American Society of Retina Specialists (ASRS)
Limited Access to Compounded Antibiotics for Intravitreal Injection

In 2016, the FDA acknowledged the need for retina specialists to have compounded drug products on hand to treat emergency infections such as endopthalmitis in its Draft Guidance, Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act:

> "**Sometimes, it is necessary for health care practitioners in hospitals, clinics, offices, or other settings to have certain compounded drug products on hand that they can administer to a patient who presents with an immediate need for the compounded drug product.** For example, 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 prescriber 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."

We agree. And we pointed out the irony that the same Draft Guidance recognizing this need actually hindered such emergency treatment by requiring non-patient-specific compounded drugs to be obtained from 503B outsourcing facilities. Antifungal antibiotics for intravitreal use were not available from a 503B facility in 2016 and they remain unavailable today.

Despite this paradox and our plea for an emergency exception to the prescription requirement, the FDA did not create one. In its final guidance it maintaining the patient-specific prescription requirement for drugs compounded under section 503A, the FDA stated: "We recognize that some state boards of pharmacy may authorize the writing of prescriptions that do not include individual patient names. Such prescriptions, however, do not meet the requirement of a patient-specific prescription in section 503A. Under section 503B, outsourcing facilities can fill such prescriptions if they meet the requirements of applicable state and federal laws."

As a result, important state exemptions in effect pending final guidance were eliminated. For example, the hospital pharmacy at Phillips Eye Institute in Minneapolis, MN, in 2016 was compounding ophthalmic antibiotics through anticipatory compounding to have stock available for emergencies. It lost an exemption provided by the Minnesota Board of Pharmacy after the FDA final guidance was published because those antibiotics were distributed without a patient-specific prescription to locations (outpatient surgery center, satellite clinics, and sister hospital) within the same hospital system several miles away from the pharmacy. Currently, patients who need such antibiotics are transferred to the central location to wait for a prescription to be filled and then to be seen for administration of the drugs rather than getting immediate treatment at the outlying hospitals or clinics. **These delays are not only an unnecessary inconvenience for patients and physicians; they harm patients by putting their vision in jeopardy when prompt treatment is critical.**

Despite enactment of the Drug Quality Security Act (DQSA) five years ago to improve the safety and availability of compounded drugs, retina specialists face increased difficulty obtaining ophthalmic medications and patients are unable to receive the prompt emergency care for fungal eye infections that they received before the DQSA. **An exception must be made to allow physicians to administer critically necessary compounded drugs to patients when those drugs are not available from 503B facilities, and at locations beyond a one mile radius of the compounding pharmacy.**

Recommendations:

FDA should uphold its position on the prescription requirement that certain compounded drug products must be on hand to administer to a patient with an immediate need or emergency, such as fungal endophthalmitis, by allowing office use of compounded drugs obtained without a patient specific prescription from 503A facilities when such drugs cannot be obtained from 503B facilities.

The FDA should strike from its draft guidance on Hospital and Health System Compounding, the words on lines 213 and 214: "and that are located within a 1 mile radius of the compounding pharmacy."

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Compounded Intravitreal Antibiotics Not Available from 503B Facilities

The following drugs are only available through 503A compounding pharmacies:

- Acyclovir
- Amikacin
- Amphotericin*
- Clindamycin*
- Foscarnet
- Ganciclovir; and
- Voriconazole

There are no 503B agents available for fungal or viral infections which often need immediate treatment. On the above list, Acyclovir, foscarnet, and gancyclovir are antiviral antibiotics used for viral eye infections, and amphoteracin and voriconazole are antifungals. Because they cannot be compounded in advance, patients must wait for a pharmacy to make them upon obtaining a patient specific prescription.

Agents used to treat bacterial endophthalmitis are currently available from 503B facilities, but limited. Intravitreal vancomycin, ceftazedime, and moxifloxacin can be kept on hand. But in the event of a patient allergy or antibiotic resistance, other excellent antibiotics for the eye, such as amikacin or clindamycin, are not available from 503B facilities.

*Although some facilities on the FDA 503B Product Report indicate that they have compounded these drugs, they are not available in an appropriate form or dosage for ophthalmic use.