April 23, 2019

The Honorable Morgan Griffith (R-VA)  The Honorable Henry Cuellar (D-TX)
U.S. House of Representatives  U.S. House of Representatives
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Our organizations are pleased to support H.R. 1959, the “Preserving Patient Access to Compounded Medications Act,” which would help ensure that physicians and patients have timely access to compounded drugs. We applaud you for your leadership on this important issue and look forward to working with your offices to secure the enactment of H.R. 1959.

Throughout the Drug Quality and Security Act (DQSA) implementation process, our organizations have communicated with the FDA about our physicians’ reliance on compounded and repackaged drugs to treat our patients. Continued access to both compounded and repackaged drugs ensures that our specialty physicians will have the necessary treatments to deliver quality care to their patients. Despite communicating our concerns to Food & Drug Administration (FDA) leadership, the agency finalized guidance that threatens timely access to compounded drugs.

The policy outlined in the FDA’s final guidance on the Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act forces practitioners to rely solely on outsourcing facilities to meet all their needs for office-use drugs. Outsourcing facilities are currently unable or unwilling to make many of the compounded drugs needed to treat dermatology and ophthalmology patients. Lack of access to these drugs is especially problematic for patients facing urgent care needs. For example, immediate access to compounded products, such as cantharidin, is critically important to dermatologists providing timely patient care and ensuring the effective treatment of skin disease. Other examples include antiviral drugs, such as gancyclovir and foscarnet, that are used by ophthalmologists to treat retinal or anterior segment infections. These drugs are used to treat urgent and emergent conditions. Delays in treatment can cause significant harm to the patient, including vision loss or blindness. Only when physicians are able to maintain a supply of compounded products within their offices are they able to immediately administer the drug and provide treatment to a patient during a single office visit. Having access to this supply in the office setting minimizes the disruption of care that a patient would otherwise experience.

Our organizations have made patient access to treatments a top priority. We strongly support your efforts to clarify congressional intent of the DQSA as it relates to access to office-use compounded drugs. H.R.1959 will ensure our patients can be treated in a timely manner and will protect patient safety. We look forward to working with you on this important bill.

Sincerely,

American Academy of Dermatology Association
American Academy of Ophthalmology
American Society for Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society for Mohs Surgery