UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

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

IN RE: DECLARATORY RULING PROCEEDING ON
THE INTERPRETATION AND APPLICABILITY OF

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:

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

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)

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

- 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 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)

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

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)

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

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

1. Connecticut requ irements

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 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

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-

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, 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.

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

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 latitud

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Endnotes:

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.

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. 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).

7. The Court of Appeals ul

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. 74

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). 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).

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.

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).

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 licensed optician.

58. Carolyn Cox and Susan Foster, The Costs and Benefits of Occupational Regulation

67. See Conn. Gen. Stat. §