July 18, 2016

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


Dear Dr. Califf,

On behalf of the more than 13,500 U.S. members of the American Academy of Dermatology Association (AADA), I appreciate the opportunity to provide input to the Food and Drug Administration (FDA) in response to its draft guidance on Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability. The Academy is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology and dermatopathology; and supporting and enhancing patient care to reduce the burden of disease.

In-Office Physician Compounding Facilitates Treatment in the Office Setting

Regarding the prescription requirement for in-office compounding, the AADA 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 the supply 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 section 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 using local anesthesia as opposed to sedation.

For section 503A, FDA recommends that a valid prescription order for a compounded drug means a valid prescription order form from a licensed
prescriber. It would include valid orders or notations written by: (1) a prescriber in a patient’s chart in an inpatient setting; and (2) a physician who compunds a drug for his or her own patient written in that patient’s chart. We are supportive of this definition of valid prescription order.

While the FDA proposes to allow in-office compounding, the United States Pharmacopeia (USP) has proposed revisions to its *Chapter 797 Pharmaceutical Compounding—Sterile Preparations*, which, if adopted by a state, would require dermatologists who prepare simple compounds or dilutions used for intradermal or subcutaneous injections to adhere to the same standards as large compounding facilities. The AADA asks that the FDA collaborate with USP as to not attempt to limit the ability of physician offices to prepare and use compounds used for intradermal or subcutaneous injections, as they have safely done for decades.

**Office-Use Compounding Should Be Allowed for Timely Patient Access**

In this draft guidance, the FDA states that a compounder must obtain a patient-specific valid prescription order to fill a compounded drug. While the drug may be compounded prior to receipt, it cannot be distributed to the patient or administering health care practitioner until receipt. 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, physician practices and their patients will have limited access to smaller volume and less frequently used compounded drugs to treat their patients. Dermatologists obtain numerous sterile compounded drugs, such as bleomycin (which is diluted to treat warts), and nonsterile compounded drugs, such as cantharidin (used to treat recalcitrant warts or molluscum contagiosum infections), patch testing agents, and liquid formulations of solid medications, from section 503A compounding pharmacies.

The FDA suggests using section 503B outsourcing facilities to obtain compounded drugs for office-use purposes. Unfortunately, the AADA has found that section 503B outsourcing facilities do not fulfill the needs of smaller practices, which is illustrated by the following two examples. First, the AADA has member dermatologists 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.

The second example involves access to the compounded drug cantharidin. 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*. The AADA is appreciative that the FDA recently published its final 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”). Consequently, dermatologists should have access to this drug but dermatologist members have reported that they cannot obtain a small amount for office use from 503A compounding pharmacies due to the patient-specific prescription requirement and section 503B outsourcing facilities are refusing to dispense smaller amounts to physicians’ offices. Clearly there is a need for office-use compounded drugs from section 503A compounded pharmacies. We request that the FDA reconsider its recommendation and facilitate access to compounded drugs in this context.

Recordkeeping Should Not Be Burdensome for Physicians

The AADA asks that the FDA consider the burden to physician practices to maintain records to demonstrate compliance with the prescription requirement in section 503A and the basis for anticipatory compounding and to simplify and provide examples of these requirements.

The AADA appreciates the opportunity to provide comments on this FDA draft guidance on the prescription requirement for compounding under Section 503A. 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 the comments in this letter or would like more information.

Sincerely,

Abel Torres, MD, JD
President, American Academy of Dermatology Association

CC: Elaine Weiss, JD, Executive Director
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