

JOSEPH P. MULHOLLAND
Economist

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
(202) 326-3683