June 3, 2016

Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Stakeholder Listening Session on Compounding

My name is Dr. Bruce Brod, MD. I am a dermatologist representing the American Academy of Dermatology Association, which has over 13,500 members in the United States. At the University of Pennsylvania in Philadelphia, I am a Clinical Professor of Dermatology and Director of the Occupational and Contact Dermatitis Clinic. I currently serve as the Vice Chairman of the Pennsylvania State Board of Medicine. I am the president of the American Contact Dermatitis Society and chair of the Academy’s Congressional Policy Committee. I practice medical and surgical dermatology in Lancaster, Pennsylvania.

**Prescription requirement under section 503A and FDA’s April 2016 draft guidance**

Regarding the prescription requirement for in-office compounding, the Academy appreciates FDA’s proposal to allow anticipatory compounding. We find that the interpretation of “limited quantities” as a 30-day supply is reasonable, assuming that it can be replenished as needed up to this limit.

A common example of anticipatory compounding is for local skin anesthesia where dermatologists administer buffered lidocaine with epinephrine and/or sodium bicarbonate to reduce pain on injection. Currently, dermatologists prepare their own buffered lidocaine syringes or obtain them from 503A compounding pharmacies. We document the administration in each patient chart, which would satisfy the prescription requirement proposed. Having access to buffered lidocaine allows dermatologists to perform surgery in an office setting and without sedation.

If the FDA finalizes its proposed guidance to prohibit office-use compounding where 503A compounding pharmacies cannot distribute compounded drugs to physician offices without patient-specific prescriptions, an access issue will result. Dermatologists obtain numerous sterile and nonsterile compounded drugs from 503A compounding pharmacies, such as...
cantharidin (recalcitrant warts or molluscum infections) and bleomycin (diluted to treat warts), patch testing agents, and liquid formulations of solid medications.

The Academy has members who are having difficulty obtaining coal tar used for phototherapy and Goeckerman therapy for patients with psoriasis from 503B outsourcing facilities without patient-specific prescriptions. This coal tar must be ordered well in advance and in bulk. At this time, dermatologists are able to obtain smaller quantities of coal tar with shorter notice from 503A compounding pharmacies.

Hospital and health system compounding and FDA’s April 2016 draft guidance

The Academy appreciates the FDA proposing to allow anticipatory compounding and distribution by hospital pharmacy. However, we find that the 1-mile radius is inadequate, especially where the hospital pharmacy compounds for its satellite offices. For example, at the University of Pennsylvania, our hospital pharmacy prepares buffered lidocaine for dermatology clinics including those further than one mile.

Many hospital pharmacies buffer lidocaine in large volumes for distribution and administration that same day. A colleague who works at the University of California San Francisco shared that the Department of Dermatology administers an average of 250 lidocaine syringes daily for biopsies, skin cancer excisions, and other dermatologic procedures. The lidocaine syringes are distributed prior to receipt of a patient-specific prescription and administered after the order is written in the patient chart.

Compounding-related concerns

As for other compounding-related concerns, at the FDA Pharmacy Compounding Advisory Committee (PCAC) meeting in March, it voted to not include quinacrine hydrochloride on the section 503A bulk drug substances list. Patients with lupus erythematosus and dermatomyositis require access to quinacrine. The Academy looks forward to continuing to work with the FDA to maintain access to this safe and effective therapy.

A segment of our membership has difficulty obtaining cantharidin, which the FDA recommended for inclusion on the bulk substance list, stating that some consider it to be a treatment of choice for molluscum contagiosum in young children and a useful treatment for warts. The PCAC voted in favor of its inclusion in February 2015 though a bulk substance list including cantharidin has not yet been published in the Federal Register. We request that the FDA finalize its guidance, “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food,
Drug, and Cosmetic Act” containing its non-enforcement policy (that the FDA does not intend to take enforcement action if it “has determined that the nomination for the bulk drug substance included adequate information for FDA to evaluate the substance and at this time, the substance does not appear to present safety concerns”).

Please contact Natasha Pattanshetti, JD, MPH, Manager of Regulatory Affairs at npattanshetti@aad.org or (202) 712-2618 if you require clarification of any of this statement or would like more information.