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Statement for the Record

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Chair, Congressional Policy Committee

Hearing

Examining Implementation of the Compounding Quality Act

Subcommittee on Health

House Committee on Energy & Commerce

U.S. House of Representatives

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Introduction

Thank you, Chairman Burgess, Ranking Member Green, and members of the Health Subcommittee for the opportunity to appear before the Committee at this hearing entitled "Examining Implementation of the Compounding Quality Act," and to speak about the importance of physician access to compounded medications to treat dermatology patients. My name is Bruce Brod. I am a board-certified dermatologist on staff at the Hospital of the University of Pennsylvania, and a clinical professor at the University's Perelman School of Medicine. I currently serve on the Board of Directors of the Pennsylvania Academy of Dermatology and Dermatologic Surgery, and as chair of the American Academy of Dermatology Association's Congressional Policy Committee. I was also in private practice for 22 years in Lancaster, Pennsylvania.

My testimony will focus on ways the Drug Quality & Security Act (DQSA) has adversely affected the practice of medicine for dermatologists in two significant ways: first, (1) with respect to maintaining a small supply of office-use compounded medications for administration when patients present; and second, (2) when dermatologists prepare low-risk sterile and non-sterile medications in the office setting.

The Academy appreciates the Committee's efforts to maintain the safety of compounded medications in wake of the meningitis outbreak from contaminated sterile drugs compounded by the New England Compounding Center that tragically resulted in dozens of deaths and hundreds of injuries. As physicians, we take an oath to "first do no harm." The well-being of our patients is our primary concern and responsibility, and having a safe supply of medications with which to treat our patients is of utmost importance.

During the drafting process of the DQSA in 2013, the Academy engaged with staff from your Committee and the Senate HELP Committee so that a final legislative solution not only provided a safe drug supply, but also would not interfere with the practice of medicine. We appreciated the public statements of Chairman Burgess, Ranking Member Green, and others that noted the importance of maintaining patient access to office-use drugs and ensuring that compounding regulations should not interfere with the practice of medicine.

Dermatologists diagnose and treat more than 3,000 skin, hair and nail diseases, including many that are chronic and disabling. We rely heavily on compounded medications that are not only medically necessary, but life changing. For decades, dermatologists have safely and effectively prepared and administered low-risk topical and intralesional compounded medications to a wide range of patients, including individuals presenting with special and emergent needs, persons

suffering from rare diseases, and children. We have a long and consistent record of safely and effectively prescribing and administering compounded medications in a clinical setting. The administration of compounded medications is not only a common type of treatment, but it is an essential component of many dermatology practices. It is critical to a dermatologist's ability to provide proper and timely care for our patients, which can result in better outcomes and lower health care costs.

Office-use Compounded Medications

In accordance with state law, dermatologists have historically obtained compounded medications from section 503A compounding pharmacies prior to receipt of a patient-specific prescription for administration to patients within their own offices, a practice referred to as "office-use." Dermatologists rely on and value the relationship with 503A compounding pharmacies to help meet our patients' needs. However, the Food & Drug Administration's (FDA) December 2016 final guidance on the *Prescription Requirement under 503A of the Food, Drug and Cosmetic Act* restricts 503A compounding pharmacies from providing office-use compounded medications prior to receipt of a patient-specific prescription. This limits physicians' access to important compounded medications.

While we understand the FDA intended for the newly created 503B outsourcing facilities to be a meaningful resource for providing physicians' office-use stock, in practice, these outsourcing facilities have not been able to meet all the needs of physicians and our patients. Less than 75 outsourcing facilities are registered with the FDA. The FDA's website lists only the facilities that are registered, but with no contact information, no real-time product availability information, and no price list. Physician practices have the administrative burden of going on a scavenger hunt to seek this

information. In addition, dermatologists have reported that the outsourcing facilities have quoted prices that are cost prohibitive. We also have no indication that 503B outsourcing facilities will provide flexibility in the various concentrations that we use in our offices, flexibility that had been guaranteed by the 503A compounding pharmacies.

Dermatologists rely on compounding pharmacies to produce compounded medications to meet their patients' needs. These compounded medications include non-sterile topicals used to treat warts, molluscum contagiosum, disfiguring birthmarks, skin cancer, alopecia areata, hyperpigmentation, psoriasis, and cutaneous T-cell lymphoma, among others, as well as intralesional drugs which are injected directly to areas of skin affected by skin cancer and sexually transmitted diseases. Recently, the FDA made public a list of compounded medications that entities listed as FDA-registered outsourcing facilities reported producing between December 2016 and May 2017. The list is retrospective, and it does not indicate if these drugs will be produced in the future. Furthermore, as the FDA indicates, not all outsourcing facilities have submitted their product list, the list is not neither exhaustive nor even complete.

The unintended consequence of the restrictive interpretation of the DQSA is limited and/or delayed access to needed treatments, which could ultimately result in increased patient morbidity. It can also result in unnecessary increases in health care expenses for both patients and the health care system, or no care at all.

If a compounded drug is not available from an outsourcing facility, under the FDA's final guidance requiring a patient-specific prescription for access, what could previously have been treated in one office visit now requires: 1) a trip to the physician office for evaluation and diagnosis, 2) a trip to the pharmacy to obtain the prescription, and 3) a follow-up visit to the physician office to

finally have the treatment administered. These two additional steps are not only inefficient for the physician practice, but also impose new burdens on the patient and delays in patient care. The patient is now confronted with an additional co-pay for a specialist office visit, which may be difficult to schedule to begin with, as well as the possibility of further missed school for a child or work time for an adult.

These hurdles undermine timely treatment and continuity of care. They increase the risk of non-adherence as well as the risk that patients will not attend follow up visits. The patient's condition could persist without the necessary care and treatment, which is safe and effective and, in most cases, inexpensive.

When compounded medications are outside a provider's chain of control, there are safety concerns regarding the proper storage, handling, and application that need to be considered. Some compounded medications require certain temperature and storage restrictions. When a provider does not maintain control of the medication and cannot be sure how it has been stored between the time the patient picks it up at the pharmacy and then returns to the physician's office for administration, there is no guarantee regarding the integrity of the medication. For example, if stored at a high temperature, there are risks of inactivating the active ingredients of Betacaine-Lidocaine-Tetracaine (BLT), a topical anesthetic.

Many compounded medications should only be administered by a licensed health care professional in an office setting. As many of the compounded medications are used topically to destroy unwanted skin lesions, there are certain risks if accidentally applied to normal areas of skin. Patients may cause harm or permanent disfigurement should they administer these drugs themselves. As such, they should be administered by the dermatologist. For example, cantharidin

can burn healthy skin and squaric acid can cause severe allergic contact dermatitis if applied improperly. A topical bleaching cream of hydroquinone, retinoid and steroid used to treat melasma, which is a pigmenatary disorder common in women, and other pigment disorders can cause permanent blue-black pigmentation if not stored or handled properly, and should be applied only for a limited duration.

Another reason a health care provider should directly supervise the application of certain compounded medications is that systematic lidocaine toxicity can occur if a numbing cream is applied for too long or over a large surface area of the skin. Seizures, cardiac arrest, and death have occurred in otherwise healthy individuals who applied this numbing cream without proper supervision of a licensed medical professional prior to certain medical procedures.

In-Office Preparations

A second unintended consequence of the DQSA having an adverse impact on patient access occurs with in-office preparation of drugs. Because the FDA's definition of compounding -- "combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient" -- is broad, many in-office preparations are considered compounding and are being subject to scrutiny though they are very simple and low risk.

A widely used local anesthetic in surgical dermatologic procedures is lidocaine buffered in the clinical setting with epinephrine and/or sodium bicarbonate. Common practice is to add sodium bicarbonate to manufactured lidocaine with epinephrine to decrease the pain of delivery, especially for children and patients requiring extensive outpatient skin cancer surgery. This allows us to perform more extensive skin cancer surgeries in a more cost effective outpatient setting, also negating the need for higher volumes of anesthesia. We have buffered lidocaine syringes readily available, as

many are used each day when patients present and are in need of in-office surgical treatment and important diagnostic biopsies. Given the shortage of manufactured lidocaine with epinephrine, dermatology practices must resort to adding epinephrine to lidocaine and other local anesthetics themselves for pain control and vasoconstriction.

Simple in-office preparations are considered "compounding" as opposed to mixing when the medication is not prepared pursuant to the manufacturer's labeling (e.g., reconstituting certain FDA approved neurotoxins with sterile saline for the treatment of hyperhidrosis). As a result, low-risk, low-volume, in-office preparations are subject to the FDA's guidance on *Insanitary Conditions at Compounding Facilities*, which is currently in draft form. Under this draft guidance, the FDA proposed that physician offices be considered a "compounding facility" subject to the same equipment and process requirements as high-volume compounders. Many of these proposed requirements, which include International Organization for Standardization Class 5 (ISO 5) area (including laminar flow hood), and gowning apparel (e.g., sterile gowns, gloves, mask, foot covers), are simply unworkable for dermatology offices both structurally and financially.

The activities we are performing should be considered the normal practice of medicine. While the FDA and U.S. Pharmacopeia are working with medical specialties to explore an urgent use exemption, we have real concerns that patient access will be harmed by an exemption based on a restrictive timeframe or that remains overly burdensome. For example, peer reviewed journal articles show that buffered lidocaine and reconstituted botulinum toxins are safe for patient use for up to four weeks, assuming that current aseptic practice is followed.

We are appreciative that the FDA's 2018 Compounding Policy Priorities Plan mentions that the agency will publish revised draft guidance and address concerns we raised about these low-risk

practices. The FDA stated it plans to define the circumstances in which mixing drugs and applying them in a manner that is low risk would not be subject to the same requirements as its risk-based approach. We look forward to working with the FDA to ensure that requirements imposed on providers do not adversely impact patient access.

On behalf of the American Academy of Dermatology Association and its member dermatologists, I thank you for holding this hearing, and for your commitment to maintaining timely access to safe and effective compounded medications. The Academy looks forward to working with you as you address the unintended interference on the practice of medicine and patient access.