June 16, 2017

The Honorable Morgan Griffith (R-VA)  
U.S. House of Representatives  
2202 Rayburn HOB  
Washington, D.C. 20515

The Honorable Henry Cuellar (D-TX)  
U.S. House of Representatives  
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The American Academy of Dermatology Association (Academy), which represents more than 13,500 dermatologists nationwide, is pleased to offer its support for H.R. 2871, the "Preserving Patient Access to Compounded Medications Act," which would help ensure that physicians and patients have continued access to compounded drugs. The Academy appreciates that H.R. 2871 would address the unintended consequences of the Food & Drug Administration’s (FDA) interpretation of the Drug Quality & Security Act (DQSA) and facilitate physician access to compounded drugs for administration in a clinical setting.

Dermatologists are committed to providing the most effective and cost-efficient care and therapies to their patients. Patients suffering from chronic, disabling skin conditions need access to compounded medications that are not only medically necessary, but life-changing. Dermatologists have a long and consistent record of safely and effectively prescribing and administering compounded drugs in a clinical setting. Physician administration of compounded drugs is safer than patients potentially improperly treating themselves at home. The administration of compounded drugs is not only a common type of treatment, but it is also an essential component of many dermatology practices and critical to dermatologists’ ability to provide proper and timely care for their patients, all of which can result in better outcomes and lower health care costs for patients.

Dermatologists rely on and value the relationship with traditional compounding pharmacists (503A) to help them meet their patients’ needs in the office setting and this is especially so with topical compounded pharmaceutical products. For these non-sterile treatments in particular, federal regulation beyond state law serves only to inhibit access to effective treatments while doing little, if anything, to ensure patient safety. The unintended consequences of a restrictive interpretation of the DQSA are limited and/or delayed access to needed treatments, which could ultimately mean increased patient morbidity and unnecessary increases in health care expenses for both patients and the health care system as well.

Since FDA began implementation of the DQSA, dermatologists have been experiencing instances in which the FDA’s actions are resulting in delayed care. The Academy is concerned that for many patients, the result will ultimately be no care at all. This has been complicated by FDA’s actions, which are undermining
the longstanding practice of allowing physicians to maintain a supply of compounded products within their offices to be administered when patients present. For example, immediate access to compounded products, such as cantharidin, is critically important to providing timely patient care and ensuring the effective treatment of skin disease. Cantharidin is an effective and painless treatment for warts and molluscum contagiosum, particularly for pediatric populations. When physicians are able to maintain a supply of a compounded products within their offices, physicians are 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.

Under the FDA’s final guidance on the Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act, which requires a patient-specific prescription for physician access to these compounded products, what could previously be done in one office visit now requires a trip to the physician office, a trip to the pharmacy to receive the prescription, and a follow-up visit to the physician office to have the treatment administered. Not only is this incredibly inefficient for the physician practice, this also imposes a new burden on the patient of having to travel to and from the pharmacy and scheduling additional office visits as well. In addition, the patient is now faced with additional co-pays for specialist office visits, which previously could have been avoided. Additional costs borne by the patient include missed time at school and/or work as well. Furthermore, delayed treatment can also have a public health impact. For example, in the case of molluscum contagiosum, which is transmissible, early and effective intervention with a treatment like cantharidin is not only important to the patient being treated but is also important in protecting the school-age population from exposure to the illness.

Under FDA’s restrictive interpretation of Section 503A, many patients face barriers in accessing timely and effective medical care. A dermatologist would no longer have access to an office supply from a traditional compounding pharmacy, nor would the dermatologist be able to have these needs met by (503B) outsourcing facilities which do not produce these compounded drugs in the small quantities needed to supply a physician’s office. As noted in the cantharidin example above, the dermatologist would have to write a prescription, wait for the pharmacist to fill the prescription, wait for the patient to go to the pharmacy to obtain the prescription, and then wait for the patient return for treatment. This would not only pose a significant burden on the patient and the physician, but it implements added steps that can undermine timely treatment and continuity of care. Even worse, it is not uncommon for patients not to return for follow-up visits. As a result, with the added steps needed to obtain care, the patient’s condition could persist without the necessary care and treatment, which is safe and effective, and, in most cases, is inexpensive.
The Academy has made patient access to treatments a top priority. The Academy strongly supports your efforts to clarify congressional intent of the DQSA as it relates to access to office-use compounded drugs. Please contact Christine O’Connor, the Academy’s Associate Director, Congressional Policy at coconnor@aad.org or (202) 609-6330 with any questions or if we can provide additional information.

Sincerely,

Henry W. Lim, MD, FAAD
President
American Academy of Dermatology Association