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*Submitted electronically via Regulations.gov*

July 29, 2019

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

**Re: Contact Lens Rule Review, 16 CFR part 315, Project No. R511995**

Dear Acting Secretary Tabor:

Johnson & Johnson Vision Care, Inc., ("Johnson & Johnson Vision") appreciates the opportunity to submit these comments in response to the Federal Trade Commission's (the "Commission") Supplemental Notice of Proposed Rulemaking ("SNPRM") following its 2016 Notice of Proposed Rulemaking ("NPRM") and its scheduled 10-year review of the 2004 Contact Lens Rule (the "Rule").

## I. Introduction and Overview of Johnson & Johnson Vision's Response

The contact lens market and eye health landscape are changing. As the global market leader in contact lenses and as part of our expansion into broader eye health needs, Johnson & Johnson Vision believes it has never been more important to ensure that our regulatory framework promotes patient eye health and safety.

As we have consistently shared with the Commission, Johnson & Johnson Vision supports growth and competition in the contact lens marketplace, while prioritizing eye health, and the assurance that patients receive the exact contact lenses they were prescribed by their eye care professional. As the market evolves, this assurance is critical to preserving eye health for the growing number of patients choosing contact lenses for vision correction and other benefits. It is professional oversight of contact lens wear that ensures we can continue to deliver innovative products to address unmet patient needs.

We would like to thank the Commission for considering our unique perspective and recommendations in its review of the Rule and as included in the SNPRM. We reaffirm our commitment to continuing to work with the Commission moving forward.

Johnson & Johnson Vision offers these comments and recommendations to the Commission on the following issues to ensure that patients have access to the contact lenses they were prescribed:

- **Prescription Alteration**
  - Expanded Definition of Prescription Alteration
  - Seller Requirement to Accept Prescription Presentation
  - Removal of the Term "Private Label"
- **Prescription Verification**
  - Additional Requirements for Sellers Using Automated Telephone Verification Messages
- **Automatic Prescription Release**
  - Confirmation of Prescription Release
- **Promoting Digital Mechanisms to Ensure Prescription Accuracy**
- **Response to Commission's Questions**

## II. Johnson & Johnson Vision's Response to Proposed Changes in the SNPRM

### A. Expanded Definition of Prescription Alteration

Johnson & Johnson Vision acknowledges the Commission's evolution on the issue of prescription alteration and appreciates both its firm affirmation of prescription alteration as illegal, and its recognition that prescription alteration is a growing problem in the market. We thank the Commission for considering our perspective on this issue, including clear consideration (as noted in the preamble of the SNPRM) of the testimony at the 2018 Contact Lens Workshop from both Johnson & Johnson Vision's past President for North America, Peter Menziuso, as well as our former Clinical Research Fellow and Head of Applied Sciences, Dr. Carol Lakkis.

The Commission raised several questions in the SNPRM regarding the incidence and risks of illegal contact lens substitution. With respect to the risks associated with illegal substitution, data shows that no single lens can provide a healthy ocular response for every single patient, and contact lenses are not freely interchangeable because each one interacts differently with the ocular surface.[1] The fit of each contact lens is based on the patient's lifestyle, eye anatomy, and physiology and the ocular response must be evaluated over time in order to provide healthy vision correction that minimizes the risk of potentially sight-threatening complications.[2]

Wearing any type of contact lens can lead to a variety of complications, from mild discomfort to severe adverse events, like inflammation and infection.[3] [4] We believe adverse events like inflammation and infection are important factors to consider in the discussion about illegal substitution because they have both health and economic implications, which can be reduced with eye care professional oversight.

A tight lens fit may, for example, be comfortable for a patient, but in some cases significantly increase the risk of corneal inflammation or infection.[5] While patients may experience obvious symptoms and remove their lenses when uncomfortable, several asymptomatic adverse events from mechanical events to infiltrative keratitis can occur without the patient knowing.[6] [7] Microbial keratitis ("MK"), an infection of the cornea and the most serious complication of contact lens wear, can result in permanent loss of vision.[8]

The annualized rates of MK in soft contact lens wear are estimated to be 2-4 per 10,000 in daily wear per year and 20 per 10,000 in extended wear per year.[9] When you consider this data in relation to the sheer number of contact lens wearers in the U.S. today—45 million—it is not insignificant.

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[1] Young G, Coleman S. Poorly fitting soft lenses affect ocular integrity. CLAO J 2001; 27: 68-74.
[2] Efron, N. (2018). *Contact Lens Practice*, Third ed. Elsevier, p. 364-384.
[3] Alipour, F., Khaheshi, S., Soleimanzadeh, M., Heidarzadeh, S., & Heydarzadeh, S. (2017). Contact Lens-related Complications: A Review. Journal of ophthalmic & vision research, 12(2), 193-204. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5423374/.
[4] Dumbleton, K. (2002, September). Adverse events with silicone hydrogel continuous wear. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/16303486./
[5] Ozkan, J., Preeji, M., Pravin, K., Sankaridugr, P., Naduvilath, T., Willcox, M., & Holden, B. Risk Factors for Corneal Inflammatory and Mechanical Events with Extended Wear Silicone Hydrogel Contact Lenses. *Optometry and Vision Science.* (2010). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3061493/
[6] Lin, M., & Yeh, T. (2017, December 06). Mechanical complications induced by silicone hydrogel contact lenses. Retrieved January 16, 2019, from https://escholarship.org/uc/item/3gc209bt
[7] Steele, Kelsy R., and Loretta Szczotka-Flynn. "Epidemiology of Contact Lens-induced Infiltrates: An Updated Review." The Canadian Journal of Chemical Engineering. September 04, 2017. Accessed January 15, 2019. https://onlinelibrary.wiley.com/doi/full/10.1111/cxo.12598
[8] O'Brien, K. S., Lietman, T. M., Keenan, J. D., & Whitcher, J. P. (2015). Microbial keratitis: a community eye health approach. *Community eye health*, *28*(89), 1-2.
[9] Stapleton, Fiona, Lisa Keay, Katie Edwards, and Brien Holden. "The Epidemiology of Microbial Keratitis With Silicone Hydrogel Contact Lenses." Eyes & Contact Lens39, no. 1 (January 2013). Accessed January 15, 2019. https://reference.medscape.com/medline/abstract/23172318.

Nearly one million people in the U.S. [10] experience eye infections or eye inflammation annually, and this takes an economic toll. In 2010, the total economic burden for keratitis (including infectious and noninfectious) and contact lens related diagnostic codes was $174.9 million on the U.S. economy, including $58 million in costs for Medicare patients and $11.9 million in costs for Medicaid patients.[11]

We believe this data underscores the importance of eye care professional oversight of contact lens wear and patients' access to their prescribed lenses. As the Commission cited in the SNPRM, and as explained by Dr. Malvina Eydelman at the 2018 Contact Lens Workshop, "the current clinical care paradigm does not support substitution of contact lens brands without a clinical evaluation".[12] The Commission has recognized this point as consistent with its continued adherence to the Rule's prohibition on illegal alteration.

> **Recommendation:** Johnson & Johnson Vision supports the Commission's proposed change to expand the definition of prescription alteration under Section 315.5(f) to include instances where a seller dispenses a brand or manufacturer of lenses other than that expressly prescribed.

*Expanded Definition of Prescription Alteration: Exception for Patient Prescription Entry*

The Commission has proposed to include an exception to the definition of prescription alteration, whereby a seller would not be responsible in instances where the patient alters their own prescription to include a brand or manufacturer other than the one on their prescription, and asks whether this provision would have an impact on the incidence of prescription alteration.

While we recognize this exception could serve as guidance for sellers to determine when they are responsible or not for an illegal prescription alteration, we believe the proposed definition of prescription alteration should be implemented without exception. The range of parameters included on a contact lens prescription varies, and we have concerns about a patient's ability to correctly enter their information given the nuances of a contact lens prescription and the meaning of the different elements therein. This practice may contribute to passive verification of an inaccurate prescription, and thus, illegal substitution.

For example, a soft contact lens prescription can be comprised of up to 11 different parameters for each eye, which could be confusing for patients who don't understand the meaning of and differences between each parameter. Common mistakes from patients attempting to communicate their contact lens prescription include, for example, confusing the plus and minus symbols in the sphere power (i.e., plus for hyperopia and minus for myopia), stating the base curve value as being the diameter or vice versa, confusing the sphere and cylinder powers in an astigmatism prescription, or confusing the sphere and add powers in a multifocal prescription.

> **Recommendation:** Johnson & Johnson Vision requests that the Commission strike the following clause from the proposed change to expand the definition of prescription alteration under Section 315.5(f): "*unless such name is provided because the patient entered it on the seller's order form when asked for the manufacturer or brand listed on the patient's prescription, or the patient orally gave the seller the name in response to a request for the manufacturer or brand listed on the patient's prescription."*

[10] Rettner, Rachael. "1 Million US Eye Infections Yearly, Most Due to Contacts." LiveScience. November 13, 2014. Accessed January 11, 2019. https://www.livescience.com/48747-eye-infections-contact-lenses.html.

[11] Collier, S., Gronostaj, M., MacGurn, A., Cope, J., Awsumb, K., Yoder, J., Beach, M. "Estimated Burden of Keratitis - United States, 2010." Centers for Disease Control and Prevention. November 14, 2014. Accessed January 11, 2019. https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6345a3.htm

[12] See CLR Panel II Tr., supra note 296, at 8. Dr. Eydelman also noted that additional research is needed to support clinical equivalency between lens brands.

*Expanded Definition of Prescription Alteration: Direction for Sellers*

If the Commission elects to move forward with its exception to allow patients to alter their own prescriptions, then we believe it will be important to clarify that it should not be interpreted as encouraging prescription alteration by the patient or encouraging sellers to direct a patient to provide a brand or manufacturer other than that listed on their prescription. Rather, it should serve as guidance for sellers as to when they are or are not responsible for incidence of prescription alteration, provided the alteration was done by the patient and without any suggestion of encouragement, even tacitly, by the seller.

> **Recommendation:** If the Commission chooses to proceed with the exception to allow patients to alter their own prescriptions, then Johnson & Johnson Vision requests that the following clarifying language be added to preamble section of the Rule to discourage improper manipulation of such an exception: *"This exception is intended to provide explicit direction for sellers as to when they are responsible for instances of prescription alteration. Under no circumstances may a seller, wishing to avail themselves of this exception, direct, encourage, motivate, or suggest, either implicitly or explicitly, that a patient enter any manufacturer or brand other than that listed on the patient's prescription."*

*Expanded Definition of Prescription Alteration: Mechanism for Patient Prescription Entry*

If the Commission elects to proceed with the exception to allow patients to alter their own prescriptions as outlined in the SNPRM, we agree that a seller should not be able to avail itself of the exception by relying on a prepopulated or pre-selected box in an online/digital form, or customers' online searches for a particular brand or manufacturer as a representation that they do in fact have a prescription for that brand or manufacturer. Additionally, we believe that the Commission should explicitly clarify that "drop down menus" and similar tools should not be interpreted as an appropriate means for a seller to avail itself of this exception under these definitions.

> **Recommendation:** Johnson & Johnson Vision requests that the Commission revise the preamble section of the Rule that provides direction for Section 315.5(f) as follows: *"A seller would only be able to avail itself of the exception by providing a mechanism for the patient to affirmatively enter his or her prescription through an open-response field. A prepopulated, preselected, or "drop-down" selection menu would be insufficient to avail the seller of this exception."*

B. Requirement to Accept Prescription Presentation

Johnson & Johnson Vision believes that the Commission's proposal to require that sellers provide patients with a mechanism for presenting them with their prescriptions is an important step in establishing a record of the prescription as written by the eye care professional, or paper trail, and would hopefully reduce the instances of sellers' verification attempts for an incorrect prescription or verification requests in general.

In response to the Commission's question about whether this proposal would decrease the incidence of illegal alterations, we believe that it could do so. With the proliferation of camera phones and the ease of texting, emailing, or even uploading pictures, there is no reason that such a requirement should be a hurdle for any patient or seller. Creating a mechanism to support a digital record of a patient's prescription is an effective way to ensure an accurate paper trail—consistent with evolving technology.

> **Recommendation:** Johnson & Johnson Vision supports the Commission's proposal to add Section 315.5(g) to require that sellers provide patients with a mechanism for presenting their prescriptions.

C. Removal of the Term "Private Label"

Johnson & Johnson Vision acknowledges that the Commission's proposal to expand the definition of prescription alteration will place additional guardrails around the practice of alteration.

We believe, however, that the term "private label" remains an important distinction to specify the only instance in which prescription alteration is permissible, particularly as the market continues to evolve and this clear direction may become more necessary. We understand that this is also consistent with the Commission's current positioning on the only acceptable instances of prescription alteration.

We recommend that if the Commission is to finalize its proposal to remove the term "private label" as currently included under Section 315.5(e) that it clarify that removal of the term should not be interpreted as allowing flexibility around prescription alteration.

> **Recommendation:** Johnson & Johnson Vision requests that the Commission add clarifying language to the preamble section of the Rule that provides direction for Section 315.5(e) such as: *"Removal of the term 'private label' is not indicative of the Commission's direction to add flexibility around prescription alteration. The omitted term continues to indicate by definition the only instance in which prescription alteration is permissible."*

D. Additional Requirements for Sellers Using Automated Telephone Verification Messages

In 2004, the Commission determined that it would permit automated telephone systems as a valid means of direct communication, citing that it would be contrary to congressional intent to prohibit the use of this technology.[13] However, in doing so, it recognized that automated telephone systems may create problems, and as such, it would continue to carefully monitor the market.

Johnson & Johnson Vision appreciates the Commission's recognition of the problems associated with automated telephone systems. In our 2015 comments in response to the Commission's 10-year review of the Rule, we noted that most consumers (65%), rely on the existing verification process to validate their prescription prior to sale[14]—indicating a clear need to ensure that this process, when necessary, is accurate and contributes to patients receiving the correct lenses as indicated on their prescriptions.

We are concerned that interpretation of automated telephone systems as consistent with congressional intent of the Fairness to Contact Lens Consumers Act (the "Act") may be counter to testimony provided during hearings examining the Act. During a September 2003 hearing, congressional members[15] and the CEO of a major online contact lens retailer[16] made statements critical of automated telephone verification, stating explicitly that fax or another verifiable method were the preferred prescription verification methods for contact lens prescriptions.

Given this testimony on the Act, the current reliance on the verification process, and the steps the Commission has proposed in this SNPRM to strengthen the prescription paper trail, we believe that the most effective way to ensure accurate verification by telephone is to ban the use of automated telephone systems. It is our understanding, however, that the Commission continues to believe that it would be contrary to the intent of the Act to prohibit their use for the purpose of prescription verification and on these grounds, declines to expressly ban them (suggesting that a change of this nature would need to be done legislatively).

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[13] Contact Lens Rule, 16 CFR part 315 (2004).

[14] APCO Insight September 24 – October 2, 2015 online survey among adult contact lens consumers 18 years of age or older who have purchased contacts online in the last six months on behalf of Johnson & Johnson Vison Care, Inc.

[15] *Fairness to Contact Lens Consumers Act: Hearing before the Subcommittee on Commerce, Trade, and Consumer Protection of the Committee on Energy and Commerce* (H. hrg. 108-41), U.S. House, 108th Cong. (2003) p. 215.

[16] *Id*. at p. 220

**Recommendation:** Johnson & Johnson Vision requests that the Commission amend Section 315.5(a)(2) to clarify that automated telephone systems are not a permissible method of direct communication via telephone for the purpose of prescription verification.

*Additional Requirements for Sellers Using Automated Telephone Verification Messages: Commission's Proposed Requirements*

Should the Commission elect to maintain that automated messages are an acceptable method of verification via telephone, we would then request that it implement additional requirements around how these messages must be delivered. We continue to believe consistent verification of contact lens prescriptions should not include reliance on automated telephone technology, use of which can ultimately lead to patients receiving incorrect lenses and suffering adverse health outcomes.

**Recommendation:** We support the Commission's proposal to amend Section 315.5 to require that if a seller verifies a prescription through calls that use, in whole or in part an automated message it must: 1) record the entire call; 2) commence the call by identifying it as a request for a prescription verification, 3) provide the verification information in 315.5(b) in a slow and deliberate manner and at a reasonably understandable volume, and 4) give the prescriber the option to repeat this information.

*Additional Requirements for Sellers Using Automated Telephone Verification Messages: Johnson & Johnson Vision Additional Proposed Requirements*

In the SNPRM, the Commission recognizes the burden on prescribers, and importantly—the potential health risk to patients from incomplete or incomprehensible automated telephone messages. Therefore, we believe it would be prudent to take additional steps to ensure these automated telephone messages protect patient health and safety and contribute to the accurate dispensing of prescriptions

**Recommendation:** We request that the Commission amend its proposed Section 315.5(d) to additionally require that if a seller verifies a prescription through calls that use, in whole or in part an automated message, the seller must:

i. Submit a transcript of the message(s) it will use in the recording to the Commission for review and approval;
ii. Confirm that the call was answered by a live person during business hours before the request is considered initiated;
iii. Confirm the call was made to the office of a legitimate eye care professional;
iv. Provide a centralized call-back number staffed by a live person for prescribers' use;
v. Provide an option as part of the message, whereby the recipient may elect an alternate means to receive the request and an alternate timeframe after which the window to respond to verification requests must be completed; and
vi. Keep on file the recording of each verification attempt made by automated message for a period of no less than three years.

E. Confirmation of Prescription Release

Johnson & Johnson Vision declines to comment specifically on the Commission's modified proposal to amend Section 315.3 to add a confirmation of prescription release. However, consistent with the intent of the Act and the Rule, we believe that all patients should have access to a copy of their prescription. Therefore, we believe that if the Commission elects to finalize this proposal it should ensure the requirement applies universally to all prescribers.

Section 315.3(c)(3) notes that the confirmation of prescription release includes exceptions for prescribers that do not have a direct or indirect financial interest in the sale of contact lenses. We believe that as the relationship between prescribers and sellers change, there is a need to "future proof" the prescription release process to better ensure that patients always receive a copy of their prescription—and ensure this provision continues to be consistent with the intent of the Act.

Although the exceptions included may sufficiently cover our current understanding of contractual agreements between prescribers and sellers, these circumstances may evolve as the market itself evolves.

**Recommendation:** Johnson & Johnson Vision requests that should the Commission finalize its proposal to amend Section 315.3 to add a confirmation of prescription release, that it strike Section 315.3(c)(3).

## III. Additional Recommendation

### A. Promoting Digital Mechanisms to Ensure Prescription Accuracy

Johnson & Johnson Vision appreciates the proposals the Commission has put forth to strengthen the verification process and ensure that patients are dispensed the lenses they are prescribed. In addition to instances in which an incorrect prescription, including the incorrect brand or manufacturer is passively verified—which the Commission has clearly recognized as an issue—we are aware of incidences where a patient may for example, submit to a seller an illegitimate eye care professional, or the contact information for a practice at which they are not a patient.

It has been publicly reported that online sellers have filled contact lens orders for patients based upon prescription information entered by the patient that indicates a phony eye care professional as the prescriber—or a health care professional that does not prescribe contact lenses.[17] We recognize that patients have always had the ability to alter their prescription and cannot be held liable, but we believe examples like this further underscore the need to reinforce the Commission's intent to create a paper trail for patients' prescriptions and reduce reliance on the verification process.

We interpret the Commission's proposals to 1) amend Section 315.3(a)(1) to allow prescribers to satisfy the automatic prescription release requirement with a digital copy of a patient's prescriptions, and 2) adding Section 315.5(g) to require that sellers provide patients with a mechanism for presenting them with their prescriptions, as indications of its intent to promote the use of technology to minimize prescription errors or inaccuracies.

**Recommendation:** If our interpretation is correct, we ask that the Commission provide additional clarification and guidance in the preamble that provides direction for Section 315.5 of the Rule indicating for example: *"flexibility indicated for prescribers to offer a digital method of prescription release and the requirement that sellers provide patients with a method for presenting their prescriptions, are consistent with the Commission's intent to encourage the use of digital technology to ensure prescription accuracy and reduce reliance on the verification process".*

[17] Griswold, Alison. *"Contact lens startup Hubble sold lenses with a fake prescription from a made-up doctor".* Quartz (December 14, 2017). https://qz.com/1154306/hubble-sold-contact-lenses-with-a-fake-prescription-from-a-made-up-doctor/.

*Promoting Digital Mechanisms to Ensure Prescription Accuracy: Johnson & Johnson Vision Request of the Commission*

We understand that monitoring utilization of the verification process will be crucial to determine the effectiveness of proposals to amend and add Sections 315.3(a)(1) and 315.5(g) respectively—and the proposal encouraging the use of digital technology to ensure prescription accuracy in the preamble—should the Commission elect to adopt it.

**Recommendation:** As such, Johnson & Johnson Vision requests that the Commission acknowledge the need for, and establish a process for monitoring prescription verification utilization upon adopting new requirements that strengthen the prescription paper trail.

## IV. Response to Commission's Questions

Johnson & Johnson Vision offers the following answers to the Commission's questions in addition to our comments. These questions are labeled per the sections and question numbers provided in the SNPRM from pages 115- 118.

A. Confirmation of Prescription Release

*Q 20, Page 115:* Under the Commission's proposal, the confirmation of prescription release and the accompanying recordkeeping provision shall not apply to prescribers who do not have a direct or indirect financial interest in the sale of contact lenses, including, but not limited to, through an association, affiliation, or colocation with a contact lens seller. Aside from associations, affiliations, and colocations with contact lens sellers, what other indirect financial interests exist in the sale of contact lenses that should disqualify a prescriber from the proposed exemption?

**Recommendation:** Johnson & Johnson Vision expects that relationships between prescribers and sellers will likely continue to change with the evolution of the marketplace. Although the exceptions currently included may sufficiently cover our current understanding of vested financial interest and contractual agreements between prescribers and sellers, these circumstances may evolve as the market itself evolves.

We believe there is a need to "future proof" the prescription release process to better ensure that patients always receive a copy of their prescription—and ensure this provision continues to be consistent with the intent of the Act, which is why we recommend the Commission strike Section 315.3(c)(3).

*Q 21, Page 116*: How do contact lens manufacturers compete for consumer business? Do they compete directly for consumers or compete to have eye-care prescribers prescribe their lenses? To what extent do eye-care prescribers choose to prescribe primarily one manufacturer's contact lenses based on financial considerations?

**Recommendation:** Johnson & Johnson Vision recognizes that we are one manufacturer of many—and that choice and competition are what make our market work. For us, competition is about the patient—innovating to address still unmet patient needs in the contact lens market and the broader eye health space. We recognize that our lenses may not always be the appropriate selection for a patient, but support an environment that offers patients that range of options and motivates us to continue to innovate.

We respect and honor the decision to prescribe our lenses as part of the eye care professional-patient relationship. We defer to the eye care professional to work closely with their patient to determine the most appropriate lenses for that patient's needs, whether ours, or those of another manufacturer.

B. Automated Telephone Verification Messages

*Q 2, Page 117*: Would each of the proposed modifications address the concerns raised by prescribers about incomprehensible or incomplete automated messages? If so, how?

**Recommendation:** Johnson & Johnson Vision believes that the Commission has taken important steps to ensure that automated telephone messages are less burdensome and contribute to the accurate verification of prescriptions through its current proposals. We believe however, that automated messages continue to present challenges and are ultimately not the most effective and accurate method of prescription verification by telephone—which is why we requested that they be expressly removed from the Rule as a permissible form of direct communication.

While the Commission's proposed modifications may alleviate some of the burden associated with these messages, we believe there are additional modifications the Commission may consider should it choose to move forward with finalizing its proposals.

These include requiring that if a seller verifies a prescription through calls that use, in whole or in part an automated message, it must:

i. Submit a transcript of the message(s) it will use in the recording to the Commission for review and approval;
ii. Confirm that the call was answered by a live person during business hours before the request is considered initiated;
iii. Confirm the call was made to the office of a legitimate eye care professional;
iv. Provide a centralized call-back number staffed by a live person for prescribers use;
v. Provide an option as part of the message, whereby the recipient may elect an alternate means to receive the request and an alternate timeframe after which the window to respond to verification requests must be completed; and
vi. Keep on file the recording of each verification attempt made by automated message for a period of no less than three years.

C. Illegal Prescription Alteration

*Q 4, Page 117:* Would the proposed amendment requiring sellers to accept prescription presentation increase, decrease, or have no effect on the incidence of illegal alterations? Why?

**Recommendation:** Johnson & Johnson Vision believes strongly that this amendment would decrease the incidence of illegal alterations. We believe this is one key proposal of several brought forth by the Commission that encourages a strong prescription paper trail and likely reduces reliance on the prescription verification process.

*Q 5, Page 117:* Would the proposed amendment requiring sellers to accept prescription presentation increase, decrease, or have no effect on the number of verification requests that prescribers must respond to?

**Recommendation:** Johnson & Johnson Vision believes strongly that this amendment would decrease reliance on the verification system and thus the number of verification requests to which a prescriber must respond. Again, we believe this is one of the key proposals of several brought forth by the Commission that encourages a strong prescription paper trail and likely reduces reliance on the prescription verification process.

*Q 6, Page 118:* Under the proposed amendment, a verification request that includes a manufacturer or brand provided by, or identical to that provided by, the consumer would not be deemed an alteration of a prescription. Would this provision increase, decrease, or have no effect on the incidence of alterations of prescriptions? Why? What risks to patients, if any, would result?

**Recommendation:** Johnson & Johnson Vision is concerned that this provision may contribute to increased incidence of prescription alteration, which is why we recommend striking this exception from Section 315.5(f). If the Commission elects to maintain the exception as part of its proposal, we believe it will be important to ensure that it does not encourage patients to enter their own prescription information, or allow sellers to encourage patients to do thus, thus contributing to incidence of prescription alteration. That is why we support, as mentioned:

i. Clarifying language in the preamble section of the Rule, such as: *"This exception is intended to provide explicit direction for sellers as to when they are responsible for instances of prescription alteration. Under no circumstances may a seller, wishing to avail themselves of this exception, direct, encourage, motivate, or suggest, either implicitly or explicitly, that a patient enter any manufacturer or brand other than that listed on the patient's prescription."*
ii. Revision to the preamble section of the Rule that provides direction for Section 315.5(f) as follows: *"A seller would only be able to avail itself of the exception by providing a mechanism for the patient to affirmatively enter his or her prescription through an open-response field. A prepopulated, preselected, or "drop-down" selection menu would be insufficient to avail the seller of this exception".*

*Q 7, Page 118:* What risks, if any, are associated with the substitution of contact lenses different and not identical to the manufacturer or brand of lenses fitted and prescribed by the prescriber? Would the proposed amendment increase, decrease, or have no effect on these risks?

**Recommendation:** Contact lenses are complex medical devices that interact directly with the delicate tissues of the eye. They differ from each other, not only based on material—which affects oxygen permeability, tear film structure and interaction, water content, lubricity, and surface deposition—just a few factors that play a role in ocular biocompatibility, but also on other common parameters such as base curve, power, and diameter.[18] However, even with similar base curve and diameters, the eyes' physiological reaction can differ because contact lenses also vary based on modulus (stiffness), sagittal height, wettability, edge design, etc. [19] [20]

No single lens can provide a healthy ocular response for every single patient, and contact lenses are not freely interchangeable because each one interacts differently with the ocular surface. [21] Risks associated with illegal substitution include a variety of physiological reactions, such as corneal disruption (staining), growth of new blood vessels into the cornea (neovascularization), conjunctival staining and increased redness, to contact lens inflammation and potentially infection.[22]

[18] Wagner, S., Conrad, F., Bakaraju, R., Fedtke, C., Ehrmann, K., Holden, B.. "Power Profiles of Single Vision and Multifocal Soft Contact Lenses." Contact Lens & Anterior Eye, 2015; 38: 2-14. Accessed January 15, 2019. https://www.sciencedirect.com/science/article/pii/S1367048414000800.
[19] Van der Worp E, Mertz C. Sagittal Height Differences of Frequent Replacement Silicone Hydrogel Contact Lenses. Contact Lens & Anterior Eye. 2015; 38: 156-162. Accessed January 15, 2019. https://www.sciencedirect.com/science/article/pii/S1367048415000065.
[20] Walline, Jeffrey J., OD PhD. "Are Contact Lenses Interchangeable?" 2017. Accessed January 11, 2019. https://www.jnjvisioncareinfo.com/sites/default/files/2017-03/OSU%20CONTACT%20LENS%20LIT%20REVIEW.pdf.
[21] Young G, Coleman S. Poorly fitting soft lenses affect ocular integrity. CLAO J 2001; 27: 68-74.
[22] Walline, Jeffrey J., OD PhD.

We believe the proposed amendment would help to decrease the incidence of illegal substitution however, and as mentioned above, the exception to the amendment may unintentionally encourage prescription alteration and illegal substitution.

When patients enter their own prescription, there is the potential to increase inaccuracies in how the prescription is relayed and subsequently contribute to incidence of illegal substitution—whether the fault of the seller or not.

*Q 8, Page 118:* In what circumstances does a contact lens prescription indicate a particular material, brand, or manufacturer because of the prescriber's medical judgment about the ocular health of the patient (for example, because the patient's astigmatism requires toric lenses)? Are these circumstances common?

**Recommendation:** Under all circumstances, the particular material, brand, or manufacturer included on a contact lens prescription should be determined based on clinical guidelines, such as the Optometric Clinical Practice Guideline for Care of the Contact Lens Patient, which includes for example the requirement of an ocular health assessment as well as the collection of thorough patient medical and ocular history. [23]

Contact lens fitting involves a comprehensive assessment of ocular health, in addition to considering other therapeutic, occupational and behavioral considerations.

These include for example consideration such as: whether the patient needs a correction for both distance and near (presbyopic/multifocal lenses), whether they have allergies where sensitivity to a certain lens solution may be an issue, or whether they have a history of eye disease that would impact safety of lens wear.

## V. Conclusion

Contact lens wear is not risk-free, even with our strong regulatory framework today. That is why we continue to support policies that ensure patients receive the lenses they were prescribed by their eye care professional—to ensure their health and safety and confidence in the contact lens marketplace.

Johnson & Johnson Vision again thanks the Commission for its careful review of these issues to ensure that as the market continues to change, there is consideration for contact lens choice and access alongside patient safety.

We are committed to serving as a resource to the Commission throughout this rulemaking process and welcome an opportunity to follow up in person as necessary to discuss our comments or other issues.

Sincerely,

/s/ Thomas Swinnen

Thomas Swinnen
President, North America
Johnson & Johnson Vision Care, Inc.

[23] American Optometric Association, Optometric Clinical Practice Guideline Care of the Contact Lens Patient. https://www.aoa.org/documents/optometrists/CPG-19.pdf.