

**The Coalition for Patient Vision Care Safety
Comments Regarding the FTC’s Regular Review of the
Contact Lens Rule
October 26, 2015**

Table of Contents

	Page
1. Introduction	2
2. Enforcement	4
a. Noncompliance of the Act: Selling Lenses Without a Prescription	4
b. The Manner in Which the Market Works Misleads Patients	6
c. Brand Substitution	9
d. Enforcement Recommendations	9
3. Quantity and Length of Prescriptions	10
a. Competition and Convenience Can Lead to Compromising Patient Safety	11
b. Limits on Quantity Can Preserve Competition and Promote Patient Safety	11
c. Lack of Quantity Limits Can Stifle Competition and Patient Choice	12
4. Passive Verification	13
a. Deceptive Practices from Sellers Regarding Prescription Verification	14
b. Should Robocalling be a Valid Method of Communication?	16
c. Possible Changes to Passive Verification and Other Options to Improve Patient Health Safeguards	17
5. Conclusion	18
6. Appendix - FTC Questions	20



October 26, 2015

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Suite CC-5610 (Annex C)
Washington, DC 20580

RE: Contact Lens Rule, 16 CFR 315, Project No. R5119955

Dear Secretary Clark:

The Coalition for Patient Vision Care Safety (the “Coalition”) is pleased to submit comments on the Federal Trade Commission’s (the “FTC” or “Commission”) review of its 2004 Final Rule (the “Contact Lens Rule” or “Rule”) implementing the Fairness to Contact Lens Consumers Act (the “Act”). Our Coalition, composed of manufacturers, eye care doctors, and medical device trade associations, seeks to ensure that the patient-doctor relationship is preserved and protected as the Commission undertakes this important review.¹ Our aim is to improve the existing Rule to maintain pro-competitive intentions of the Act and Contact Lens Rule without allowing anticompetitive practices to undermine patient health and safety.

Introduction

The Coalition believes firmly that there is a continuing need for the Rule, and would be strongly opposed to significant changes that weaken the Rule or the statute. Since enactment, and the FTC’s subsequent implementation, the market for contact lenses has become extremely competitive and is now one of the most heated markets in the country. This competition has led to increased investment in research and development, and a proliferation of innovation that has served to benefit the nearly 44 million Americans who use contact lenses every day. Today, the U.S. contact lens consumer has numerous choices as to how to procure and where to purchase their contact lenses, as well as competitive choices among manufacturers of these medical devices. Be it an online seller, a traditional retail store, or a doctor of optometry or ophthalmologist, patients do not lack for choices in their purchasing options. Because of the strength of the market and the accessibility of these medical devices to patients, the FTC should view its authority over the marketplace as a safeguard for patients seeking to fill their prescription for their contact lenses, which are regulated medical devices.

¹ The Coalition consists of the following members: The American Optometric Association (AOA); Vision Care – a Johnson and Johnson Company; Bausch + Lomb; CooperVision, Inc.; Alcon – a Novartis Company; AdvaMed, and The Contact Lens Institute.

While most FTC rules and related statutes are primarily concerned with prices and innovation for consumers, the Contact Lens Rule has a significant impact on the competition to supply contact lenses in a manner that enhances patient safety and the patient-doctor relationship, as well as the regulation of contact lenses, which are Class II and Class III medical devices as approved by the Food and Drug Administration (FDA). As such, any examination of the rules and their effectiveness should be viewed, at least in part, with an eye toward patient health and safety, and whether anticompetitive conduct fails to preserve and protect confidence in the patient-doctor relationship. As an FTC staff report from 2004 importantly noted:

“The primary health care concern with contact lenses appears to be ensuring that contact lens wearers return to their doctors regularly for eye examinations . . . 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. 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. *Consumers may thus endanger the health of their eyes if they obtain and wear replacement contact lenses without a valid prescription.*”²

In the spirit of protecting patients’ eye health, we would ask the Commission to implement improvements in three areas of the Rule:

1. The FTC should strengthen enforcement of provisions of the statute and Contact Lens Rule, and simplify the process where patient and prescriber complaints are filed with the Commission.
2. The FTC should impose reasonable limits with respect to prescription expiration and to the quantity of contact lenses permitted to be prescribed and sold so as to ensure patients:
 - Receive appropriate professional supervision when using these regulated medical devices;
 - Receive contact lenses that are appropriate for the patient’s ocular health and needs;
 - Receive contact lenses that match the lens brand and type delineated on a valid prescription, regardless of where the contact lenses are purchased; and
 - Receive regular attention to their ocular health care issues.
3. The FTC should enhance the verification process, to protect against unverified sales of contact lenses and ensure that patients receive the contact lenses prescribed by their doctor of optometry or ophthalmologist.

We believe that without undermining the Act, the Commission can make specific changes to its Rule to better protect the ocular health of the nearly 44 million Americans wearing contact lenses

² *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*. A Report from the Staff of the Federal Trade Commission; March 2004. pp. 8-9 (emphasis added).

today, and to ensure that the desire for profits is not placed above the need to protect the eye health of patients.

Enforcement

The Coalition believes the Commission should increase significantly the enforcement of the Act. The FTC has asked about the effects of the Rule on the flow of truthful and deceptive information to consumers. The Coalition believes noncompliance with and loopholes within the law have resulted in a deceptive flow of information to contact lens patients, and have the potential to compromise seriously the vision health of patients.

The FTC, the FDA, and the Department of Justice (DOJ) all possess varying degrees of jurisdiction over the enforcement of legislation governing the contact lens marketplace; however, Congress gave the FTC explicit marketplace enforcement jurisdiction over the Act. The FTC has specific authority, under all appropriate enforcement provisions of the Federal Trade Commission Act, to issue complaints or bring actions against contact lens sellers who violate the Act. The Coalition understands that the FTC's jurisdiction is primarily related to enforcement against companies that make misleading claims about their products or services. Moreover, under its unfairness jurisdiction, the Commission can regulate marketing practices that cause or are likely to cause substantial consumer injury, are not reasonably avoidable by consumers, and are not outweighed by countervailing benefits to consumers or to competition.

The Act's mandate is clear. As is the Rule, which states that any "person that engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, there is evidence that contact lenses may be obtained without a prescription."³ In today's marketplace; however, contact lenses are often obtained either without an accurate and valid prescription or without any prescription at all. The opportunities for violating the prescription requirements in the Act are much greater than when the Act passed in 2003. These opportunities exist largely because the use of the Internet has increased exponentially in the last 11 years and overall product purchasing (and, in particular contact lenses product purchasing) is simpler than it once was. As a result, the Coalition members have all encountered increasing examples of noncompliance and exploitation in numerous areas.

Noncompliance of the Act: Selling Lenses Without a Prescription

Technological advances since the passage of the Act have made online contact lens purchases easier. But these advances have also occasioned competition-quashing and deceptive contact lens marketing from sellers. Increased website access and social media (through such sites as Facebook, eBay, Amazon, and others) offer illegal online traders and resellers a massive and often unsuspecting customer audience. Social media and the Internet have also helped foreign companies that promote the fact that they do not verify prescriptions easily reach thousands of consumers. The example below, NextDayLenses.com, is a U.K. company shipping contact lenses globally, "including the U.S.A."

³ Federal Register 40504; July 2, 2004.

DAILY MONTHLY 2-WEEKLY COLOURED TORIC/ASTIGMATISM BI/MULTIFOCAL SOLUTIONS & ACCESSORIES

1. Find your contact lenses > 2. Give us your prescription > 3. Checkout and get your lenses today

FIND YOUR CONTACT LENSES

Browse all contact lenses and find yours in two clicks

Shop by Family

- 1 Day ACUVUE
- ACUVUE 2
- ACUVUE ADVANCE
- ACUVUE BIFOCAL
- ACUVUE OASYS
- AIR OPTIX AQUA
- Avaira
- Biofinity
- Biomedics
- Clarity
- CooperVision Expressions

Contact Lenses Without a Prescription

As long as you are happy that your current prescription is correct, you can buy contact lenses online without a prescription from NextdayLenses.com. We know some people are reluctant to provide their Optician's contact information because they don't want their Optician to know they're ordering their lenses for a cheaper price online.

It is important that you ensure your prescription is kept up-to-date and you still make regular visits to your Optician for eye checkups.

We stock the exact same brands as on the High Street, and source all our products direct from trusted manufacturers such as CIBA Vision / Alcon. This means we can sell top quality products for low prices.

You can buy contact lenses from NextdayLenses.com whether your postal address is in the UK or abroad as we ship to many different destinations, including the USA.

Note that while this company does tell patients that “it is important to ensure your prescription is kept up to date...” they lead with “As long as you are happy that your current prescription is correct, you can buy contact lenses online without a prescription...”⁴

It is telling that a now seven-year-old Journal of Optometry study on the Act, and on online contact lens marketplaces, found poor eye care practices among patients who purchased contact lenses online and predicted additional unhealthy practices. The report concluded, in 2008, that online contact lens purchasers “are less likely to regularly visit their doctor and [are] at greater risk for unhealthy eye care practices.”⁵ The significant increase in online lens sales growth has only exacerbated this risky behavior. Fast forward to 2015, and it is apparent to the Coalition that the 2008 predictions have come true. According to a 2015 APCO Insight Survey of contact lens wearers who purchase online, numerous consumers admit to ordering contact lenses with expired or close-to-expired prescriptions and online retailers are encouraging this practice.⁶ One-in-three (32 percent) purchasers admit to ordering contacts using an already expired prescription.⁷ The same survey found that, of those who believe a prescriber should be contacted directly by a lens retailer to fill a prescription, only 35 percent report that the retailer contacted their doctor directly to get the prescription.⁸

⁴ <http://www.nextdaylenses.com/buy-contact-lenses-online-without-a-prescription-last accessed on 10/24/2015>

⁵ Journal of Optometry 2008 Report, p. 34 “Contact lenses purchased over the Internet place individuals potentially at risk for harmful eye care practices.” Joshua Fogel, PhD., and Chaya Zidile.

⁶ From September 24 to October 2, 2015 APCO Insight conducted an online quantitative survey among U.S. consumers who purchased contact lenses online. APCO surveyed 500 contact lens wearers over 18 who had purchased online in the previous six months.

⁷ Id.

⁸ Id.

The American Optometric Association (AOA) also recently reported to the Coalition that it has identified several online contact lens retailers who, in the Coalition’s view, inappropriately allow consumers to purchase contact lenses without a prescription, contravening either the intent or the Act itself. For example, during the order process AAlens.com does not request any prescriber information to verify a prescription and AAlens.com does not appear to request a copy of the patient’s prescription. Rather, the retailer indicates, “Our terms and conditions are simple: All customers who order replacement contact lenses must have a valid prescription which must be less than 24 months old. Your order must be for the same contact lenses that you are already successfully wearing. We accept no responsibility for our customers' lack of suitability to wear contact lenses.”⁹ Similarly, Saveonlens.com does not request prescriber information to initiate the verification process and does not require the patient to provide a copy of a prescription to complete an order.¹⁰ There are also several retailers who sell cosmetic lenses seemingly without following the requirements of the Act.¹¹ Therefore, it appears that there is a practice by some online retailers to either sell without a prescription or to avoid contacting a prescriber directly to obtain or confirm information required by the Act. We believe that these violations are going largely unchecked.

The Manner in Which the Market Works Misleads Patients

According to the 2015 APCO Insight Survey, and from numerous anecdotal accounts provided to the Coalition, lens patients are ordering, and are being encouraged to order, large quantities of contact lenses, particularly just prior to a prescription’s expiration in order to circumvent federal prescription mandates. There are even online blogs offering advice as to how to do so, as detailed below:¹²



Best Answer: Presumably you wear one of the national brands which means only sites within the US/Canada/UK sell them.

The US has laws governing the sale of contact lenses that the sites within the US have to obey. Even sites in Canada or the UK have agreed to follow the US demand (as a good will gesture) that the prescription be validated before shipping. If the shipping address is in the US , no one will send them without verifying with the Dr.

One trick is to call and order when you know they won't be able to get a hold of the Dr's office for several days, because of vacation or something. After 2 or 3 days, they consider that as having tried, and send the order. So if your Dr. is in a small office, they may be closed for a few days next week because of the July 4th holiday....a good time to try. If he is in a mall, then it is always open so that won't work.

It's frustrating at times, but that is the laws of the land.

Source(s):
Optician

Six-in-ten online purchasers (62 percent) say they have ordered contacts using a prescription less than a month from its expiration date.¹³ While not an outright violation of the Act, it is troubling that online contact lens sellers encourage and market the “stocking up” of contact lenses just prior to a prescription’s expiration. While the Act does not limit the number of contact lenses

⁹ <http://www.aalens.com/faq.html#Q2>

¹⁰ http://www.saveonlens.com/contact_lenses_no_prescription.html

¹¹ <https://www.honeycolor.com>; www.pinkyparadise.com; <http://thedolleye.com>

¹² <https://answers.yahoo.com/question/index?qid=20130627093112AAEu68o>

¹³ APCO Insight Survey.

that can be sold, it does require that, absent an outright prescription, the quantity of contact lenses be included in the verification request that is sent to the prescriber. In 2004, the FTC thought that providing such information would prevent the patient from receiving more contact lenses than are available through the remainder of the prescription. In the Rule, the FTC declared that “the verification process itself. . . generally allows prescribers to prevent patients from ordering excessive contact lenses.”¹⁴

In practice; however, patients are regularly “ordering excessive contact lenses.”¹⁵ This is despite the purported quantity reporting safeguard that the FTC believed would limit excessive ordering. Just because the quantity is required to be reported, does not mean that a consumer has to limit the number of contact lenses ordered.

Furthermore, if a patient provides a copy of a contact lens prescription to a retailer, that prescription is not required by the Rule to include any quantity information. Additionally, when a complete copy of a contact lens prescription is provided to a retailer, the verification process is not triggered. So, while the FTC previously believed that the verification system provided a safeguard against the purchase of excessive contact lenses, the FTC did not seem to account for retailers seeking to obtain a complete copy of the contact lens prescription to circumvent verification. Clearly, more needs to be done to ensure that retailers do not encourage the purchase of large numbers of contact lenses that might no longer meet the eye care needs of the patient and may allow threats to a patient’s vision to fester.

There are obvious examples of these practices. For example, Lens.com allows consumers to purchase up to 50 boxes of a 90-day pack of daily disposable contact lenses for each eye, which provides 4,500 contact lenses per eye. This is more than a 12-year supply of contact lenses, well over a one year’s supply, which if purchased virtually eliminates the doctor-patient relationship in its entirety.

The screenshot shows the Lens.com website interface. At the top, there is a navigation bar with links for Home, All Products A to Z, Reorder, FAQ, and About, along with the phone number 1-800 LENS.COM (536-7266). Below the navigation bar is a search bar with dropdown menus for 'Select Contact Lenses', 'Select Manufacturer', and 'Select Lens Type'. The main content area features a product listing for 'Dailies AquaComfort Plus Contact Lenses' with a price of '\$39.99 per box'. A 'BUY MORE SAVE MORE!' banner offers a discount for buying 3+ boxes. Below the product details is an 'Enter Prescription' section with a table for inputting contact lens information.

	Quantity	Base Curve	Diameter	Power	Price per Box (as low as)
Right Eye (OD)	50 Boxes	8.7	14.0	Select	\$39.99
Left Eye (OS)	50 Boxes	8.7	14.0	Select	\$39.99
Lens Solutions	Add biofresh Multi-Purpose Solution Bottles: Select				\$0.00

¹⁴ Federal Register 40488; July 2, 2004.

¹⁵ Id.

Additionally, 1-800-CONTACTS allows a patient to purchase eight boxes of 90-day packs for each eye, which provides 720 contact lenses per eye, which is about a 2-year supply, stocking most patients with contact lenses well beyond their prescription's expiration date. With 1-800-CONTACTS dominating the online market (the company itself asserts that it holds 75 percent of the online market),¹⁶ it is not surprising that patients are uneducated as to the need for regular visits to their eye doctor or the importance of maintaining an updated prescription.



The Coalition believes that the selling of excessive amounts of contact lenses unfairly disadvantages competition, discourages patients from seeking regular visits with their eye doctor and is not in the best interest of patient health. Regular visits allow doctors not only to determine changes in a patient's vision, but also serve as a forum to inform patients how dangerous some eye health habits can be, and assess whether their patients are engaging in such risky behavior. According to a recent report published by the Centers for Disease Control and Prevention (CDC), more than 99 percent of survey respondents reported engaging in at least one risky behavior with regard to contact lens habits.¹⁷ The CDC's research found that some of these riskier behaviors include:

- Patients keeping contact lens cases for longer than recommended (82.3 percent);
- Adding new solution to the existing solution instead of emptying the case out fully before adding new solution (55.1 percent); or
- Patients wearing their contact lenses while sleeping (50.2 percent).

As this survey data demonstrates, the importance of annual eye exams and the preservation of the patient-doctor relationship is critical not only to determine the patient's prescription needs, but also to examine their overall eye health habits, ensuring their safety when using contact lenses.

¹⁶ <http://www.judiciary.senate.gov/hearings/watch?hearingid=12e98234-5056-a032-52ea-90f98e940d9b>

¹⁷ http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6432a2.htm?s_cid=mm6432a2_w

Brand Substitution

An additional area of concern related to patient safety involves significant incidences of contact lens brand substitution, which is prohibited under the Act. Again, according to the 2015 APCO Insight Survey, consumers do not want brand substitutions, yet many say they have received a substitution without advance notice or that their online retailer has advised them to substitute when out of stock.¹⁸ One-in-four (24 percent) online purchasers reported having received – without warning – a different brand of contact lenses than those which were ordered.¹⁹ Another three-in-ten (31 percent) reported having experienced supply issues with their online retailer and being advised to get another brand of contact lenses as a solution.²⁰ While the Act allows for substitution of contact lenses by the same manufacturer if such contact lenses are the same but sold under a different label, substitutions from one manufacturer to another are prohibited and, yet, are routinely practiced by online sellers.²¹ This is potentially quite dangerous for the contact lens patient. A 2015 Ohio State University report showed clearly how the ocular response to each contact lens is significantly different and leads to a variety of physiological reactions, even when fitting the same patient with various contact lenses.²² Thus, maintaining and enforcing the current requirement that prescribers must include the specific brand and product name on patient prescriptions and prohibiting substitution is absolutely necessary to minimize the risk of potentially sight-threatening complications.

The Coalition understands and supports the spirit of increased competition, small business opportunity, and patient convenience envisioned by the Act. But we strongly believe that some online contact lens sellers have sought to reduce competition among retail and medical eye care providers and manufacturers through noncompliance or outright violation of the Act. This can be prevented with stronger enforcement.

Enforcement Recommendations

Operation Double Vision, a short-term program run primarily by U.S. Immigration and Customs Enforcement (ICE), seized 20,000 illegal pairs of contact lenses in 2014.²³ And, yet, there is currently no dedicated office, online category, or phone number at the FTC assigned to Contact Lens Rule complaints. The FTC, in fact, routes eye contact complaints about non-compliance to its general complaint lines. These include complaints regarding:

- Sale or advertising of contact lenses without a prescription;
- Fake prescriptions;
- Filling of expired prescriptions;
- Supplying inappropriate and exorbitant quantities of contact lenses;
- Ignoring the eight-hour passive verification period by prescribers;

¹⁸ APCO Insight Survey.

¹⁹ *Id.*

²⁰ *Id.*

²¹ 15 U.S.C. 7603; §4(f).

²² Ohio State University 2015 Report. “Are Contact Lenses Interchangeable?” Jeffrey J. Walline, OD PhD.

²³ U.S. Immigration Customs & Enforcement Press Release; 10-12-2015.

- Substituting contact lenses without the consent of prescriber;
- Unintelligible recorded robocall messages; and
- Failure to provide reasonable access to any actual contact person to verify the prescription.

We believe the general routing of complaints both discourages reporting of complaints and does not provide the FTC with adequate and accessible information to enforce the Rule. We believe that dedicated personnel paired with, a dedicated website or phone number within the FTC, and/or a dedicated office, would go a long way toward protecting the contact lens patient. We also recommend:

- An analysis be conducted and made available by the FTC that provides compliance and enforcement details about the Act – including, but not limited to, how many complaints the FTC receives about the Act annually, the nature of those complaints, how often the FTC processes complaints, and how many investigations, complaints, and enforcement proceedings and fines the FTC has completed to date;
- Significantly increased enforcement of the Act;
- A requirement that a live person be available for doctors to verify or reject a prescription or information about a prescription, with a phone number to such person clearly identified, as part of the verification process; and
- A determination that robocalling is not a “completed” communication for the purposes of the verification process.

There is overwhelming evidence of continued deceptive and misleading practices by some in the online contact lens marketplace, and we urge the Commission to hold these entities accountable. We, therefore, urge the Commission to pursue our requested enforcement-related recommendations.

Quantity and Length of Prescriptions

The Act preempted state laws that specified prescription expiration dates “less than one year after the issue date of the prescription.”²⁴ The Act permits prescriptions longer than one year to the extent the laws of the state in which the prescription was written permit longer terms.²⁵ And the Act otherwise requires that prescriptions shall expire “not less than one year after the issue date of the prescription.”²⁶ The exception in the statute pertaining to ocular health is not pertinent to these comments.

The Commission in its Contact Lens Rule essentially codified the above referenced statutory language, except for some added clarity with respect to prescriptions shorter than one year. The Coalition urges the Commission to retain the prescription limits imposed in the Rule and also strengthen the Rule to provide increased protections for patient eye safety and health.

²⁴ 15 U.S.C. 7604; §5(a)(2).

²⁵ 15 U.S.C. 7604; §5(a)(1).

²⁶ 15 U.S.C. 7604; §5(a)(2).

The reasoning behind the prescription limits in the Rule was, as the Commission noted in its publication of the Contact Lens Rule, to “prevent prescribers from selecting a short expiration date for a prescription that unduly limits the ability of consumers to purchase contact lenses from other sellers[.]”²⁷ The Coalition agrees that expiration dates should not be unduly restrictive; however, we do not believe that prescribers would have selected short expiration dates so as to limit consumer choice. The one-year rule now serves a separate yet equally important purpose which is not fully realized.

Competition and Convenience Can Lead to Compromising Patient Safety

To be specific, the one-year limit serves to make it more likely that patients requiring renewals of their prescriptions will undergo regular and annual eye exams. Any alteration to the Rule toward lengthening the time frame would undermine this vital health benefit. The competitive benefits behind the Rule have been mostly achieved but the health benefits that the Rule encourages need to be protected and, to some degree, have yet to be realized. As discussed earlier, some patients do not prioritize regular eye exams with their doctor, and retailers regularly encourage this behavior with misleading information about the importance of regular eye care. This is concerning as 87 percent of contact lens patients had an eye exam last year, and of those, 94 percent reported a change in their prescription since their last visit.²⁸

As the above numbers suggest, around 13 percent of contact lens patients did not see a licensed practitioner for an exam last year. Put another way, around five million contact lens patients did not receive the care they need. Why is this? The Coalition believes there are two predominant factors: first, when the Commission crafted Rule §315.6, it did not, and perhaps could not, take into account the proliferation of sellers that deliberately or inadvertently ignore verification requirements and sell large supplies of contact lenses to patients after or close to the expiration of their prescription. Second, the Commission could not anticipate that many consumers would flock to such sellers, and that sellers would be willing to disseminate misleading information regarding the need for regular eye exams and valid, updated prescriptions with little concern about the health benefits the patient may be foregoing.

Limits on Quantity Can Preserve Competition and Promote Patient Safety

Fortunately, the solution is quite simple. The Coalition urges the FTC to strengthen the Rule as implemented by adding quantity limits – along with the enhanced verification standards we recommend below, to better protect patient safety and health.

The Act gives the Commission the authority to impose quantity limits. In fact, 15 U.S.C. § 7607 gives the FTC broad rulemaking authority “to carry out this Act.” Putting reasonable limits on prescriptions does not contravene the statute and is consistent with the goals of protecting consumers and competition. The Act contemplates quantity limits in its requirement that sellers include the specific quantity of contact lenses ordered in their verification requests.²⁹

²⁷ Federal Register 40504; July 2, 2004.

²⁸ APCO Insight Survey.

²⁹ 15 U.S.C. 7603 §4(c)(3).

Consistent with the recommendations of the Contact Lens Rule, the majority of states have prescription expiration standards of one year. However, as cited above, sellers will often contact patients toward the end of their prescription and urge them to buy more, and in some cases, several years' supply of contact lenses. Also, consumers will often seek to buy contact lenses without a new prescription thinking they do not need a visit to their eye doctor. In both cases, the patients forego regular eye care, fail to receive a valid new prescription, and miss an important opportunity to be evaluated for other health conditions. For example, doctors of optometry and ophthalmologists are often the first health care practitioners to examine persons with undiagnosed diabetes mellitus or ocular manifestations of diabetes.³⁰ These providers also identify other chronic conditions such as multiple sclerosis, Crohn's disease, and juvenile rheumatoid arthritis.

The Coalition urges the FTC to adopt several complementary quantity limits to address these interrelated problems. In light of the fact that most prescriptions are one-year in length, the Coalition urges the FTC to forbid retailers to sell in a single transaction a quantity of contact lenses that exceeds a single year's supply. An alternative approach could be for the FTC to require that sellers only provide a supply equal to the length of the underlying prescription. During the initial comment period after the Act was passed, commenters expressed concern that patients lose or damage their contact lenses and therefore argued against such limits. In such circumstances; however, patients can always buy more contact lenses, so long as their prescription is still valid. However, to avoid the practice of sellers and/or consumers attempting to get a year or more of contact lenses toward the end of their prescription, the Coalition recommends the Commission prohibit the sale of a quantity of contact lenses that exceeds the length of time before the prescription will expire.

In the 11 years since the publication of the Rule, a significant number of patients have ordered and received contact lenses that were never verified and never in fact even prescribed. Oftentimes, sellers, in sending these contact lenses, are not technically violating the rules in the sense that they are sending the new supply while the original prescription is still valid (usually in the final month of the prescription). But they are violating the spirit of the rules in the sense that they are sending quantities well beyond the amount left on the original prescription. Given that 94 percent of patients require a change in their prescription when they actually have an eye exam; this practice seems to do a disservice to the patient.

Lack of Quantity Limits Can Stifle Competition and Patient Choice

With respect to competition, an area the FTC is charged with protecting and promoting, there is a subtle, anticompetitive effect at play, particularly in the online market for contact lenses. That effect would be mitigated should the Commission adopt the rule changes urged in these comments. In the online market, one player, 1-800-CONTACTS, dominates the playing field, by its own estimates, controlling 75 percent of online sales.³¹ When any merchant sends patients a year or more supply of contact lenses toward the end of their year's prescription, they are in

³⁰ <http://aoa.uberflip.com/i/374890-evidence-based-clinical-practice-guideline-diabetes-mellitus>

³¹ <http://www.judiciary.senate.gov/hearings/watch?hearingid=12e98234-5056-a032-52ea-90f98e940d9b>

essence locking up that patient for the foreseeable future, and forestalling competition for that patient's loyalty. Instead, as the data shows, a large percentage of patients that do receive regular eye exams actually learn of changes with their eyes, changes that result in changes to their prescriptions, and changes that should lead to competition for their purchasing dollar. Instead, when 1-800-CONTACTS simply sends a two years' supply to a patient, that practice "unduly limits the ability of patients to purchase contact lenses from other sellers[.]"³²

In its explanation of the Contact Lens Rule in 2004, the FTC opined that "[t]he verification process itself thus generally allows prescribers to prevent patients from ordering excessive contact lenses."³³ In reaching this conclusion, the Commission deduced that because verification requests were required to include the quantity of contact lenses ordered, prescribers would have ample opportunity to "treat a request for verification of a prescription as 'inaccurate.'"³⁴ But as these comments and the data in the field demonstrates, it is possible that a significant number of Americans are getting large quantities of contact lenses beyond the length of their initial prescription, without getting a new prescription, despite the fact that their initial prescription would most likely change had they in fact gone for an eye exam.

The FTC should impose reasonable limits with respect to the quantity of contact lenses permitted to be prescribed as well as sold. The Coalition makes the following recommendations to the Commission regarding quantity limits:

- Require the inclusion of quantity limits on the patient's prescription to ensure patients receive appropriate and regular medical supervision when using these regulated medical devices;
- Permit retailers to provide a quantity of contact lenses equal to a single year's supply in a single transaction;
- Prohibit the sale of a quantity of contact lenses that exceeds the amount reasonably necessary for use before the prescription will expire; and restrict the sale of contact lenses on a prescription that is nine months after issuance or older to up to 25 percent of the prescription's course; and
- Prohibit sellers from acting as outright agents of patients in terms of filling a prescription thereby requiring patients to take a more active and ongoing role in their eye care health.

Passive Verification

When the Act was originally considered by the Congress, some versions of the draft legislation did not adopt a specific approach to prescription verification, recognizing benefits to both passive and active verification processes. Former FTC Consumer Protection Director Howard J. Beales testified before the House Energy and Commerce Committee in 2003 during a Committee hearing on the bill, and noted – "Proponents of passive verification favor this approach because it allows the seller to presume verification if the eye care practitioner does not take affirmative action to correct any errors in the prescription... By contrast, proponents of active verification

³² Federal Register 40504; July 2, 2004.

³³ Federal Register 40488; July 2, 2004.

³⁴ Id.

systems express concern that passive verification may allow sellers to ship contact lenses even if the customer has an invalid or incorrect prescription...[C]ustomers may face serious health risks if they obtain and wear contact lenses based on such a prescription."³⁵

As passed by Congress, the Act adopted a passive verification mechanism – which may help the contact lens *consumer*, but adversely affect the contact lens *patient*. Subsequently, the FTC's intent in designing the verification process in the Rule was to provide flexibility and choice to consumers in purchasing contact lenses, but also put in place a critical safeguard that patients receive the correct contact lenses as prescribed by their eye care professional. Importantly, the FTC also sought to ensure that individuals are not able to circumvent the prescription expiration requirements.

The Coalition does not believe that these safeguards have been achieved and, therefore urges the FTC to reexamine the passive verification system to ensure that patients are receiving contact lenses that are tied to an accurate and valid prescription. There are several areas of particular concern for the Coalition, over which we believe the Commission has the authority to act, including taking steps to:

1. Ensure, through enforcement, that online sellers are not able to advertise or communicate that they sell contact lenses without a valid prescription, or advertise reorders of prescription contact lens prescription after the prescription has expired;
2. Examine the various methods of communication between a seller and provider, including robocalling, and in particular look at whether existing methods actually constitute "direct communication"; and
3. Study how the current passive verification system could be modified to better protect patients' health.

Deceptive Practices from Sellers Regarding Prescription Verification

After 11 years of the Rule, it has become clear that the passive verification process can vary substantially in practice. The Coalition has heard reports from patients and prescribers of instances in which consumers have received contact lenses based on expired prescriptions; stockpiled contact lenses that last well beyond the prescription expiration; or duplicate orders of contact lenses. Not only do these examples raise concerns around patient health and safety, but they also suggest that the safeguards that Congress and the FTC created aren't protecting patients as intended.

³⁵ Fairness to Contact Lens Consumers Act: hearing before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce, House of Representatives, One Hundred Eighth Congress, first session, on H.R. 2221, September 12, 2003.

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The Coalition is aware of multiple online sellers that advertise their ability to provide contact lenses *without* a valid prescription. These sellers include DaySoft.com, a contact lens company that markets to patients in the United States. DaySoft's business practices are in violation of the Act because it does not require a verified prescription. Instead, the company directs patients to enter in the brand of contact lenses they were previously prescribed and then DaySoft replaces them with what they deem to be an adequately equivalent lens.³⁶ We are aware of individuals who were personally able to purchase contact lenses through this site, and also received contact lenses that were other than those that were prescribed by their eye care professional. The homepage of their website includes a testimonial from a patient in New York;³⁷ these sites are clearly reaching patients in the United States.

The Coalition urges the FTC to examine these deceptive practices, and consider enforcement actions against these online sellers who are endangering the eye health of many Americans who purchase their contact lenses online. According to the Rule, "The Commission emphasizes that the sale of contact lenses based on a verification request which does not contain all of the required information constitutes a Rule violation."³⁸ The FTC has the authority and the responsibility to act against these bad actors.

³⁶ <https://www.daysoftcontactlenses.com/US/Buy.aspx#.Vh-qrdKrSM8>

³⁷ <http://www.daysoftcontactlenses.com/US/CountryHomepage.aspx#ThisMonth>

³⁸ Federal Register 40496; July 2, 2004.

Should Robocalling be a Valid Method of Communication?

Another area of increasing concern to the Coalition is the growth of robocalling by retailers is leading to more and more prescriptions being verified passively. According to the Rule, once the eye care professional receives the request to verify the prescription, they have eight business hours to verify the information. If the eye care professional fails to verify the prescription within eight business hours, the patients' prescription is automatically filled.³⁹

The Rule allows for a variety of methods of communication for sellers to verify prescriptions, ranging from outdated communication via fax to seller-initiated robocallers leaving voice messages on prescriber's office phone lines, often after hours and without a return number or seller contact. As a result, prescribers are often unable to provide the proper verification of the patient's prescription information within eight business hours.

With regard to the definition of "direct communication," the Commission ultimately decided in the Rule that an automated phone call would qualify as a completed communication to verify a prescription, even though the Commission received a "substantial"⁴⁰ number of comments opposed to the use of automated telephone systems. That decision should be revisited. There is an important amount of critical patient information that must be communicated by the seller and verified by the prescriber, and that is very difficult to communicate in a robocall.⁴¹ In fact, the AOA has received numerous complaints from doctors of optometry that robocalls from online sellers, such as 1-800-CONTACTS, are difficult to understand or do not include all of the legally required patient information to verify the prescription. As a result, patients may receive contact lenses that are based on outdated or incorrect prescription information. The Coalition believes that the FTC and the FDA share the responsibility for the health and safety of contact lens patients. The fact that patients are receiving contact lenses based on incorrect, outdated, or unverified prescription information runs counter to the FDA's medical device safety standards, and can also lead to serious vision issues.

Additionally, in the FTC's 2004 publication, *The Contact Lens Rule: A Guide for Prescribers and Sellers*, the FTC states that "direct communication by telephone requires *reaching and speaking* to the intended recipient, or leaving a voice message on the telephone answering machine of the intended recipient."⁴² This definition runs counter to the inclusion of automated phone calls (which do not allow for human feedback) as a valid method of verification. For example, a voice mail box may have a time limit within which to leave a message, and yet an autodialed message cannot by its very nature adapt to time constraints, and may therefore be cut

³⁹ Federal Register 40483; July 2, 2004.

⁴⁰ Federal Register 40489; July 2, 2004.

⁴¹ "(1) The patient's full name and address; (2) The contact lens power, manufacturer, base curve or appropriate designation, and diameter when appropriate; (3) The quantity of lenses ordered; (4) The date of patient request; (5) The date and time of verification request; (6) The name of a contact person at the seller's company, including facsimile and telephone numbers; and (7) If the seller opts to include the prescriber's regular business hours on Saturdays as "business hours" for purposes of paragraph (c)(3) of this section, a clear statement of the prescriber's regular Saturday business hours." Federal Register 40496; July 2, 2004.

⁴² *The Contact Lens Rule: A Guide for Prescribers and Sellers*. Federal Trade Commission, Bureau of Consumer Protection, Office of Consumer and Business Education. October 2004. pp. 3-4. (emphasis added).

off before conveying in entirety the patient's information. As such, prescribers often get calls without information, or without a return phone number; this invariably leads to sales when in fact the prescription has never been fully received or verified.

The FTC wrote in the Rule that "the Commission will continue to monitor whether full, valid requests for verification of a prescription are being made through the use of automated telephone systems. If evidence demonstrates that sellers are not making valid verification requests but are providing consumers with contact lenses despite deficient requests, the Commission may revisit this issue."⁴³ The Coalition requests that the FTC publish its findings, if any, in this regard. The Coalition believes that the FTC will find that there is substantial evidence that sellers' attempts to verify vital patient information are deficient, and the Commission should ban the use of automated phone systems.

Possible Changes to Passive Verification and Other Options to Improve Patient Health Safeguards

Given that Congress permitted a passive verification system in the Act, we recognize that the Commission is unlikely to alter significantly this portion of the rule without Congressional action. While the Coalition supports the elimination of passive verification, we believe that modifications to the passive verification standards under the FTC jurisdiction could be made to provide a better baseline for patient safety standards. In a 2004 staff report, the FTC recommended that "prescription release requirements and prescription verification requirements 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 contact lenses are less expensive and/or more conveniently available."⁴⁴ To meet this standard while ensuring that patients are receiving optimum vision care, we support the following modifications:

- Completion of the study on how the passive verification system affects patients' eye health;
- Modification of the eight-hour period of communication when the initial communication begins prior to a holiday or on a weekend when a doctor is not conducting normal office hours; and
- Rejection of any weakening of the current prescription verification standards.

⁴³ Federal Register 40489; July 2, 2004.

⁴⁴ *Possible Anticompetitive Barriers to E-Commerce: Contact Lenses*. A Report from the Staff of the Federal Trade Commission; March 2004. Page 31.

Conclusion

On behalf of the Coalition, we have suggested in this submission ways for the Commission to both maintain certain protections and make needed changes to the Contact Lens Rule in order to accommodate appropriately all the technological and medical advances that have occurred over the last 11 years. To summarize, our suggestions are as follows:

1. The FTC should strengthen the enforcement of provisions of the statute and Contact Lens Rule. To accomplish this, the Coalition recommends the following actions:
 - Simplify the process whereby patient and prescriber complaints are filed with the Commission, including dedicated personnel tasked with receiving and reviewing these complaints;
 - Conduct and publish an analysis providing compliance and enforcement details about the Act – including, but not limited to the annual totals of complaints the FTC receives regarding violations of the Act, the nature of the complaints, how often the FTC processes complaints, and how many investigations, enforcement proceedings and fines the FTC has completed to date; and
 - Increase enforcement penalties to deter retailers from advertising that they are able to sell contact lenses without an accurate and valid prescription.

2. The FTC should impose reasonable limits with respect to the quantity of contact lenses permitted to be prescribed as well as sold. The Coalition makes the following recommendations to the Commission regarding quantity limits:
 - Require the inclusion of quantity limits on the patient’s prescription to ensure patients receive appropriate and regular medical supervision when using these regulated medical devices;
 - Permit retailers to provide a quantity of contact lenses equal to a single year’s supply in a single transaction, or the length of the underlying prescription; and
 - Prohibit the sale of a quantity of contact lenses that exceeds the amount reasonably necessary for use before the prescription will expire.

3. The FTC should enhance the verification process, to protect against unverified sales of contact lenses and ensure that patients receive the contact lenses prescribed by their doctor of optometry or ophthalmologist. The Coalition makes the following recommendations regarding the communication between retailers and doctors:
 - Examine the various methods of communication between a seller and provider to determine whether existing methods actually constitute “direct communication”;
 - Issue a determination that robocalling is not considered a “completed” communication for the purposes of the verification process;
 - Study how the current passive verification system could be modified to better protect patients’ health; and
 - Reject any weakening of current prescription verification standards.

We are hopeful that the Commission will adopt our suggested modifications with regard to enforcement, length and quantity of prescriptions; and passive verification; we believe these modifications comport with the underlying Act and will create an environment for contact lens patients that will promote truthful interactions with sellers and providers. It is our ultimate goal to promote better eye health and safety with regard to the prescription and dispensing of contact lenses, while retaining a robust market for patients. We believe that the changes we suggest will also create a more level and competitive playing field for all those involved in the contact lens business – whether those involved be medical professionals, manufacturers, online retailers or small and large bricks and mortar retailers.

We stand ready to provide additional comments or any other material the Commission deems necessary to inform the best policies to protect patients and consumers of contact lenses.

Appendix – FTC Questions

1. Is there a continuing need for the Rule? Why or why not?

According to the Fairness to Contact Lens Consumers Act (P.L. 108-164), the FTC is tasked with prescribing rules under its jurisdiction to carry out the Act. The Coalition believes firmly that there is a continuing need for the Rule, and would be strongly opposed to significant changes that weaken the Rule or the statute. In the years prior to the enactment of the Act, significant advances in medical technology were achieved that made the wearing of contact lenses more appealing and available to patients. In the years since the Contact Lens Rule was finalized, even more technological advances have occurred both in the contact lens medical device industry as well as in the contact lens marketplace. Because of the strength in the market and the accessibility of these medical devices to patients, the Coalition urges the Commission to view its authority over the marketplace as a safeguard for the contact lens *patient*, rather than the contact lens *consumer*.

2. What benefits has the Rule provided to consumers? What evidence supports the asserted benefits?

The Coalition believes that the Act led to numerous choices for patients regarding how and from whom they purchase their contact lenses. The nearly 44 million Americans that wear contact lenses have a robust marketplace that includes online sellers, traditional retail stores, or a doctor of optometry or ophthalmologist. However, this is only beneficial to patients when their ocular health is also protected within the marketplace. Because of the growth in the market and the accessibility of these medical devices to patients, the FTC must now view its authority over the marketplace as a safeguard from unfair business practices for patients seeking access to necessary regulated medical devices from entities that might care more about sales than safety.

3. What modifications, if any, should be made to the Rule to increase its benefits to consumers?

- a. What evidence supports the proposed modifications?**
- b. How would these modifications affect the costs the Rule imposes on businesses, including small businesses?**
- c. How would these modifications affect the benefits to consumers?**

As referenced in our comments, the Coalition believes that the FTC should approach the review of the Act with an eye toward patient safety, and examine whether the sanctity of the prescriber-patient relationship is being preserved to ensure patients are truly benefitting from the protections of the Act. To that end, we have identified three improvements to the rule that would be beneficial to patients in this marketplace.

First, the FTC must enforce the statute and Contact Lens Rule and ease the process whereby patient complaints could be filed with the Commission, thereby enhancing enforcement on the front end. This will allow patients to better inform the Commission when their eye health has potentially been compromised.

Second, the FTC should include reasonable quantity limits of contact lenses to be dispensed on a single prescription. This enhancement will ensure patients are receiving the quality of eye health care that they expect and deserve, and will reduce the burden on the patient to know if they are receiving the most recent version of this complex medical device.

Finally, the Commission should improve the prescription verification process. This modification would protect patients from unverified sales of contact lenses and ensure the accuracy of the prescriptions provided to them.

4. What impact has the Rule had on the flow of truthful information to consumers and on the flow of deceptive information to consumers?

The Act has effectively expanded the marketplace to retailers that do not have face to face interactions with the patient seeking to obtain these medical devices. This allows for deceptive information to flood the market regarding the need for a prescription to obtain contact lenses, the importance of adherence to the prescription, including the brand, and diminishes the importance of the doctor-patient relationship. As our comments reflect, the Coalition believes that the Act contains within it the authority granted to the FTC, the ability to reprimand and penalize those that disseminate this misinformation. We urge the Commission to consider enhancing its enforcement in an effort to reduce the incidences of deception we outline in our comments.

5. What significant costs, if any, has the Rule imposed on consumers? What evidence supports the asserted costs?

The improper use of contact lenses can lead to several serious conditions which require intensive treatment by doctors, adding not only additional monetary costs to the patient, but also impose serious health costs as well. The CDC estimates that, in 2014, costs associated with emergency room visits for keratitis alone, an impairment associated with the improper wearing of contact lenses added more than \$175 million to the overall health care system.⁴⁵ In addition to the medical costs incurred by the patient, there are additional costs related to loss of productivity as well as long term health consequences.

6. What modifications, if any, should be made to the Rule to reduce any costs imposed on consumers?

a. What evidence supports the proposed modifications?

b. How would these modifications affect the benefits provided by the Rule?

As the FTC reviews and modifies the Act, the Coalition strongly opposes significant changes that would weaken the Rule or the statute. Since enactment, and the FTC's subsequent implementation, the market for contact lenses remains extremely competitive. Today, the U.S. contact lens consumer has numerous choices as to how to procure and where to purchase their contact lenses, as well as competitive choices among manufacturers of these medical devices. Be it an online seller, a traditional retail store, or a doctor of optometry or ophthalmologist, patients do not lack for choices in their purchasing options. While most FTC statutes and rules

⁴⁵<http://www.cdc.gov/media/releases/2014/p1113-eye-infections.html>

are primarily concerned with prices, the Contact Lens Rule has a significant impact on competition for patient safety and the patient-doctor relationship, as well as the regulation of contact lenses, which are Class II and Class III medical devices. As such, any examination of the rules and their effectiveness should be viewed in part with an emphasis on patient health and safety, and whether the sanctity of the patient-doctor relationship is being preserved and protected adequately.

7. What benefits, if any, has the Rule provided to businesses, including small businesses? What evidence supports the asserted benefits?

The Act and the Contact Lens Rule were established to increase access by patients to medical devices. Since its implementation, the online retail market for contact lenses has grown exponentially, however, by its own admission, 1-800-CONTACTS maintains 75% market share of the online retail market.⁴⁶ Therefore there is little additional room for small businesses or other online retailers to reach these patients.

8. What modifications, if any, should be made to the Rule to increase its benefits to businesses, including small businesses?

- a. What evidence supports the proposed modifications?**
- b. How would these modifications affect the costs the Rule imposes on businesses, including small businesses?**
- c. How would these modifications affect the benefits to consumers?**

As we outline in our comments, the Coalition believes that there are several modifications that can be made to the Rule that will increase its benefits to patients as well as small businesses such as independent practices owned by a doctor of optometry or ophthalmologist. We believe that streamlining the process by which doctors, which are often also small business owners, communicate with these large online retailers by requiring a dedicated channel of communication and eliminating “robocalling” would ease the burdens on small eye care practices. We also believe that simplifying the process by which patients and eye care professionals are able to report potentially dangerous and misleading activities by large online retailers would serve the dual purpose of increasing patient safety and benefit these small practices.

9. What significant costs, if any, including costs of compliance, has the Rule imposed on businesses, including small businesses? What evidence supports the asserted costs?

Many of the practices discussed in our comments reflect costs to small practices that are focused on serving and treating patients. When any doctor substitutes time they should focus on patient care with time spent unsuccessfully attempting to reach a retailer in order to correct an incorrect or false prescription or report potentially dangerous activity to the FTC, that time results in costs to that business, whether large or small.

⁴⁶ <http://www.judiciary.senate.gov/hearings/watch?hearingid=12e98234-5056-a032-52ea-90f98e940d9b>

10. What modifications, if any, should be made to the Rule to reduce the costs imposed on businesses, including small businesses?

a. What evidence supports the proposed modifications?

b. How would these modifications affect the benefits provided by the Rule?

As we address in our comments, the Coalition believes that the overall review of the Contact Lens Rule should focus on patient safety and maintaining the relationship between the patient and their doctors, which are often also small business owners. The resulting savings in cost to a small business should only be a byproduct of policies that protect patient's vision health.

11. What evidence is available concerning the degree of industry compliance with the Rule?

The Act was intended to allow sufficient patient access to their prescribed contact lenses. The Act specifically preempted state laws with respect to prescription expiration dates of fewer than one year after the issue date, and allows for states to permit prescriptions longer than one year. However, it is clear that some, if not many retailers are misleading patients as to the need for a prescription at all, or are encouraging patients to purchase large amounts of contact lenses beyond what is reasonably necessary for the duration of a prescription. The Coalition urges the FTC to strengthen the Act by adding reasonable quantity limits to the prescription to correct this practice and protect the patients served by this FTC regulated industry. The Coalition urges the FTC to consider enforcement mechanisms that provide meaningful deterrents to bad actors in the system that will greatly decrease the number of improper dispensing of contact lenses and the associated ocular health conditions. As laid out in our comments, the Coalition believes that the FTC should utilize its enforcement authority to protect patients by increasing the investigations and associated penalties assessed to violators of the Act.

12. What modifications, if any, should be made to the Rule to account for changes in relevant technology or economic conditions? What evidence supports the proposed modifications?

The Coalition urges the FTC to redesign the passive verification process to ensure that retailers are not able to readily circumvent the prescription expiration requirements. Our comments reflect our belief that the passive verification system could be "modernized" to reflect the changes in the contact lens marketplace. We believe the FTC should exercise its authority to define the "communication" between a seller and a provider to not include the practice of robocalling. The Coalition also believes that providing doctors and patients with a more streamlined, dedicated complaint process will enable them to alert the FTC to potentially dangerous practices before the harm, and cost, is inflicted.

13. Does the Rule overlap or conflict with other federal, state, or local laws or regulations? If so, how?

a. What evidence supports the asserted conflicts?

b. With reference to the asserted conflicts, should the Rule be modified? If so, why, and how? If not, why not?

The Coalition believes that the FTC and the FDA share the responsibility for the health and safety of contact lenses and contact lens wearers. Evidence of this overlap exists in the FDA's website. In its Contact Lens section, it states: "If you find a Web site you think is illegally selling contact lenses over the Web, you should **report it to FDA.**" The FDA allows for the reporting of unlawful sales of medical products on the Internet.

The FDA evaluates these medical devices for safety and efficacy assuming that the contact lenses will be marketed as a prescription medical device. The FDA can only make reliable determinations about the utilization of these devices with certainty that the FTC is utilizing its jurisdiction to ensure that contact lenses are not misbranded by online retailers as an over-the-counter device dispensed without a valid prescription.

Currently, the FTC requests all complaints regarding contact lenses be submitted through a "generic" Complaint Assistant online form. To file report related to contact lenses, individuals must first know to select "other" and then "health and fitness." Should they appropriately make these selections, the FTC asks if the individual has a concern with telemarketing practices as it relates to the National Do Not Call registry. It is only after navigating the gauntlet of these selections and questions that the patient or doctor is asked about the retailer specifically. This can be a confusing and onerous process for confused patients as well as busy doctors. The Commission should work with the FDA to design a more streamlined complaint system.