IN RE: PETITION FOR DECLARATORY RULING CONCERNING SALES OF CONTACT LENSES

PETITIONER: JOHNSON & JOHNSON VISION CARE

CONNECTICUT BOARD OF EXAMINERS FOR OPTICIANS

MEMBERS:
Raymond Dennis, L.O.
Albert Winnick, L.O.
Ann Tosca

DECLARATORY RULING
MEMORANDUM OF DECISION

Procedural Background

On September 27, 2001, the Connecticut Board of Examiners for Opticians ("the Board") received a request dated September 26, 2001, from Johnson & Johnson Vision Care ("Johnson & Johnson"), to issue a declaratory ruling regarding the following three questions:

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

On October 27, 2001, the Board agreed to conduct a declaratory ruling proceeding in accordance with Connecticut General Statutes §4-176.

The Attorney General of the State of Connecticut ("the Attorney General"), Johnson and Johnson, and 1-800 Contacts, Inc. ("1-800 Contacts") were designated as parties to the proceeding (Board Exhs. A, Q, R); and, the following individuals and organizations were designated as intervenors: the Connecticut Board of Examiners for Optometrists ("the Optometrists Board"); the Connecticut Society Of Eye Physicians ("the Society of Eye Physicians"); the Connecticut Opticians Association ("the Opticians Association"); the Connecticut Association of Optometrists ("the Optometrists Association"); and, the Federal Trade Commission ("FTC"). These intervenors provided pre-filed testimony, which they adopted under oath during the hearing, and the witnesses were available for questioning and cross-examination. Board Exhs. S-Y.1

Assistant Attorney General Steven M. Rutstein, Esq., appeared on behalf of the Office of the Attorney General; Ted Cruz, Esq., Director, Office of Policy Planning, appeared on behalf of the FTC; William M. Rubenstein, Esq., appeared on behalf of 1-800 Contacts; Benjamin A. Solnit, Esq., Paul Bade, Esq., Melissa B. Kimmel, Esq., and Elizabeth B. McCallun, Esq., appeared on behalf of Johnson & Johnson; Edward Pinn, O.D., Chairman of the Optometrists Board, appeared on behalf of the Optometrists Board; Elwin G. Schwartz, M.D., President of the Society of Eye Physicians, appeared on behalf of the Society of Eye Physicians; Robert F. Frankel, Esq., appeared on behalf of the Optometrists Association; Rene Rivard, Executive Director of the Opticians Association, appeared on behalf of the Opticians Association; Board Exhs. AF-AI.

On May 28, 2002, 1-800 Contacts filed a Motion in Limine objecting to the inclusion in the record of certain evidence offered by Johnson & Johnson. On June 5, 2002, the Board denied the motion without prejudice. Board Exhs. AC, AD.

The hearing was held on June 12, 2002. At the end of the June 12th hearing, the Board set additional hearing dates for July 16, 2002 and July 17, 2002. On June 28, 2002, Johnson & Johnson filed a Motion to Continue the Hearing. The Board granted the motion and the hearing

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1 The Connecticut State Medical Society and the American Academy of Ophthalmology were also designated as intervenors; however, on April 22, 2002, and September 30, 2002, respectively, they filed Notices of Withdrawal of Intervenor Status. Board Exhs. O, A-K.
was held on October 9 and 10, 2002. The parties and intervenors provided exhibits and pre-filed testimony, which they adopted under oath during the hearing, and the witnesses were available for questioning and cross-examination.

**Findings of Fact**

1. Contact lenses are personalized to given formulas. Tr., 10/9/02, pp. 257-259, 272-273.

2. Contact lenses can seriously impact one’s vision and eye health if used improperly. Tr., 10/9/02, pp. 243-246, 277-279, 317.

3. A prescription requirement for contact lenses reduces the risk of harm to the public. Tr., 10/9/02, pp. 277-278, 325.

**Discussion And Law**

This Declaratory Ruling addresses the applicability of the following Connecticut statutes and Regulations of Connecticut State Agencies (“the Regulations”) to the sale of contact lenses to consumers in Connecticut by entities located both inside and outside of the State.

Conn. Gen. Stat. §20-150 provides that:
No optical glasses or kindred products or other instruments to aid vision . . . 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.

Conn. Gen. Sta. §20-139 provides that:
It is declared that regulation is required of all optical appliances, eyeglasses, lenses, optical instruments intended to be used for the human eye, as well as any aids to human vision, sold, dispensed, or supplied to the ultimate wearer or consumer in this state; and that persons . . . engaged in the practice of optical dispensing . . . shall be licensed, and that all optical establishments, offices, department or stores, as well as all optical shops and laboratories, shall be registered pursuant to the provisions of the statutes governing opticians . . .

Conn. Gen. Stat. §20-151 provides that:
Any licensed optician and any optical department in any establishment, office or store may apply to said department for a registration certificate to sell at retail optical glasses and instruments from given formulas and to make and dispense reproductions of the same, in a shop, store, optical establishment or office owned and managed by a licensed optician as defined in section 20-145, or where the optical department thereof is under
the supervision of such a licensed optician, and said registration shall be designated as an optical selling permit . . .

Conn. Gen. Stat. §20-153 provides that:
The department may grant annually, upon the filing of an application as required by it, an optical permit to any optical establishment, office, department or store conducted under the personal and direct supervision of a licensed optician, for permission to sell, dispense or supply to the ultimate wearer optical aids to vision, instruments, applicances, eyeglasses, spectacles and other kindred products . . .

Conn. Gen. Stat. §20-162 provides that:
The provision of this chapter shall not be construed to apply to certified optometrists licensed to practice under the provisions of chapter 380 nor to deny to physicians or surgeons particularly trained and specializing in diseases of the eye and licensed under the provisions of chapter 370 from the same right to fit, apply and dispense contact lenses or other ophthalmic materials to their patients in the course of their practice as is accorded licensed optometrists . . .

Conn. Gen. Stat. §20-571(7) specifically excludes contact lenses from the definition of “devices” that pharmacies are permitted to sell.
“Device” is defined as “instruments, apparrantes and contrivances, including their components, part and accessories, intended (A) for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals, or (B) to affect the structure or any function of the body of humans or other animals, but does not mean contact lenses . . .

Section 20-141-10 of the Regulations provides 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 in licensed optical establishments . . .

Section 20-141-10a of the Regulations provides that:
The sale of contact lenses in the State of Connecticut is included under the provision that optical glasses, instruments and kindred products to aid vision may be sold by licensed opticians in licensed optical establishments. Contact lenses may be fitted by licensed opticians in licensed optical establishments upon prescriptions for contact lenses prescribed by licensed physicians or surgeons or licensed optometrists or in any other location under the direction of a licensed physician or surgeon. This regulation does not apply to physicians or surgeons or certified optometrists exempt under section 20-162 of the general statutes.

Section 20-141-11 of the Regulations provides that:
Any establishment under the personal and direct supervision of a licensed optician may be granted permission to sell at retail, dispense or supply to the ultimate wearer
prescription glasses and optical instruments from given formulas which are optical aids to
vision, instruments, eyeglasses, spectacles, and other kindred products and reproduction
of the same; . . . to sell at retail optical goods as merchandise . . . .

Section 20-141-12 of the Regulations provides that:
Any licensed optician or any optical department in any optical establishment, office,
department or store conducted under the personal and direct supervision of a licensed
optician shall file an application of facts to qualify for an optical license selling permit
when requesting permission to sell, dispense, or supply to the ultimate wearer optical aids
to vision, instruments, eyeglasses, spectacles and other kindred products . . . . Any
applicant qualifying for the optical license selling permit shall be issued an annual
certificate which shall be valid at the one and only address named therein and shall expire
on the first day of September of each year . . . .

Section 20-141-17 of the Regulations provides that:
To ‘dispense or supply’ is to prepare, make or furnish as well as to distribute to the public
optical glasses or ophthalmic instruments as aids to vision to the ultimate wearer or
consumer, or any kindred products of optical glasses, whether or not the act of such
dispensing or supplying or distribution is construed as technically involving a sale.

Section §20-141-19 of the Regulations provides that:
Each individual retail or service unit located at a recorded address is a separate
establishment requiring a separate permit; and this is true although such a store or unit is
part of an interstate or intrastate chain.

Section 20-141-20 of the Regulations provides that:
Every licensed optician is required to have an optical license permit for the declared
establishment, location or premises where he proposes to act as such licensed optician. A
licensed optician is responsible for any optical department, firm or establishment of
which he is in charge, being deemed to be in charge of the same only when he is the
owner or manager or equal in authority with another similarly licensed optician, and from
which he receives his complete or major means of livelihood and to which he gives the
major part of his time. Such an optical license permit shall be issued for more than one
such optimal establishment or location if such licensed optician assumes supervision of
other locations or establishments; but in all instances such permits shall include the name
of the responsible licensed optician in charge and under whose supervision such
establishment or location is being operated, and shall be subject to the provision that such
licensed optician transfer such individual license to the location or establishment at
which he is functioning and that he is personally responsible for all acts or omissions . . .
pertaining to the opticians’ law and its regulations, under which such establishment or
location holds itself open as an optical establishment or department . . . .

1. Is a contact lens seller located in Connecticut in compliance with Connecticut law if it
sells contact lenses to Connecticut residents and does not hold a Connecticut optician
license, an optical establishment permit, or an optometric or medical license?
The answer to this question is: no. Contact lens sellers in Connecticut are required to hold a license in Connecticut as an optician or optical establishment.

Conn. Gen. Stat. §20-139 provides that “regulation is required of all optical appliances, . . . lenses . . . sold, dispenses, or supplied to the ultimate wearer or consumer in this state . . .” Regulations of Connecticut State Agencies §20-141-10a, provides that the “sale of contact lenses in the State of Connecticut is included under the provision that optical glasses . . .and kindred products to aid vision . . . may be sold by licensed opticians . . .” When both the seller and the consumer are located within the state, all of the activity is occurring within the State of Connecticut. Therefore opticians and optical establishments located in Connecticut must be licensed by the State of Connecticut in order to sell contact lenses, glasses, instruments and kindred products to aid vision.2

2. Is a contact lens seller located outside Connecticut in compliance with Connecticut law if it sells contact lenses to Connecticut residents and does not hold a Connecticut optician license, an optical establishment permit, or an optometric or medical license?

The answer to this question is: yes. Contact lens sellers located outside the State of Connecticut who sell lenses to Connecticut residents are not required to hold a Connecticut license.

As mentioned above, where the transaction occurs in Connecticut, a Connecticut optician’s license is required. However, whether the statute and regulations apply to a seller located out of state is a question of statutory interpretation, specifically focusing on what is meant by the phrase “sale in the State of Connecticut”. Conn. Gen. Stat. § 20-139 uses the terms “sold” and “in this state”. Both § 20-141-10 and 20-141-10a of the Regulations use the phrase “the sale of contact lenses in the State of Connecticut . . .” If a sale takes place in Connecticut, a license is required. However, the term “sale” is not defined in either the statutes or regulations.

The Connecticut Supreme Court in State v. Cardwell, 246 Conn. 721 (1998), construed the Uniform Commercial Code in determining where a sale occurs. Distinguishing between “shipment” and “destination” contracts in the sale of goods, the Court found that contracts are generally deemed to be “shipment” contracts unless an explicit agreement has been made to

2 Certified optometrists and physicians or surgeons trained in the diseases of the eye are exempted from these requirements.
deliver the goods to a particular destination or to bear the risk of loss until delivery to the buyer. In “shipment” contracts, sellers ship goods to buyers, but they are not required to deliver them at a particular destination. Once the goods are delivered to either the post office or a commercial carrier, the sale is deemed consummated. In the case of the sale of contact lenses, sellers located outside Connecticut, without an explicit agreement by the seller to deliver the contact lenses to a particular destination or to bear the risk of loss until delivery to the buyer, complete the sale once they ship the lenses. Since the shipment occurs outside the State, the sale is deemed complete outside the State of Connecticut. See, 246 Conn. At 731, 732.

This is also consistent with an opinion of the Attorney General stating that, “it is our opinion that foreign mail order firms who solicit hearing aids in Connecticut strictly by mail are excluded from the licensing requirement . . . .” Opinion of the Attorney General to the Commissioner of Health, March 17, 1975. Party 2 Exh. A-5.

Thus, if the sale is consummated outside the state of Connecticut, said sale is not regulated by pertinent Connecticut law; thus the out of state seller is not required to obtain a Connecticut license.

3. Is a contact lens seller, whether located inside or outside Connecticut, that sells contact lenses to Connecticut consumers without first receiving a prescription from a licensed physician or licensed optometrist in compliance with Connecticut law?

The answer to this question is: no. Contact lens sellers may only sell contact lenses pursuant to a lawfully issued prescription.

Pursuant to Conn. Gen. Stat. §20-139, and §§20-141-17, 20-141-10a, and 20-141-11 of the Regulations, licensed opticians may sell at retail, dispense or supply to the ultimate wearer of contact lenses from given “formulas.” Formula is a reference to an individual assessment, i.e. a prescription. In addition, § 20-141-10a specifically provides that contact lenses may only be fitted upon prescriptions. If a prescription was not necessary, this part of the regulation would be superfluous. From the inception of the applicable statutes, it is clear that the purpose of legislative policy as it relates to the dispensing of optical goods is to protect the health, welfare and safety of the citizens of Connecticut.

The requirement of a prescription protects the public health. Dr. Oliver D. Schein, M.D., M.P.H., testified that there is a potential for a variety of adverse events related to poorly fitted or maintained contact lenses such as corneal inflammation which results when small vessels develop
and infiltrate the cornea. In addition, based upon the Board’s own expertise, the Board is aware of public health issues if contact lenses are dispensed without a prescription. A person who develops such condition may be unaware of the inflammation which can easily be diagnosed, corrected, and even cured with the proper prescription of contact lenses. To permit providers to dispense contact lenses without the required prescription is not only contrary to the regulatory language, but would endanger the public health and safety. Therefore the Board concludes that selling contact lenses without a prescription would violate the standard of care and could also potentially subject the seller to other claims, such as the Connecticut Unfair Trade Practices Act.

Accordingly, the Board finds that providers of contact lenses, whether in or outside of Connecticut, may not sell contact lenses to residents of Connecticut unless they have a proper prescription.

**Conclusion and Ruling**

A preponderance of the evidence, a reasonable construction of the statutes and regulations, sound public policy, and the need to protect the public health and safety, all mandate the adoption of each of the following conclusions.

1. A contact lens seller located in Connecticut is not in compliance with Connecticut law if it sells contact lenses to Connecticut residents and does not hold a Connecticut optician license, an optical establishment permit, or an optometric or medical license.

2. A contact lens seller located outside Connecticut is in compliance with Connecticut law if it sells contact lenses to Connecticut residents and does not hold a Connecticut optician license, an optical establishment permit, or an optometric or medical license.

3. A contact lens seller, whether located inside or outside Connecticut, that sells contact lenses to Connecticut consumers without first receiving a prescription from a licensed physician or licensed optometrist is not in compliance with Connecticut law.

June 24, 2003

Raymond Dennis, L.O., Chairperson,
Connecticut Board of Examiners for Opticians