



January 30, 2017

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

By electronic submission

Re: Proposed Rule Concerning the Contact Lens Rule, 16 CFR Part 315, Project No. R511995; RIN 3084-AB36

Dear Secretary Clark:

The Coalition for Patient Vision Care Safety (“Coalition”) submits these comments in response to the above-referenced proposed rule¹ that was issued by the Federal Trade Commission (“FTC” or “Commission”) in December 2016. The proposed rule (“Proposed Rule”) was issued pursuant to the FTC’s 10-year regulatory review of the Contact Lens Rule,² which implements the Fairness to Contact Lens Consumers Act³ (the “Act”). In September 2015, the Commission requested comments from the public for purposes of its regulatory review,⁴ and those comments are addressed in the Proposed Rule.

The Coalition consists of healthcare providers, medical device manufacturers, and academic institutions supported by patient advocacy and health research organizations.⁵ We recognize the safety risks involved in wearing contact lenses, and our mission is to promote the eye health of patients. The Coalition seeks to ensure that the balance struck in the Act between two important public policy goals—competition and safety—is maintained. We are concerned that, to the detriment of patients, the Proposed Rule does not fully achieve this balance.

Congress intended for patients to receive their written prescriptions in order to promote competition in retail sales of contact lenses. Equally important, Congress intended that the Act safeguard patients’ eye health. Eye care professionals (prescribers) are dedicated to protecting the well-being of their patients and act to ensure that those patients use contact lenses—a type of medical device—safely and appropriately to achieve the best outcomes regarding vision and eye health. Congress certainly did not intend to establish policies that would hinder the ability of eye care professionals to play their proper role in maintaining the health of the patient; however, the

¹ 81 Fed. Reg. 88526 et seq. (December 7, 2016).

² 16 CFR part 315; 69 Fed. Reg. 40482 et seq. (July 2, 2004).

³ Public Law 108-164 (15 U.S.C. 7601 et seq.).

⁴ 80 Fed. Reg. 53272 et seq. (September 3, 2015) (FTC September 2015 Request for Comments).

⁵ The executive members of the Coalition are the American Optometric Association (AOA); Alcon (a Novartis company); Bausch + Lomb; CooperVision; and Johnson & Johnson Vision Care.

Coalition believes that certain aspects of the original Contact Lens Rule have had this effect in actual practice. The Proposed Rule, unfortunately, fails to address this fundamental problem.

Specifically, the Coalition urges the Commission to address patient-safety issues concerning passive-verification robocalls, excessive-quantity sales, and lens substitution. Each of these issues has a potential significant effect on eye health. Moreover, taken together, these issues create a system whose de facto effect is to treat the purchase of contact lenses as a mere economic transaction, without sufficient regard to the need for the patient to undergo regular eye-health examinations. This is contrary to the intent of Congress and is contrary to the recommendations of the Food and Drug Administration (“FDA”) and the Centers for Disease Control and Prevention (“CDC”).

Further, it is important to note that contact lenses are regulated by the FDA as class II or III medical devices since they are worn on the eye and interact with the delicate ocular tissues. They are a safe and effective form of vision correction; however serious eye injury—such as scarring, infection, allergic reactions, corneal ulcers, and impaired or even lost vision—may result from problems associated with wearing contact lenses and using contact lens care products. To reduce these risks, periodic eye examinations are extremely important for contact lens wearers. Therefore, the “Standard of Care” dictates that patients who wear contact lens need to see their eye care professional on a regular basis in order to determine proper ocular response and to ensure ongoing safe and effective wear. These “Precautions and Warnings” are clearly outlined in FDA-mandated package inserts.

In the Proposed Rule, the Commission is not proposing action on robocalls, excessive-quantity sales, or lens substitution. In contrast, it is proposing a requirement for prescribers to have their patients sign an acknowledgement confirming that they have received their prescriptions. This proposal does little to advance the goals of the Contact Lens Rule and is overly burdensome.

As explained in greater detail below, the Coalition recommends the following for the Commission’s consideration:

- With respect to the verification procedures, the FTC should not consider robocalls to be within the Act’s definition of “direct communication”. In practice, this would likely mean that e-mails would become the preferred method of communication for many sellers.
- The Commission should implement reasonable sales quantity limits when the seller has actual knowledge of a prescription’s expiration date. Selling excessive numbers of lenses has the effect of discouraging patients from seeing their eye care professionals regularly in accordance with public health recommendations.
- The FTC should prohibit online sellers from suggesting to a patient that reordering contact lenses before the prescription expires will avoid the need to “see your doctor” about whether an updated prescription is needed.
- The Commission should increase its enforcement activities with respect to sellers illegally substituting contact lenses for the lenses specified in the prescription.

- The FTC should not establish a signed acknowledgment requirement for prescribers, as the quality of evidence is not sufficient to support the need for this requirement.

I. Overview

A. Brief Summary of the Act

When a licensed prescriber completes a contact lens fitting, the Act requires the prescriber to provide the patient a copy of the contact lens prescription, whether or not requested by the patient.⁶ This is known as the “automatic release requirement”.⁷ The terms “fitting” and “prescription” are defined.⁸ The definition of “prescription” includes the issue date and the expiration date, but not the lens quantity to be purchased.

A seller may sell contact lenses only in accordance with a contact lens prescription for the patient that is (1) presented to the seller by the patient or prescriber directly or by facsimile; or (2) verified by direct communication.⁹ The verification process, therefore, applies only when the prescription has not been presented to the seller. The term “direct communication” is defined as including communication by telephone, facsimile, or electronic mail.¹⁰

Under the verification process, the seller is required to provide certain information to the prescriber, such as the lens quantity to be purchased; the manufacturer; technical lens information (e.g., power and base curve); the date and time of the verification request; and contact information for the seller (including facsimile and telephone number).¹¹ The list of required information does not include the expiration date of the prescription. When there is an exchange of statements between the prescriber and the seller, the prescription is considered verified if (1) the prescriber confirms for the seller that the prescription is accurate; or (2) the prescriber informs the seller that the prescription is inaccurate and provides the accurate prescription to the seller.¹²

A seller is prohibited from filling the prescription if the prescriber states to the seller that the prescription is inaccurate, expired, or otherwise invalid and that statement is provided within eight business hours (or a similar time as defined by the FTC) after receiving the required information from the seller.¹³ When the prescriber finds that a prescription is invalid, the prescriber must specify to the seller the basis for the inaccuracy or invalidity of the prescription.¹⁴ The reasons for which the prescriber can consider the prescription to be inaccurate

⁶ Section 2(a) of the Act (15 U.S.C. 7601(a)).

⁷ Proposed Rule at 88530.

⁸ Under section 11 of the Act, the term “fitting” is defined as the process that begins after the initial eye examination and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in prescription is required. The term “prescription” is defined as including the name of the patient; the date of examination; the issue date and expiration date; name of the prescriber and contact information; power, material or manufacturer or both; base curve or appropriate designation; diameter, when appropriate; and as applicable, information concerning private label contact lens.

⁹ Section 4(a) of the Act.

¹⁰ Id. at section 4(g).

¹¹ Id. at section 4(c).

¹² Id. at section 4(d)(1), (2).

¹³ Id. at section 4(e).

¹⁴ Id.

include the quantity of contact lenses to be sold.¹⁵ If the prescription is inaccurate but not expired, the prescriber is required to correct it.¹⁶

If the prescriber has received the required information and fails to communicate with the seller within the period of business hours referred to above, the prescription is considered to be verified and therefore the sales transaction may proceed.¹⁷ This is known as “passive verification”.¹⁸

Sellers are prohibited from altering a contact lens prescription, except that if the same contact lens is manufactured by the same company and sold under multiple labels to individual providers, the seller may fill the prescription with a contact lens manufactured by that company under another label.¹⁹

The expiration date of a prescription must be at least one year after the issue date, and may be longer than one year after the issue date if the law of the State involved specifies a longer period, except that the prescriber may specify a shorter period than otherwise would apply based on the medical judgment of the prescriber with respect to the ocular health of the patient.^{20, 21}

B. Congressional Intent Regarding Eye Health; FDA and CDC Recommendations

Concerns about eye health were emphasized during the floor debate leading to the Act’s final passage by the House of Representatives in 2003:

[Under the Act] patients are told they must go back regularly to their eye doctors and get their contact lens prescriptions renewed. If patients try to buy contact lenses with expired prescriptions, sellers by law cannot fill their orders.²²

* * *

While consumers have a right to shop for the best deal when purchasing contact lenses, Congress, doctors, and industry all have a duty and an interest in making sure that patient safety is not compromised in the process. The Food and Drug Administration

¹⁵ Contact Lens Rule at 40501 (“the quantity ordered may be a legitimate basis for a prescriber to treat a request for verification of a prescription as ‘inaccurate,’ because Congress indicated in section 4(c) of the Act that the quantity of lenses ordered is relevant information”); Proposed Rule at 88537 (footnote 130) (“if a prescription verification request lists a quantity of lenses that is excessive, the prescriber can deem such a request ‘inaccurate.’”)

¹⁶ Section 4(e) of the Act; Contact Lens Rule at 40502.

¹⁷ Section 4(d)(3) of the Act.

¹⁸ Proposed Rule at 88528.

¹⁹ Section 4(f) of the Act.

²⁰ *Id.* at section 5.

²¹ Other provisions of the Act include the following: (1) Under section 6, a manufacturer or seller may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription. (2) Under section 7, a prescriber may not waive or disclaim the liability or responsibility of the prescriber for the accuracy of the eye examination. (3) Under section 8, the FTC has rulemaking authority to carry out the Act. (4) Under section 9, a violation of the Act or a rule under the Act is treated as a violation of a rule under section 18 of the Federal Trade Commission Act regarding unfair or deceptive acts or practices. With respect to enforcing the Act, the Commission has the same jurisdiction, powers, and duties as it has under the Federal Trade Commission Act.

²² Statement by Representative Richard Burr, 149 Congressional Record 168 at H11563 (November 19, 2003) (relating to consideration of H.R. 3140). Representative Burr (now Senator Burr) was the lead House sponsor of the Act and was the Republican floor manager for its consideration.

mandates that contact lens sales require a valid prescription from an eye care professional. With the increasing prevalence of mail order contact lens providers, whether through the Internet or 1-800 numbers, I believe it is important we give consumers expanded access while adhering to the FDA requirements.²³

Clearly, eye health was a paramount concern for the authors of the Act. Congress intended that the recommendations of federal health agencies be followed. The FDA has the following advice for patients:

Wearing contact lenses puts you at risk of several serious conditions including eye infections and corneal ulcers. These conditions can develop very quickly and can be very serious. In rare cases, these conditions can cause blindness.²⁴

You can not determine the seriousness of a problem that develops when you are wearing contact lenses. You have to get help from an eye care professional to determine your problem.²⁵

Make sure your prescription is current. Don't order with an expired prescription, and don't stock up on lenses right before the prescription is about to expire. If you haven't had your eyes checked within the last year or two, you may have eye problems that you are not aware of, or your lenses may not correct your vision well.²⁶

Make sure that you get the exact brand, lens name, power, sphere, cylinder (if any), axis (if any), diameter, base curve, and peripheral curves (if any) noted on the prescription. If you think you've received an incorrect lens or brand, check with your eye care professional. (The correct brand is important because there are differences in the water content and shape among the brands.) Don't accept any substitution unless your eye care professional approves it.²⁷

Similarly, the CDC advises patients, "Visit your eye doctor yearly or as often as he or she recommends."²⁸ The agency further advises that "failure to wear, clean, and store [contact lenses] as directed can increase the risk of eye infections, such as microbial keratitis."²⁹

²³ Statement by Representative Jan Schakowsky, 149 Congressional Record 168 at H11563 (emphasis added). Representative Schakowsky, one of the original cosponsors of the Act, was the Democratic floor manager for consideration of the legislation. Her floor statement also noted that she is a contact lens user.

²⁴ FDA, "Contact Lens Risk"; available at <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/ContactLenses/ucm062589.htm>.

²⁵ Id.

²⁶ FDA, "Focusing on Contact Lens Safety [. . .] Tips for Buying" (emphasis added); available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048893.htm>.

²⁷ Id.

²⁸ CDC, "You only have one pair of eyes, so take care of them! Healthy Habits = Healthy Eyes [. . .] Your Eye Doctor"; statement available at <https://www.cdc.gov/contactlenses/protect-your-eyes.html>.

²⁹ CDC, "Healthy Contact Lens Wear and Care"; statement available at <https://www.cdc.gov/contactlenses/>.

The Coalition strongly agrees with the FDA and CDC and is, therefore, respectfully requesting the Commission to do more to address patient-safety concerns.³⁰ Over 40 million Americans wear contact lenses, but the risks involved in not receiving regular eye-health examinations are often not fully appreciated. It is important to bear in mind that contact lenses are regulated by the FDA as medical devices. Many patients use extended-wear contacts, which are in the highest risk category of the device classification system under the Federal Food, Drug, and Cosmetic Act (class III).³¹ All other types of contact lenses are in class II.³²

C. FTC’s General Reaction to Safety Concerns

The FTC acknowledges in the Proposed Rule that “the use of contact lenses involves significant health issues” and therefore “the Act requires that contact lenses be sold only to patients with valid prescriptions”.³³ The Commission could do more to promote ways of addressing the eye-health concerns highlighted by the FDA and CDC. When the FTC has initiated the rulemaking process under the Act, it generally has not discussed any of the risks these public health agencies have raised with respect to contact lenses. Specifically, these risks were not discussed in the Commission’s proposed rule in 2004³⁴ or in the request for public comments in September 2015.³⁵ The Commission’s discussions of risk factors have largely been in response to public comments.

In the Proposed Rule, the Commission states that “[m]any commenters discussed the fact that the use of contact lenses presents certain eye health risks”,³⁶ but the agency concludes that it “does not find the evidence proffered in this Rule review sufficient to support a conclusion that the Rule inadequately protects consumer eye health.”³⁷

This statement from the FTC highlights one of our chief concerns—that the Commission’s approach with the Contact Lens Rule has minimized the safety risks raised by prescribers, even though the FDA and CDC warn patients about exactly the same risks. As explained below, the FTC is acting on the basis of survey and anecdotal evidence submitted by sellers, but at the same time is dismissing concerns and proposals of eye care professionals, manufacturers and other commenters that are based on the same types of evidence. In weighing the evidence (and apparently the credibility of prescribers), it refers to prescribers’ pre-enactment “long history of failing to provide prescriptions to patients even when obligated by state law”.³⁸ The agency, however, ignores the statement of the lead sponsor of the Act in the House of Representatives that “many contact lens sellers do not ask for physicians’ contact information because the sellers have no intention of verifying the prescriptions. Multiple provisions in this bill will make this behavior illegal.”³⁹

³⁰ This position of the Coalition has been mischaracterized by some commenters as an effort to stifle access to affordable contact lenses. See e.g., https://www.ftc.gov/system/files/documents/public_comments/2015/10/00614-99428.pdf (page 2).

³¹ 21 CFR 886.5916, 886.5925; see section 513(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a)(1)).

³² Id.

³³ Proposed Rule at 88527.

³⁴ See 69 Fed. Reg. 5440 et seq. (February 4, 2004).

³⁵ See FTC September 2015 Request for Comments.

³⁶ Proposed Rule at 88529.

³⁷ Id. at 88530.

³⁸ Id. at 88530 (footnote 71) and 88532.

³⁹ Statement of Representative Burr, 149 Congressional Record 168 at H11563.

It is best at this point to move beyond general characterizations of prescribers and sellers. The objective is to serve the interests of patients. Their interests are served by having a choice of sellers, which results in competitive pricing. Equally, the interests of patients are served by heeding the advice of the FDA and CDC concerning eye health, as intended by Congress. As noted, one author of the Act stated that “Congress, doctors, and industry all have a duty and an interest in making sure that patient safety is not compromised”. Another author stated that the Act tells patients “they must go back regularly to their eye doctors and get their contact lens prescriptions renewed.”

As explained below, however, passive-verification robocalls and last-minute excessive-quantity sales work against the health interests of patients and reflect an attitude that the purchase of contact lenses is a mere economic transaction. Perhaps the FTC believes that safety issues are the responsibility of the FDA and CDC, not the Commission. These public health agencies, however, have no authority to take action regarding robocalls; they have no authority to take action regarding excessive-quantity sales. These practices by sellers should be prohibited. The FTC should also prohibit online sellers from suggesting to a patient that reordering contact lenses before the prescription expires will avoid the need to “see your doctor” about whether an updated prescription is needed.

II. Robocalls

Due to the use of robocalls by sellers, prescribers are often unable to provide the proper verification of the patient’s prescription information within eight business hours, triggering the passive verification. As a result, patients may receive contact lenses based on outdated or incorrect prescription information.⁴⁰

The Commission declined to prohibit robocalls⁴¹ and made no other proposals to address the issues their use creates. With respect to the verification procedures, the FTC takes the position that the changes requested by prescribers are not necessary because the procedures under section 4 of the Act already give prescribers the ability to ensure that sales of contact lenses are made only with valid prescriptions.⁴² This ignores marketplace realities. The Coalition generally supports the passive verification procedures because we recognize that there must be a deadline for responses by prescribers in order to facilitate competition. At the same time, we strongly believe that the Commission has the authority and the duty under the Act to modernize the verification procedures to give prescribers a meaningful opportunity to address the safety concerns raised by Congress, the FDA, and the CDC.

Robocalls do not provide prescribers with a meaningful opportunity to respond to sellers. The legislative history for the Act includes the statement that “[i]t is the intent of the Committee that ‘direct communication’ means a message has been both sent and received. Transmitting the request . . . does not, in and of itself, constitute a direct communication.”⁴³ Unlike other forms of communication (e.g., e-mail), robocalls often do not meet this standard for direct

⁴⁰ See Proposed Rule at 88539.

⁴¹ Id. at 88541.

⁴² Id. at 88546 (“no amendment is necessary because the current regulatory framework sufficiently prohibits the use of expired prescriptions”).

⁴³ Committee on Energy and Commerce, House Report 108-318 at 10 (October 15, 2003) (relating to H.R. 3140).

communication. Robocalls impose significant operational costs on prescribers by forcing them to obtain information that was missing, incomplete, or unintelligible in the robocall, which in turn could affect whether the patient received the correct contact lens. Their use does not achieve overall efficiencies and costs savings for the verification system.

The FTC's position on robocalls has created a public health problem. When a patient goes through the online process of purchasing contact lenses, it may be legal under the Contact Lens Rule for there to be no mention—by the seller or the prescriber—of the issue of whether the purchase order is contrary to the prescription or whether it is time for the patient to receive an eye-health examination and an updated prescription. This results from the combination of (1) online purchase options that make no reference to the expiration date, and (2) the use of passive-verification robocalls. This is not the marketplace reality envisioned by Congress in writing the Act.

In declining to prohibit robocalls, the Commission focused on objections from sellers. One seller explained that it has found that automated telephone calls are the most efficient means of handling the large volume of verification requests it receives, and that it has invested significant resources in developing its automated-call system.⁴⁴ The Coalition responds that the key consideration is the health of the patient, as recognized in the Act. The use of robocalls has a negative effect on eye health, and the preferences of sellers cannot trump the health of patients. Also, the use of robocalls is not just a cost-and-convenience issue for sellers. Their use involves costs and inconvenience for prescribers. Sellers should not receive preference over prescribers with respect to the cost-and-convenience issue.

The Commission is, of course, correct that the Act's term "direct communication" includes communication by telephone. The Commission, however, determined—without any substantiation—that "telephone" is commonly understood to include automated telephone systems. It stated its concern that prohibiting robocalls would seem to be contrary to Congressional intent.⁴⁵ It also stated that "the Act does not permit prescribers to limit the communication mechanisms sellers may use to submit verification requests" because the Act specifies three different communication mechanisms that sellers may use—telephone, facsimile or electronic mail.⁴⁶

In light of the challenges evidenced by the use of robocalls, the FTC should use its powers to address this issue. Neither the Act nor its legislative history mention robocalls, and there is no indication that Congress considered the matter. The burden of robocalls on prescribers is in direct conflict with the public policy goal of Congress, as stated in the House floor debate on passing the Act, that the FDA requirements should be met. The Commission has the authority to interpret the statute to implement the intent of Congress. It has express rulemaking authority under section 8 of the Act.

The Commission should amend the Contact Lens Rule to prohibit robocalls. Other forms of communication meet the standard of "direct communication". For example, e-mails are an extremely efficient way of communicating a verification request. They have substantial

⁴⁴ Proposed Rule at 88539.

⁴⁵ Contact Lens Rule at 40489; Proposed Rule at 88540.

⁴⁶ Proposed Rule at 88542.

advantages over robocalls—they automatically create a written record; they are legible, and they provide an easy, efficient way for prescribers to respond if there is a problem.

III. Quantity Limits

Some sellers make available quantities of contact lenses far in excess of the number required for the remaining life of a prescription. This practice undermines FTC and FDA requirements that contact lenses must be sold under a valid prescription. It has the de facto result of influencing patients to avoid regular visits to their eye care professionals. The Commission itself acknowledged that stockpiling lenses close to the expiration date indicates intent to avoid appointments with eye care professionals, and it cautioned sellers in this regard.⁴⁷

The Coalition and its individual members have provided a significant amount of information to the FTC regarding excessive-quantity sales. For example, the Commission acknowledged a survey by Johnson & Johnson Vision Care, Inc. showing that “58% of the online consumers that were surveyed indicated that they had received an email or letter from their retailer reminding them that their prescription was expiring soon and that the majority of these consumers had ordered more lenses as a result.”⁴⁸ These reminders occurred when the prescriptions were about to expire and the quantity of lenses offered by the sellers far exceeded the remaining life of the prescription.

In declining to adopt proposals for quantity limits, the Commission claimed, unpersuasively, that there is a lack of evidence and there are implementation challenges.

One of the situations contemplated by section 4 of the Act is when the seller has the prescription and therefore has actual knowledge of the expiration date. When the seller has the prescription, there is no requirement for verification and therefore the prescriber does not have the opportunity to prevent an excessive-quantity sale. An example is a high quantity of contact lenses sold in the 11th month of a one-year prescription. There is evidence that this occurs regularly. The Coalition recommends that, when the seller has the prescription, no sale should exceed a supply of lenses necessary to last the remaining period of the prescription.

It is essential that sellers respect the terms of the prescription and that the Commission enforce the Rule in a way recognizing the integrity and importance of the period of the prescription’s validity. That is the basis of the Coalition’s recommendation that, in no case, should any sale exceed the supply necessary for the life of the prescription.

Moreover, the above recommendation of the Coalition would not be difficult to administer. When the seller has the actual prescription, it has actual knowledge of the expiration date. It knows the typical rate of usage and therefore knows the typical quantity that would constitute a supply lasting the remaining period of the prescription.

Turning to enforcement matters, the Coalition recommends (in addition to the above recommendations) that the Commission bring enforcement actions in cases where sellers knowingly violate the terms of a prescription. This includes cases, not only when the prescription has actually expired, but also when the sale is for a supply of lenses that is far in excess of the

⁴⁷ Id. at 88549.

⁴⁸ Id. at 88548.

number required for the remaining life of the prescription. While the Rule does not clearly state that the sale of excessive quantities of lenses would violate the Rule, that conclusion is clearly implied. For example, in a case where the seller has the prescription, the seller can only sell lenses “in accordance with a contact lens prescription”. See section 315.5(a) of the Rule. A sale that the seller knows far exceeds the life of the prescription is not “in accordance with . . . a prescription” and should be considered to be a violation of the Rule. The same principle should apply when the seller becomes aware of the expiration date, through the patient or otherwise. The Coalition recommends that the Commission enforce this limitation and issue an enforcement policy statement indicating that is the Commission’s interpretation of the Rule.

IV. Substitutions

With respect to the issue of contact lenses substitutions (the alteration of contact lenses prescriptions by sellers), the FTC acknowledged comments from prescribers that contact lenses are being treated like commodities, rather than restricted medical devices regulated by the FDA, and that contact lenses, even those with similar refractive specifications, are not interchangeable. Prescribers further noted the harm that could result, such as scarring, infection, allergic reactions, corneal ulcers, impaired or even lost vision.⁴⁹

The Commission decided that “unauthorized alterations violate the Rule as currently written, and thus there is no need to amend the Rule to address this issue.”⁵⁰ It also declined to require, as recommended by one commenter, that sellers be required to provide a substitution warning statement with each order because “we have no evidence that the benefit of imposing such a requirement on sellers would outweigh the costs.”⁵¹

Given that the FTC stated that “[i]t is unclear how frequently illegal substitutions are occurring, or how many sellers are engaged in this activity”,⁵² the Coalition urges the Commission not to take the position (as it implied) that it will take action only if it receives further evidence that sellers are engaged in illegal substitutions.⁵³ The Commission has already received a significant number of comments expressing concerns about illegal substitutions. As noted by the FDA, patients may be at significant risk from substitutions; therefore, the Commission should increase enforcement efforts in this regard. It noted that “the rule review process has been instrumental in identifying areas that need further investigation.”⁵⁴ The Coalition urges the FTC to consider illegal substitution to be among such areas.

V. Automatic Prescription Release; Signed Acknowledgment Form

The FTC proposes to establish a signed acknowledgment requirement.⁵⁵ In other words, the prescriber must request that the patient acknowledge receipt of the contact lens prescription by signing a form once the prescriber has presented the prescription to the patient.⁵⁶ The Commission further proposes to require that “prescribers maintain the signed acknowledgments

⁴⁹ Id. at 88551.

⁵⁰ Id. at 88552.

⁵¹ Id.

⁵² Id. at 88551.

⁵³ See id. at 88552.

⁵⁴ Id. at 88554.

⁵⁵ Id. at 88534.

⁵⁶ Id. at 88535.

for a period of not less than three years, so that the signed acknowledgments are available for inspection by the Federal Trade Commission.”⁵⁷

This proposal, offered in response to allegations that prescribers do not provide patients with copies of their prescriptions, is unnecessary and is not sufficiently supported by the evidence. If the FTC is convinced that some action should be taken in response to these allegations, alternative approaches should be used, such as strengthening education campaigns.

In addition, independent of the issue of whether establishing a signed acknowledgment requirement is good public policy, the FTC’s evidentiary approach to deciding the issue is important for procedural reasons. It raises the issue of whether the Commission has truly been impartial in its deliberations. Apparently, the FTC accepts survey and anecdotal evidence from sellers but not from prescribers and manufacturers. Accordingly, the Commission has decided in favor of establishing a signed acknowledgment requirement but against prohibiting robocalls and excessive-quantity sales.

Consider the evidence relied upon by the FTC to support establishing a signed acknowledgment requirement. In the Proposed Rule, the Commission noted that several commenters stated that “prescribers routinely fail to comply with the automatic prescription release requirement” and that these comments “are, in general, concordant with complaints the Commission has received from numerous consumers apart from this rule review process.”⁵⁸

The Commission, however, realized that some consumer complaints may be inaccurate:

Some consumer complaints . . . may be based on a misunderstanding of the Rule, as there can be confusion about when or under what conditions patients should receive their prescriptions. For example, the Rule requires that a prescription be provided after the completion of the contact lens fitting, not necessarily at the conclusion of the initial visit with the prescriber. Because a fitting may not be complete until a follow-up visit, a patient might incorrectly believe that she should have been provided with her prescription at the conclusion of the first visit.⁵⁹

In addition, the Commission conceded that “[m]any reports of compliance and noncompliance are anecdotal, and robust empirical data are sparse.” It stated that it would consider survey evidence, although it would “prefer better empirical evidence about compliance and noncompliance” and it does not consider survey evidence to be “definitive”, but rather only “suggestive”.⁶⁰

It then concluded that “the overall weight of evidence in the rulemaking record—including the surveys, the high number of verifications, the ongoing pattern of consumer complaints and anecdotal reports, and the industry’s long history of failing to provide prescriptions to patients

⁵⁷ Id.

⁵⁸ Id. at 88530.

⁵⁹ Id. at 88530-88531.

⁶⁰ Id. at 88531.

even when obligated by state law—indicates that compliance with the automatic prescription release provision could be substantially improved.”⁶¹

The Commission continues that it “acknowledges, however, that the absence of documentation makes it difficult to determine whether a prescriber did or did not provide a patient with a prescription”.⁶²

The Coalition does not understand how or why the FTC concluded that the evidence was sufficient to support a decision to establish a signed acknowledgment requirement. It references a finding by unidentified sources that roughly three-quarters of third-party contact lens sales require prescription verification;⁶³ it then states that “[s]eemingly contrary to this data” are survey results provided by Johnson & Johnson Vision Care;⁶⁴ and it concludes that “[t]he Commission does not have enough data or insight to determine if either of these surveys accurately reflects industry practice.”⁶⁵ But notwithstanding that conclusion, the Commission states that “[t]he sheer number of verifications conducted by third-party sellers also may suggest that many consumers are not automatically receiving their prescriptions from prescribers, or are not receiving complete prescriptions.”⁶⁶

It does not seem consistent for the FTC to take action on the basis of the “sheer number of verifications” when it concedes it “does not have enough data or insight to determine if either of these surveys accurately reflects industry practice” (particularly when the source of one of those “surveys” is unidentified “discussions with industry”). Even if one assumes for discussion purposes that the number of verifications is high, the Commission itself offers the possibility that “some consumers could have received their prescriptions from prescribers but misplaced them, forgot them, or simply thought it easier to obtain the refraction information from their contact lens boxes.”⁶⁷ Moreover, the Commission states that “[i]t is also evident, based on the comments submitted, that many prescribers feel there are too many verification requests, and that it would be helpful if more patients provided a copy of their prescription to sellers rather than rely on the verification process.”⁶⁸ It is not logical to assume that these “many” prescribers are complaining about the number of verification requests concerning their patients but are failing to provide copies of prescriptions to those patients. It is logical to assume from those complaints that, for whatever reason, patients themselves may be responsible for the number of verification requests. Indeed, some patients with expired prescriptions may have realized that the online process for ordering contact lenses includes an option that does not prompt them to provide the expiration date of the prescription.

The conclusion of the Commission regarding a signed acknowledgment requirement is in stark contrast to its responses to requests from prescribers and manufacturers for changes to the

⁶¹ Id. at 88532; see id. at 88530 (footnote 71).

⁶² Id. at 88533.

⁶³ Id. at 88531 (“[a]ccording to discussions with industry, roughly three-quarters of third-party contact lens sales require prescription verification”).

⁶⁴ Id. (the survey found that 61 percent of responding patients gave the prescription to retailers the last time they purchased lenses online or by telephone).

⁶⁵ Id.

⁶⁶ Id.

⁶⁷ Id. at 88531-88532.

⁶⁸ Id. at 88532.

Contact Lens Rule for safety-related reasons. The Commission declined to make those changes because, for example:

- There was not “any *empirical evidence* showing that the passive verification mechanism has actually resulted in the renewal of expired prescriptions.”⁶⁹
- “Commenters did not provide *sufficient reliable empirical evidence* that the current Rule leads to the increased acquisition of contact lenses without a valid prescription or increased incidence of contact lens related eye disease or adverse eye conditions.”⁷⁰
- “Other examples of patient harm identified by commenters were either *hypothetical or anecdotal*.”⁷¹
- With respect to concerns about purchases without valid prescriptions, commenters “provided *anecdotal* examples of patients who avoided regular eye examinations by purchasing lenses online.”⁷²

Yet, in deciding to establish a signed acknowledgment requirement, the Commission conceded that consumer complaints may be inaccurate, that many reports of compliance and noncompliance are anecdotal, and that robust empirical data are sparse. It acknowledged that the absence of documentation makes it difficult to determine whether a prescriber did or did not provide a patient with a prescription. It relied on complaints received “apart from this rule review process.”⁷³ It accepts with respect to competition concerns the same types of evidence it rejects with respect to safety concerns. It decided to impose new requirements on prescribers but not on sellers.

In weighing the evidence (and apparently the credibility of prescribers), the FTC emphasizes that, before the Act was enacted, prescribers had a “long history of failing to provide prescriptions to patients”, but ignores the statement of the lead House sponsor of the Act that “many contact lens sellers do not ask for physicians’ contact information because the sellers have no intention of verifying the prescriptions. Multiple provisions in this bill will make this behavior illegal.”

VI. Conclusion

The marketplace for contact lenses has changed significantly since the Contact Lens Rule was issued in 2004. As noted by the Commission, the U.S. market for contact lenses has grown from an estimated annual \$3.3 billion in 2006 to between \$4 billion and \$5 billion, and the estimated online sales percentage of the market has grown from less than 13 percent in 2006 to 18 percent. Moreover, 16 percent of the online sales are from online-only companies (no brick-and-mortar retail facilities).⁷⁴ Approximately 44 million people now use contact lenses, and the Coalition believes that circumstances have changed significantly since the Contact Lens Rule was first adopted. As noted above, some market practices—such as passive-verification robocalls and

⁶⁹ Id. at 88529 (emphasis added).

⁷⁰ Id. at 88530 (emphasis added).

⁷¹ Id. at 88529 (emphasis added).

⁷² Id. at 88530 (emphasis added).

⁷³ Id.

⁷⁴ Id. at 88528.

excessive-quantity sales—can threaten patient safety. As a result, the Rule is not following the intent of Congress that the FTC should appropriately balance the public-policy goal of providing access to affordable lenses and the public-policy goal of protecting the eye health of patients in accordance with the recommendations of the FDA and CDC.

In the Proposed Rule, the Commission is careful to present the views of all commenters, but in the end, the agency apparently accepts survey and anecdotal evidence from sellers but not from prescribers and manufacturers. The Coalition reluctantly concludes that the decisions made by the Commission in the Proposed Rule appear to be arbitrary and capricious.

The Coalition believes there are commonsense approaches the FTC could adopt that would effectuate the intent of Congress and be consistent with the eye-health recommendations of the FDA and CDC. Our recommendations are as follows:

- With respect to the verification procedures, the FTC should not consider robocalls to be within the Act’s definition of “direct communication”. In practice, this would likely mean that e-mails would become the preferred method of communication for many sellers.
- The Commission should implement reasonable sales quantity limits when the seller has actual knowledge of a prescription’s expiration date. Selling excessive numbers of lenses has the effect of discouraging patients from seeing their eye care professionals regularly in accordance with public health recommendations.
- The FTC should prohibit online sellers from suggesting to a patient that reordering contact lenses before the prescription expires will avoid the need to “see your doctor” about whether an updated prescription is needed.
- The Commission should increase its enforcement activities with respect to sellers illegally substituting contact lenses for the lenses specified in the prescription.
- The FTC should not establish a signed acknowledgment requirement for prescribers, as the quality of evidence is not sufficient to support the need for this requirement.

The Coalition appreciates this opportunity to provide these comments on the Proposed Rule and thanks the FTC for considering the comments.

Sincerely,

The Coalition for Patient Vision Care Safety