FDA Public Hearing: Drugs Compounded for Office-Use by Outsourcing Facilities
Testimony – Damien F. Goldberg, MD
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My name is Damien Goldberg, MD, and I am speaking today on behalf of the American Society of Cataract and Refractive Surgery (ASCRS) and the patients we serve. ASCRS is a medical specialty society representing nearly 9,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care.

We appreciate that the FDA is attempting to address our concerns with policies related to office-use that require a physician to obtain a compounded drug from an outsourcing facility if he or she does not have a patient-specific prescription by revising requirements related to stability testing, including flexibility when assigning beyond-use dates (BUDs), and testing requirements related to batch release. However, we are concerned that the revisions made in the revised draft guidance do not address the barriers in securing ophthalmic compounded drugs needed for office-use to treat emergent conditions because outsourcing facilities will not produce drugs in small quantities needed by ophthalmologists. We ask the FDA to allow physicians to obtain small quantities of drugs needed to treat emergent conditions without a patient-specific prescription.

ASCRS has repeatedly advocated that ophthalmologists need to have an immediate pathway to secure drugs for office-use to treat emergent conditions; however, FDA maintains that without a patient-specific prescription, a physician must obtain compounded products from an outsourcing facility. This is not a viable option for my colleagues or me when our patients present with emergent conditions because outsourcing facilities, even after FDA's revisions to the draft guidance, are not willing to compound in the quantities needed by ophthalmologists.

Every year, I have a couple of patients who visit my private practice in the South Bay region of Los Angeles, California, who present with a rare and potentially blinding eye infection called acanthamoeba keratitis. It's an infection caused by a microscopic ameba that lives in all types of water, including pools, lakes, and even the tap water in your home. Typically, the patients I see who present with acanthamoeba keratitis are young contact lenses wearers who have contracted the infection because they rinsed their contact lenses with tap water. The infection can be painful, sight-threating, and in severe cases, a corneal transplant may be necessary before complete loss of vision occurs. The infection may worsen significantly if not treated with compounded medication within hours.

Typically, these patients are given compounded polyhexamethylene biguanide (PHMB). The problem with obtaining compounded PHMB from outsourcing facilities to treat a patient with acanthamoeba keratitis is that it is not feasible for the outsourcers to compound drugs for small-volume orders. In fact, before coming to speak in front of you today, I called some of the most frequently used outsourcing facilities by ophthalmologists to determine if they would fill a single order for 0.02% PHMB compounded solution. The answer was no.

Since drugs for emergent conditions are not used in ophthalmic practices on a regular basis, my colleagues and I generally order smaller quantities, which make it less cost-effective for the outsourcing facilities to manufacture. As a result, many outsourcing facilities do not currently produce compounded drugs needed for emergent conditions in the amounts needed by ophthalmologists, thus limiting physician and patient access to these drugs. This problem has existed since the advent of outsourcing facilities. Following the release of the FDA's updated draft guidance, ASCRS spoke to some of the major ophthalmic outsourcing facilities, and they indicated that the revised draft guidance will not prompt them to begin producing in small quantities needed in ophthalmology.

While physicians have the option to obtain compounded medications from a 503A compounding pharmacy using a patient-specific prescription, this policy raises concerns of patient safety and timely access to drugs for office-use, especially when treating an emergent condition. In the final FDA guidance, "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act," the FDA even acknowledged the need for timely access to ophthalmic drugs:

> "If a patient presents at an ophthalmologist's office with a fungal eye infection, timely administration of a compounded antifungal medication may be critical to preventing vision loss. In such a case, the ophthalmologist may need to inject the patient with a compounded drug product immediately, rather than writing a prescription and waiting for the drug product to be compounded and shipped to the prescriber."

However, in the footnote of this example, the FDA states, "such compounding would be subject to all of the conditions of section 503A or 503B . . ." This means I have two options: (1) call the outsourcing facilities, who have already indicated they will not compound PHMB, or (2) use time the patient does not have to write a patient-specific prescription, submit it to the 503A compounder, and wait for the drug product to be compounded and shipped to my office. What is most alarming to me is that the agency has recognized the importance of the availability of compounded medications for office-use, yet does not provide a pathway to secure critical compounded medications to treat patients with an emergent condition in a timely manner from a 503A or 503B compounding facility.

I want to reiterate that emergent ocular conditions requiring compounded medications are rare, but it is important for our patients' health and safety that we have an immediate pathway to secure drugs for treatment. We believe the FDA should allow 503A compounders to supply physicians with limited quantities of compounded drugs needed to treat emergent conditions without a patient-specific prescription. As already indicated, the FDA has maintained that physicians may secure compounded medications without a patient-specific prescription from outsourcing facilities; however, this is not a viable option for ophthalmologists due to outsourcing facilities' unwillingness to compound low-volume drug orders needed for emergent conditions.

I strongly urge the FDA to prioritize the needs of patients with emergent conditions by allowing physicians to access compounded drugs for office-use from 503A compounding pharmacies in limited supply without a patient-specific prescription. We encourage the agency to recognize that access to compounded drugs for office-use is not only essential to the practice of medicine, but also a vital tool for patient care.

I appreciate the opportunity to speak in front of you today. We look forward to continuing to work with the FDA to ensure the creation of policies that enhance patient care and health outcomes. At this time, I would be happy to answer any questions.