



HEALTH CARE ALLIANCE FOR PATIENT SAFETY

May 11, 2020

Joseph Simons
Chair
Federal Trade Commission
600 Pennsylvania Avenue NW
Suite CC-5610 (Annex B)
Washington, D.C. 20580

Re: Patient Medical Device Safety During the Coronavirus (COVID-19) Public Health Emergency

Dear Chairman Simons,

The Health Care Alliance for Patient Safety (APS) is comprised of health care providers, medical device manufacturers, and vision insurers that support the need for heightened awareness regarding pressing threats to patients' eye health and safety. Our mission is to build public and government awareness of patient safety issues and advocate for the enforcement of laws designed to safeguard public health. We thank the Federal Trade Commission (FTC) for all that this agency has done in response to the COVID-19 public health emergency and appreciate the opportunity to provide these comments.

While doctors of optometry across the country are continuing to provide essential care for emergency issues, their hours and staff have been significantly reduced to comply with CDC guidance.¹ Recent Jobson Optical Research data shows that over 90% of respondents' practices are in a locality under a stay-at-home order, which means doctors are not in their offices unless there is an emergency issue.² The report also shows that up to 60% of optometrists have had to let go of staff as a result of the pandemic, and that 44.5% of those doctors have had to lay off their entire staff.

Given this data, APS urges the FTC to increase its enforcement of the federal patient health safeguards related to contact lens sales during this time. Our members are concerned that online contact lens sellers that continue to violate the patient safety standards as written in the Contact Lens Rule and the Fairness to Contact Lens Consumers Act (FCLCA) pose an increased risk to patient safety during the crisis.

Specifically, we ask for the FTC's immediate action to protect patients in these two areas:

1. Require online contact lens retailers use a written electronic means of communication for verifying a patient's contact lens prescription. In a time when many vision doctors' offices are closed indefinitely and short-staffed, written electronic communication, like e-mail, offers an easy, efficient and low-cost means of protecting patients' eye and vision health.
2. Scrutinize and examine certain contact lens retailers who are steering an increasing number of patients to their own brand of contact lenses that have not been prescribed or evaluated on the patients' eye, and are relying on outdated modes of prescription verification that can lead to prescription alteration.

¹ <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html>

² <https://jobsonresearch.com/coronavirus-ecp-study-wave-7/>

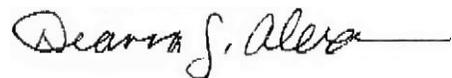
Certain online retailers' continuing use of antiquated robocall prescription verification is deeply disturbing during this pandemic when doctors are not physically in the office and/or do not have the staff capacity to answer the calls. Even during normal times, these robocalls require significant follow-up by doctors and their staff, as the information they provide is often incomplete, difficult/impossible to understand, or related to a person who has never been a patient of the eye doctor receiving the call. Additionally, they too frequently provide no option to replay the call to confirm the information or a valid call-back number to contact if the information about the prescription is incorrect.

The Centers for Disease Control and Prevention (CDC) estimates that 45 million Americans rely on contact lenses.³ When worn and cared for properly and as prescribed by an eye doctor, they are a safe and effective form of vision correction. However, failing to wear/care for lenses appropriately – or wearing contact lenses that were not evaluated and fit on the patient's eye by an eye doctor – can result in eye infections, acute trauma to the surface of the cornea, and in extreme cases, permanent vision loss.

Manufacturers and prescribers agree that substituting contact lenses can result in significant injury, including corneal ulcers and impaired or full loss of vision. One common adverse health event related to improper contact lens wear/the use of lenses is keratitis, a painful eye infection that leads to 1 million doctor and hospital visits annually, at a cost of \$175 million to the U.S. healthcare system.⁴ If we are to properly ensure patient safety and effectively expand available hospital capacity during the COVID-19 pandemic, we must close regulatory loopholes that allow for the sale of nonprescribed lenses that result in patient harm.

The APS supports the modernization of the contact lens prescription verification process⁵ and will continue to advocate for the use of written verification methods to ensure compliance on all sides. We appreciate the FTC's ongoing commitment to protect Americans⁶ and urge the Commission to conduct oversight and remain vigilant of practices within the contact lens online retailer space that could lead to patient harm. Thank you for your review of these comments and for your consideration.

Sincerely,



Deanna Alexander, O.D.
Chair, Health Care Alliance for Patient Safety

³ <https://www.cdc.gov/contactlenses/fast-facts.html>

⁴ <https://www.cdc.gov/media/releases/2014/p1113-eye-infections.html>

⁵ <https://www.congress.gov/bill/116th-congress/house-bill/3975/text?r=2&s=1>

⁶ <https://www.ftc.gov/news-events/blogs/competition-matters/2020/03/changes-bureau-procedure-during-covid-19-coronavirus>