

UNITED STATES OF AMERICA Federal Trade Commission Washington, D.C. 20580

Office of the Chairman

TO:April TaborFROM:Michael PesinDATE:October 31, 2019SUBJECT:Contact Lens Rule: Summary of comments to be placed on the public record

On October 9, 2019, representatives of the Health Care Alliance for Patient Safety ("APS") met with FTC Chairman Joseph J. Simons and other agency staff¹ to discuss amendments to the FTC's Contact Lens Rule ("Rule") proposed in the May 2019 Supplemental Notice of Proposed Rulemaking ("SNPRM").

APS is comprised of health care providers, medical device manufacturers, vision insurers, and online contact lens sellers that support the need for heightened awareness regarding threats to a patient's eye health and safety.

APS explained that prescribers are complying with the Rule and are giving patients their prescriptions. APS supports the SNPRM's proposal to require that contact lens sellers provide a mechanism that would allow patients to present their prescriptions directly to the seller because it provides a more reliable method than passive verification to transfer a patient's prescription information to the seller, while also creating a paper trail.

APS asserted that the FTC should increase enforcement actions against contact lens sellers that are violating the Rule. Specifically, it believes that the FTC should verify that sellers are selling contact lenses exactly as prescribed by the physician. APS explained that when a patient purchases contact lenses from a retailer, the doctor does not know the exact contact lens purchased; only the reseller knows this information. APS proposed that the seller should be required to retain a record of the sale and provide it to the prescribing doctor.

APS noted that 1 in 4 consumers reported receiving a different brand of contact lenses than they had ordered without any notification. A Johnson & Johnson survey showed that 94% of consumers believe that it is important to receive the exact brand of contact lens they order.

APS explained that brand substitution not only may have consequential health impacts, but also undermines the doctor-patient relationship. APS explained that freely substituting contact lenses could result in significant injury, including keratitis, corneal ulcers, and impaired or full loss

¹ In attendance on behalf of the Health Care Alliance for Patient Safety were Dr. Deanna Alexander, O.D. and Chase Cannon. In attendance on behalf of CooperVision was Clay Arnold. In attendance on behalf of Johnson & Johnson were Dr. Mike Mayers, O.D. and Riley Swinehart. In attendance on behalf of the American Optometric Association was Matt Willett. In attendance on behalf of Cornerstone was Susan Sweat. In attendance from the FTC were Chairman Joseph J. Simons, Morgan Kennedy, Michael Pesin, Mary K. Engle, Andrew Wone, and Richard Cleland.

of vision. Moreover, APS stated that illegal substitutions undermine patients' confidence when they cannot be guaranteed they are receiving the exact lenses prescribed to them by their doctor. APS explained that when contacts do not fit correctly, patients may stop wearing contacts altogether. APS also expressed concern about the possibility that patients may provide an online contact lens retailer with a manufacturer or brand not specified by their prescriptions when ordering contact lenses online. The SNPRM proposes to amend the prohibition on seller alteration of prescriptions by specifying that alteration includes a seller providing the prescriber with a verification request with the name of a manufacturer or brand other than that specified by the patient's prescriber, unless such name is specifically provided by the patient. APS urged the Commission to clarify that a patient providing the name of a manufacturer or brand not prescribed does not supersede what was indicated on the patient's prescription so that the patient receives exactly what the doctor prescribed.

APS expressed concern about the Commission's proposal to permit automated telephone calls for prescription verification. APS noted that an automated verification call may allow a patient to receive a different contact lens than was prescribed because there may not be a way for the prescriber to respond to the call to correct the prescription. In addition, APS explained that automated verification calls are burdensome for prescribers' offices because they require someone to transcribe the prescription information transmitted in the phone calls. APS estimated that the average office receives approximately 6-10 verification requests per day.

Instead of the SNPRM's proposal to address incomplete or incomprehensible automated telephone verification messages, APS explained that it supports elimination of the use of automated telephone calls as a verification method. According to APS, other methods of verification, such as a live phone call, fax, or email, provide for more efficient and accurate verification of prescriptions. APS acknowledged that while some prescribers may not have email, they would likely have fax machines.

Finally, APS expressed concern that the SNPRM did not address issues surrounding the sale of excessive quantities of contact lenses. APS explained that contact lens retailers encourage consumers to reorder more lenses when their prescriptions are nearing expiration. APS expressed concern that this practice encourages consumers to stock up on their lens supply, thereby allowing them to forgo an eye exam with their doctor to renew their prescription. APS proposed that within the last 30-60 days of a valid prescription, there should be a cap on the number of lenses that a consumer can purchase. APS explained that it does not want to limit a consumer's choice regarding how many lenses to buy; rather, they want to encourage a consumer to discuss how many lenses are needed with her doctor.