



March 31, 2017

The Honorable Jeff Sessions
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Ave, NW
Washington, DC 20530-0001

Re: Hubble Contacts

Dear Mr. Attorney General:

The American Optometric Association (AOA) hereby reports to you that Hubble Contacts, a nationwide distributor of contact lenses based in the State of New York appears to be engaged in a pattern of illegal and deceptive activity that includes repeatedly and deliberately using the internet and mail to market and sell contact lenses that have not been prescribed by doctors, while failing to appropriately verify contact lens orders with customers' physicians, all in direct violation of the Fairness to Contact Lens Consumers Act (15 U.S.C. Chapter 102). The AOA requests that the Department of Justice investigate this matter, which we believe represents an organized and sustained deception scheme that violates the law, including 18 U.S.C. §1341 (relating to mail fraud), §1343 (relating to wire fraud), and the Racketeer Influenced and Corrupt Organizations statute (18 U.S.C. Chapter 96), and is an active threat to public health and safety and patient confidence in the health care system.

The AOA is the voice of the nation's family eye doctors and the leading authority on eye health and vision care, representing more than 33,000 doctors of optometry and optometry students. As you may know, doctors of optometry prescribe the majority of contact lenses for patients in the United States. When prescribed by an eye doctor, contact lenses are an effective, safe, and popular choice for vision correction. However, the involvement of an eye doctor is essential to mitigating health risks associated with contact lens wear and ensuring that the use of contact lenses results in optimal vision for the patient.

It must be emphasized that contact lenses are Food and Drug Administration regulated, prescription-only 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).ⁱ All other types of contact lenses are in class II, which also requires substantial regulatory controls to provide assurance of safety and effectiveness.ⁱⁱ The sale of contact lenses without a prescription is unlawful and puts the public at direct risk as the lenses can be misused and cause serious eye injuries. As regulated medical devices that are placed directly on the eye, the process to determine the best contact lens for optimum eye health is extensive.ⁱⁱⁱ Once this process is complete and the best lens for the patient is selected, the doctor will provide the patient with their specific contact lens prescription.

Hubble Contacts' business model, according to its own marketing materials and our investigation, appears to be based around shipping its own brand of contact lenses to customers through the mail based on

orders taken over the internet, with deliberate disregard for whether the patient actually has a prescription for Hubble contacts (or any prescription at all). The company also is selling lenses without any concern for whether patients have been appropriately evaluated to wear the Hubble Contacts product. Our legal counsel has specific examples of the above activity by Hubble Contacts which I would be happy to share as part of any fact-finding investigation.

As an organization committed to public health and the safety of our patients, the AOA is prepared to serve as a resource for the Justice Department as this matter is investigated. We look forward to detailing our own findings at the earliest opportunity. I've directed Michael Stokes, Esq., AOA General Counsel, (1-(800) 365-2219 / mastokes@aoa.org) to be in contact with your office and to provide documentation as needed. Thank you for your consideration and decisive action.

Sincerely,



Andrea P. Thau, O.D.
President, American Optometric Association

ⁱ 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)).

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ⁱⁱⁱ The typical process for prescribing new contact lenses to a patient is as follows: an eye doctor performs a comprehensive eye examination; evaluating the tear film and corneal surface of the patient's eye, and measuring the corneal surface. Then the doctor will determine the most compatible lenses for a patient taking into consideration many factors (oxygen transmission; water content; lens thickness; corneal curvature; corneal diameter and prescription needs available). At that point, the doctor performs a trial fit on the patient. During this process, doctors may choose several lens types by various lens manufacturers to try on the patient's cornea for best fit and comfort. Once the lens is on the cornea, the doctor will examine the fit using a biomicroscope, and evaluate how the lens moves on the eye; how the lens responds to the patient's tears; the prevalence of protein deposits; and overall patient comfort. Only after this process is the prescription written for a specific brand of lens. During an annual checkup thereafter, the eye doctor performs a comprehensive eye examination, and evaluates whether the current prescription continues to be the correct one for the patient.