

**SUMMARY OF POSITION OF THE NAOO FOR WORKSHOP ON “POSSIBLE
ANTICOMPETITIVE EFFORTS TO RESTRICT COMPETITION ON THE
INTERNET,” CONTACT LENS INDUSTRY PANEL**

The National Association of Optometrists and Opticians (the “NAOO”), an organization with a longstanding commitment to both competition and public health in the optical industry, presents this summary of its position on possible anticompetitive efforts to restrict competition on the internet in the contact lens industry.

For important health and safety reasons, all manufacturers and distributors have the legal and ethical responsibility to sell contact lenses to the public only upon the order of an eye doctor (a “prescription”). Unfortunately for the public, most stand alone internet sellers of contact lenses have shirked this important responsibility. Lack of jurisdiction among concerned regulators and lack of concern among regulators with jurisdiction have prevented legal imposition of the prescription responsibility on these businesses. This differential enforcement of prescription laws, however, has resulted in an important anticompetitive barrier in the industry and has also endangered public health. It creates an unbalanced competitive landscape preventing strong legitimate competitors from commencing or expanding their direct sales of contact lenses on and off the internet.

There is a great deal of state regulation in the optometric field having nothing to do with the contact lens prescription requirement. Much of that regulation concerning the ways optometrists and non-optometrists can do business is protectionist in purpose, burdensome in effect and devoid of welfare justification. But, with the exception of laws in a very few states possibly prohibiting any sale of contact lenses except by optometrists, these regulations have little impact on the internet competition in the field.

Similarly, past prescribing practices of some optometrists and distribution practices of some manufacturers may have retarded the development of the stand alone replacement lens channel. Today however, these are no longer significant impediments to the legitimate sale of contact lenses pursuant to a valid prescription on or off the internet. On the other hand, non-compliance with the prescription requirement distorts the competitive field; the absence of a level playing field serves as a significant anticompetitive barrier.

The FTC and other regulators unaffiliated with the industry should focus on consistent enforcement of the contact lens prescription requirement to support public health and enhance competition on and off the internet. The cause of competition does not require sacrifice of the rule of law or the public health. To the contrary, consistent enforcement of the prescription requirement will bring more competitors offering consumers more choices into the field with greater investment and enthusiasm.

I. THE NAOO

The NAOO is a nonprofit Delaware corporation that seeks to foster the trade, commerce and interests of the retail ophthalmic goods and services industry, promote fair and vigorous competition in that industry, and represent the interests of its members before government bodies on matters affecting the industry. NAOO members sell prescription eyewear, including contact lenses (some through mail order and internet channels) and provide or arrange eye examinations through numerous locations in

all fifty states.¹ For more than three decades, NAOO members have provided competitive prices, services and product choices in full compliance with federal and state health and safety laws and regulations.

Various NAOO members (and their predecessors) take credit for innovation and competitive initiatives that have shaped the industry. They offer customers the lowest prices anywhere on replacement contact lenses and on contact lens eye examinations. They have also instituted industry innovations including price advertising (disclosing the costs of glasses, contact lenses and exams) and in-store immediate production of eyeglasses. This service, innovation and competition has evolved within and in compliance with the basic framework of the health and safety law governing the optical industry.

II. REGULATIONS CONCERNING THE BUSINESS RELATIONSHIPS BETWEEN BUSINESS CORPORATIONS AND OPTOMETRISTS

A great deal of state regulation in the optical industry has been promoted by local owner-operators, especially optometrists, to reduce and limit competition by out-of-state companies. Many optometry boards demonstrate how captive regulators can work to protect their industry from business innovation. Historically, this hostility has focused primarily on national chains and mass merchants. The most harmful regulations restrict the physical, business and legal relationships between optometrists and business corporations. These regulations and their enforcement results in higher prices and fewer choices for consumers with no health, safety or other consumer benefits whatsoever.

In a few states, the resulting laws and regulations would impact the online sales of contact lenses if the administrators had the jurisdictional reach over companies that have no business in the state or arrangements with professional licensees. At the present time, however, these regulations have not stopped stand alone lens vendors from competing on the internet. To the contrary, companies with physical presence in many states and important arrangements with optometrists are subject to easy enforcement by optometry boards while online-only vendors are not. So, state regulations have had less impact on the free and fair competition in the internet sales of contact lenses than the differential enforcement and compliance with prescription requirements.

III. ANTICOMPETTIVE BUSINESS PRACTICES

Historically, there has also been a concern that prescribing practitioners have been reluctant to tell direct fulfillment operators about the prescriptions the doctors had written for their customers. This refusal to release contact lens prescriptions created an anticompetitive barrier because patients were limited to buying their contact lenses from the prescribing physician. Several states now have legislation mandating the release of contact lens prescriptions. More importantly, the experience of NAOO members has been that prescribing practitioners now release prescriptions on customer request provided the prescription is valid and has not expired.

A perception remains in the industry that the non-release of prescriptions is still an issue. This view seems to arise from the fact that many consumers attempt to purchase contact lenses without a valid

¹ The NAOO's current membership roster includes: Cole National Corporation ("Sears Optical" and "Pearle Vision"), Consolidated Vision Group, Inc. ("America's Best Contacts & Eyeglasses"), Eye Care Centers of America, Inc. ("Eyemaster"), Eyemart Express, Empires Vision Centers, For Eyes Optical, LensCrafters, Inc., Shopko, Standard Optical, US Vision, Inc. ("J.C. Penney Optical") and Wal*Mart Vision Centers.

prescription or after their prescription has expired. When a doctor states that a patient has no valid prescription it is often because the customer never finished the fitting and prescribing process with the doctor, because the patient is trying to by a lens different from the one prescribed or because the prescription is years out of date. Consumers and vendors seem to be confusing these circumstances with continued hostility to prescription release when they actually reflect successful implementation of the purposes of the prescription requirement.

IV. THE PRESCRIPTION REQUIREMENT

Contact lenses are prescription medical devices whose safety and effectiveness are closely regulated by the Food and Drug Administration (“FDA”) under the federal Food Drug, and Cosmetic Act (“FDCA”) and its implementing regulations.² Among other requirements, contact lenses may not lawfully be sold without a prescription from an appropriately-licensed medical professional. In fact, labeling approvals require a message such as: “Federal (US) law prohibits dispensing without a prescription.”³ According to the FDA:

[T]he safety and effectiveness of a contact lens is a function of the complex interrelationship of material, design, and manufacture that result in a unique set of physical, chemical, mechanical and optical characteristics. ***When prescribed and fitted properly***, a lens with this set of characteristics should provide safe and effective visual correction in a human eye with a specific diagnosed [abnormality].⁴

The FDA’s Center for Devices and Radiological Health recently published a web site cautioning against internet vendors that “sell prescription medical devices [such as contact lenses] without asking for a prescription.” Another FDA web site advises consumers to have a current, correct prescription when they order contact lenses and notes that it is a violation of Federal prescription device regulation for a company to sell contact lenses without a prescription.

In addition to federal requirements, individual states regulate contact lens prescribing and sales—including prescription requirements—under statutes and regulations governing professional licensing of optometry. Taken together, the FDA’s authority over contact lens labeling and the various state laws restricting contact lens prescribing and dispensing create a regime where contact lenses cannot lawfully be sold to consumers in the United States without a valid, current prescription from an optometrist or ophthalmologist.

The prescription requirement is designed to protect consumer health and safety. Lenses have both a corrective power and a fit. Lenses that fit too tightly deprive the cornea of needed oxygen. Lenses that fit too loosely provide erratic correction and can pop out of the eye unpredictably, endangering the

² 21 U.S.C. § 321 *et seq.*; 21 C.F.R. §§ 800.10 – 800.898.14. This classification reflects the FDA’s judgment that the use of lenses is “not safe except under the supervision of a practitioner licensed by law to direct the use of such devices.” 21 C.F.R. § 801.109 (prescription of medical devices); 21 C.F.R. §§ 886.5916-5925 (contact lens requirements).

³ See also 21 C.F.R. § 801.109(a)(2) (indicating that medical devices are not safe except under the supervision of a licensed practitioner).

⁴ 49 *Fed. Reg.* 17,523, 17,526 (April 24, 1984) (withdrawing proposal to reclassify “soft” contact lenses to a stringent medical device regulatory class that would not require a prescription) (emphasis added). Related regulations prohibit a manufacturer from selling contact lenses to a seller known to retail the product without a prescription.

wearer. Accordingly, determination of the correct contact lens requires professional judgment and examination of the eye. Similarly, a contact lens wearer cannot safely switch to a new lens from a different manufacturer without the intervention of a professional. Risks from non-prescription lens use often include permanent vision loss.

The prescription requirement is a substantive not a procedural rule. While we understand that certain contact lens distributors have taken the position that compliance with the prescription requirement is achieved by attempting to validate a prescription, even if the attempt fails, the NAOO believes that unsuccessful attempts at validating a prescription do not satisfy the prescription requirement.

Contact lenses are approved by the FDA for sale only pursuant to the order of a licensed professional. Distributors are responsible for limiting their sales to the requirements of this rule. Where a sale is made without a prescription from a licensed professional, the sale violates the rule. Distributors must set up their own procedures for ensuring that a current, non-expired prescription by a professional licensed in the state of practice exists prior to sale. To interpret the rule otherwise would lead to a slippery slope with significant health and safety implications.

V. DIFFERENTIAL ENFORCEMENT OF THE PRESCRIPTION REQUIREMENT CREATES AN ANTICOMPETITIVE BARRIER AND ENDANGERS HEALTH

While it is clear that the prescription requirement has serious health and safety implications, the FTC and FDA historically have chosen to forego action to enforce this requirement, instead deferring to the individual states. States attorneys general, however, have also refused to enforce the prescription requirement, deferring to their professional boards. The boards not only suffer from a reputation for an anticompetitive bent, they generally lack jurisdictional reach over out of state distributors.

As a result, brick-and-mortar retail establishments are subjected to enforcement of the prescription requirement while internet-only vendors are not. This biased playing field has created a serious barrier to competition in the industry, forcing many legitimate competitors to limit or to forego internet sales completely.

The internet-only vendors argue that the prescription requirement makes it virtually impossible for contact lenses to be sold over the internet. This is simply not true. NAOO members have for many years shown that compliance with prescription regulations and competition in the disposable contact lens market are not mutually exclusive. In fact, several NAOO members sell contact lenses by mail and via the internet and have demonstrated that this can be done legally and responsibly.

But compliance costs money. The NAOO members who sell contact lenses by mail and via the internet expend significant resources and effort to comply with the prescription requirement by: (1) establishing procedures and training their employees to ensure that a valid prescription is obtained and verified for each and every contact lens sold; and (2) refusing to fulfill a substantial number of the orders it receives because a prescription never existed, is no longer valid or cannot be verified.

Many internet and mail order contact lens businesses evidently choose not to meet this same standard. Indeed, the merchants best positioned to compete in the online sales of contact lenses cannot match the convenience and cost of a vendor that ignores prescription requirements with impunity. The differential implementation and enforcement of the prescription requirement keeps legitimate participants out of the online contact lens business, significantly reducing competition. This reduction

in competition is demonstrated by the fact that, unlike in ordinary retailing, none of the major internet-only players offer the lowest costs in the field.

Moreover, internet-only vendors are deceiving the public into believing that they are validating prescriptions when in fact they are not. Indeed, the websites of the major internet-only vendors expressly acknowledge the necessity and importance of requiring a prescription before filling contact lens orders, promise compliance with prescription requirements and advertise prescription verification as an important part of their contact lens replacement services. Yet investigation by NAOO members has revealed that many of the major internet-only vendors routinely sell contact lenses to consumers without obtaining or verifying the existence of a valid prescription. As a result, the internet vendors' advertising dupes consumers into believing that they are receiving the benefit of the health safeguards of the prescription regulations when they are not.

Thus, the differential enforcement of the prescription requirement results in a twofold threat: (1) a substantial decrease in competition in the market because internet-only vendors can convert customers by providing convenience and services that legitimate competitors cannot as long as the legitimate competitors refuse to sell without a prescription and (2) a serious threat to health and safety, both because it promotes dangerous self-prescription by the public and because many consumers are led to believe that their prescriptions are being validated when they are not.

Violation of the prescription requirement has given direct fulfillment competitors a distinct competitive advantage, driving legitimate competitors from the field at the expense of health and safety. It is precisely this kind of race to the bottom that section 5 of the FTCA was intended to prevent. Conversely, leveling the playing field would not only protect public health and safety but would also increase competition by inducing legitimate competitors to enter the market or increase their alternative distribution activity. This would reduce consumer prices and increase consumers' choices from among legal and legitimate suppliers.

VI. CONCLUSION

The online contact lens business is a national business. The prescription requirement is a federal requirement. Yet many distributors ignore their obligations to their customers and violate the law by selling a high volume of contact lenses without any prescription. The states have failed to enforce the prescription requirement. The optometry boards have a reputation for pursuing enforcement in an anti-competitive manner and do not, in any event, have jurisdictional reach over internet-only vendors. Consumers rely on vendors to verify prescriptions and are deceived when their vendors fail to do so. For these reasons the FTC should form an interagency working group with the FDA and the Department of Justice similar to the one that attacked the non-prescription sales of pharmaceuticals on the internet to consistently enforce the prescription requirement on a national basis. Distinguishing between legal and illegal distribution and promoting active enforcement of prescription requirements will enhance legitimate competition while promoting the health and safety of eye wear consumers.

ADDENDUM: MYTHS ABOUT THE CONTACT LENS BUSINESS

Contact Lens Myth # 1: *Existing federal and state regulations already provide significant protections for the health and safety of contact lens wearers.*

While the federal prescription rule could provide adequate protection, the complete lack of enforcement of the prescription requirement deprives consumers of the health and safety benefits of the prescription rule. Millions of lenses are finding their way into the hands of consumers without prescriptions. They suffer a risk that laws and regulations should protect them from but the lack of enforcement at the national level exposes them to.

Contact Lens Myth # 2: *Stand-alone sellers of replacement contact lenses sell only replacement lenses for which the customer has already been fitted by an eye care professional.*

Many NAOO customers have attempted to buy 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. Since many direct fulfillment distributors sell to such customers regardless of the absence of a prescription, it is certain that many of their customers have bought lenses for which they were never fit by an eye care professional.

Contact Lens Myth # 3: *Virtually no consumer is likely to try to self-prescribe contact lenses.*

Many consumers try to self-prescribe contact lenses. Some eyeglass wearers want to try contacts for the first time. Some want to change lenses because of cost, to get colored lenses or to change replacement modality. Because wearers are often unable to tell an unhealthy contact lens fit by their visual acuity or comfort, such self-prescription is extremely dangerous.

It is even more common for consumers to try to buy lenses for years after the expiration of their prescription. This ubiquitous form of self-prescription puts consumers at risk because lens fit can change with time in ways imperceptible to the wearer but significant for ocular health.

Contact Lens Myth # 4: *The medical purpose of the prescription requirement is to induce the customer to have regular eye exams.*

The medical purpose of the prescription requirement is that customers need professional assistance to determine not only the corrective power of the appropriate lens (the lens with the right curve on the front) but also the lens that fits properly on the cornea (the lens with the right curve on the back). Thus, proper instructions for use of a contact lens cannot be provided to a user without professional intervention. That is why the devices are only approved for sale pursuant to the order of a licensed professional.

Furthermore, both fit and power can change over time. Thus, rather than the prescription requirement being designed to induce eye exams, reasonable expirations on contact lens prescriptions (and the eye exams consumers should have if they wish to continue wearing lenses) are designed to ensure that the purposes of the prescription requirement—that patients have good fitting lenses even if they cannot tell the difference—are fulfilled.

Contact Lens Myth # 5: *Consumers can easily determine if they have the correct contact lens product by checking the box to ensure that it matches the prescription.*

Even if consumers purchase the same lenses with the same parameters, over time, they cannot tell if their lenses still fit them properly. Furthermore, consumers cannot determine when a change from one lens in a given parameter can be safely changed to another lens in similar or even identical parameters. Lastly, consumers self-prescribing lenses for the first time have no way to determine that they have the correct contact lens product.

Contact Lens Myth # 6: *State law determines what is included in a valid prescription.*

The correct understanding of the prescription requirement is that FDA rule requires an order (called a prescription) for a particular lens from a licensed professional prior to the permitted sale of the lens. The scope and content of the order is up to the professional. It is the responsibility of the distributor to ensure that the sale conforms to the scope of the order.

State law determines who is a licensed professional authorized in the state to write such prescriptions. In addition, in a few states, statutes or regulations also dictate certain things a licensee must do when such a prescription is given, such as specifying particular parameters, signing a prescriber's name, providing information to the patient or performing certain tests as part of an exam. These control prescription activity within a state but the nature and requirement of a valid prescription is a requirement of the FDA.

Contact Lens Myth # 7: *Consumers are not remotely likely to try to obtain contact lenses without first being fitted for them by an eyecare professional.*

Consumers seek to obtain contact lenses without a prescription in three ways: people who have never had any contact lens fit for them by a professional attempt to obtain lenses (most frequently to change eye-color but for vision correction as well); people successfully fit attempt to obtain lenses significantly different from the lenses fit for them by a professional (to save money, to change wearing modality and to change eye color); and patients attempt to obtain lenses for years after their most recent prescription has expired. While the third type of problem is most common and the least dangerous of the three, it has risks associated with it that the prescription requirement should protect the public from because eyes change over time and fit changes as eyes change. The first two types of non-prescription purchase are also very common and extremely dangerous.

Contact Lens Myth # 8: *Consumers can save substantial sums of money by purchasing contact lenses online.*

The least expensive source of contact lenses and related services are mass merchants and national chains, not online sellers. The cheapest online sources for many or most lenses (including shipping and handling costs) are online sources associated with national chains or mass merchants. Internet-only vendors are not saving consumers substantial sums of money today. On the contrary, by unfairly circumventing the prescription requirement internet-only vendors are limiting the attractiveness of the field and preventing competitors from beginning or expanding their online businesses.