



March 17, 2021

To Whom It May Concern:

The American Optometric Association (AOA) represents 33,000 doctors of optometry and optometry students. The AOA is the voice of the nation's doctors of optometry. We are writing during Patient Safety Awareness Week to notify you about our concerns with Amazon Alexa's partnership with WebEyeCare¹ and about this company's potential violations to federal medical device policy, which Amazon may not be aware of.

WebEyeCare² may be selling contact lenses without appropriately verifying and/or requiring a valid prescription, which is illegal under the Fairness to Contact Lens Consumers Act (FCLCA) (P.L. 108-164). While the AOA is not a regulatory enforcement entity, a central mission of the AOA is to serve as a resource to the public for reliable and current information related to eye care and health care policy.³ Considering Amazon's partnership with WebEyeCare via Alexa Skills, we would like to inform you of the regulatory and legal requirements that relate to the sale of contact lenses in the United States. The Food and Drug Administration (FDA) regulates contacts as medical devices. The improper wear and care of contact lenses can cause eye infections that can lead to serious, long-term damage, including vision loss. As such, we believe it is dangerous to consumers to sell such devices to individuals within the United States without appropriate prescriber supervision.

The FCLCA also includes certain patient protection provisions. The law indicates that a contact lens 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."⁴ WebEyeCare appears to allow for the sale of contact lenses without properly verifying contact lens prescriptions, which we believe is an FCLCA violation. An AOA member doctor of optometry informed our organization that individuals from "the Healthcare Division for Amazon Alexa" had called him on six separate occasions, leaving voicemails with phone numbers that he called back, but all calls go to voicemail. Therefore, he is unable to verify patient information that the company seeks since there is no appropriate means of contacting the "Amazon Alexa" healthcare representative. We would be interested in learning more about Alexa/WebEyeCare's partnership and how prescription verifications are conducted to ensure that all federal laws intended to protect patient eye and vision health are being followed.

Additionally, we are concerned with your partner's online vision test service.⁵ The AOA has long warned⁶ patients and the public about the dangers of these online services; there is currently no FDA-approved, at-home device or app that people can use to self-conduct all of the elements of a proper eye examination. Online vision tests like WebEyeCare's may give inaccurate or misleading information and can give

¹ <https://www.amazon.com/Webeyecare-com-Webeyecare/dp/B07T4PC5CB>

² <https://webeyecare.com/>

³ The U.S. Food and Drug Administration, the Federal Trade Commission, and various state agencies have enforcement authority over regulations governing the prescribing and sale of contact lenses.

⁴ <http://www.gpo.gov/fdsys/pkg/PLAW-108publ164/pdf/PLAW-108publ164.pdf>

⁵ <https://webeyecare.com/contacts-vision-test/>

⁶ <https://www.prnewswire.com/news-releases/aoa-warns-patients-to-be-cautious-of-at-home-eye-exam-or-vision-test-product-claims-301054321.html>

patients a false sense of security. By using WebEyeCare's vision test, which has been marketed by the company as a viable alternative to seeing a doctor (one advertisement even states: "No dilation or puffs of air required.") patients may delay their own or their children's essential, sight-saving treatment or, in even more serious situations such as patients with asymptomatic ocular melanoma, *life*-saving treatment. Our organization wanted to ensure that Amazon was aware that, as the leading authority on eye health, vision care, and patient safety issues, we do not support this aspect of your partner's business and believe it to be misleading and potentially dangerous for the consumers who use it.

When you made the business decision to partner with WebEyeCare through Amazon Alexa you may not have been fully aware of the legal and regulatory requirements that surround the sale of contact lenses as medical devices in the United States. At this point, we believe it is your responsibility to guarantee that your partners are compliant with federal laws and regulations governing the sale, marketing, and distribution of these medical devices. We urge you to review these legal and regulatory requirements carefully and consider your partnership with a company that is potentially evading these laws to the detriment of patient health.

Thank you for your attention to these concerns. Please contact AOA's Associate Director of Regulatory Policy, Emily Dalgo, edalgo@aoa.org with any questions.

Sincerely,

A handwritten signature in black ink that reads "William T. Reynolds O.D." The signature is written in a cursive style with a large, stylized 'W' and 'R'.

Bill Reynolds, O.D.
President, American Optometric Association