

Committee on Energy and Commerce
Subcommittee on Health

“Examining Implementation of the Compounding Quality Act”

Statement of the American College of Mohs Surgery

2123 Rayburn House Office Building Washington, D.C. 20515

January 30, 2018

Thank you for organizing this hearing to examine the U.S. Food and Drug Administration’s (FDA) implementation of Title I of the Drug Quality and Security Act (DQSA), which was enacted nearly five years ago in the wake of the fungal meningitis outbreak caused by the New England Compounding Center (NECC).

The American College of Mohs Surgery (ACMS) represents more than 1,400 Mohs micrographic surgeons who have successfully completed extensive fellowship-training in Mohs micrographic surgery following their dermatology residency training. Mohs micrographic surgery is the most effective and efficient treatment for advanced or difficult to treat skin cancers. In line with its mission, ACMS sets and promotes the highest standards of patient care relating to Mohs micrographic surgery.

Skin cancer is the most common form of cancer in the United States and a growing epidemic.^{1, 2} There are more new cases of skin cancer diagnosed each year than the combined incidence of cancers of the breast, prostate, lung and colon.³ One in five Americans will develop skin cancer in the course of their lifetime.⁴

We appreciate that the subcommittee will hear testimony from physician compounders, including a dermatologist. The ability to prepare local anesthetics in our offices is critical to the continued provision of integrated, coordinated, high quality and cost-effective skin cancer care.

Preparation of Local Anesthetics by Mohs Surgeons is Safe, Effective, and Poses No Documented Risk to Patient Safety

Mohs surgeons prepare local anesthetics in their offices within 24 hours of Mohs micrographic surgery. Specifically, Mohs surgeons prepare buffered or diluted lidocaine to ease pain and discomfort during Mohs micrographic surgery by adding commercially purchased sodium bicarbonate solution to commercially purchased 1% lidocaine hydrochloride with epinephrine. This simple step significantly decreases the painful/burning sensation at the time of injection and speeds up the onset of anesthesia.⁵ The enhanced tolerability of the local anesthetic achieved

¹ <https://www.cdc.gov/cancer/skin/statistics/index.htm>

² https://www.cdc.gov/cancer/skin/call_to_action/index.htm

³ Stern RS. Prevalence of a history of skin cancer in 2007: results of an incidence-based model. *Arch Dermatol.* 2010;146(3):279-282.

⁴ <https://www.skincancer.org/skin-cancer-information/skin-cancer-facts>

⁵ McKay W, Morris R, Mushlin P. Sodium bicarbonate attenuates pain on skin infiltration with lidocaine, with or without epinephrine. *Anesth Analg.* 1987;66(6):572–574. doi: 10.1213/00000539-198706000-00015.

allows the procedure to be performed without the need for systemic anesthetics, thereby greatly reducing cost and risk of complications.

To achieve the proper anesthetic mixture or concentration, Mohs surgeons prepare buffered or diluted lidocaine using the aseptic technique -- a practice that has been proven safe and effective for decades.^{6, 7, 8} Mohs surgeons only prepare buffered or diluted lidocaine for use in their offices for their own patients – not distribution or resale. This process is required, as buffered and diluted lidocaine with epinephrine, while remaining safe, begins to lose its vasoconstrictive efficacy after 7 days.⁹ Thus, it would be difficult to receive the compounded drug through a large distributor, such as an outsourcing facility.

The Scientific Advisory Committee of ACMS, composed of leading Mohs surgeons who practice at highly regarded institutions across the country, with many who serve on the National Comprehensive Cancer Network Guideline panel for Non-melanoma Skin Cancer, agree that use of the aseptic technique for preparing buffered or diluted lidocaine in the office is safe, appropriate, and consistent with the current literature.¹⁰

We emphasize that the practice of medicine includes preparing local anesthetics. State boards of medicine are responsible for regulating the practice of medicine. However, from the viewpoint of the FDA, Mohs surgeons would generally be preparing buffered or diluted lidocaine in accordance with section 503A of the Federal Food, Drug and Cosmetic Act (FD&C Act) and with patient specific prescriptions.

Impact of FDA Guidance on Physician Office Compounding

In August 2016, FDA released draft guidance -- “*Insanitary Conditions at Compounding Facilities*” -- that sets forth new standards for physician offices that compound under section 503A. For example, physician offices would be required to have engineering control devices capable of maintaining an ISO Class 5 environment or be deemed “insanitary.” The FDA and Centers for Disease Control and Prevention (CDC) have yet to produce any scientific evidence to suggest there has been a problem to warrant this level of precaution with respect to physician office preparation of compounded medications.

Because Mohs surgery is overwhelmingly performed in the office setting, Mohs surgeons would need to equip their offices as if they were compounding pharmacies to comply with the guidance, if finalized as currently drafted. The expense and impracticality would prohibit most Mohs surgery practices from making such a conversion, despite the current safety record of the use of

⁶ Kimyai-Asadi, A., Goldberg, L., Peterson, R., Silapint, S., and Jih, M. The incidence of major complications from Mohs micrographic surgery performed in office-based and hospital-based settings. *J Am Acad Dermatol* 2005;53:628-34.

⁷ Melman, D., & Siegel, D. (1999). Prefilled Syringes: Safe and Effective. *Dermatologic Surgery*, 492-493. Retrieved May 29, 2017, from <http://www.ncbi.nlm.nih.gov/pubmed/10469100>

⁸ Larson PO, Ragi G, Swandby M, Darcey B, Polzin G, Carey P. *Stability of buffered lidocaine and epinephrine used for local anesthesia*, *J Dermatol Surg Oncol*. 1991 May;17(5):411-4.

⁹ Pascuet E, Donnelly RF, Garceau D, Vaillancourt R. Buffered Lidocaine Hydrochloride Solution With and Without Epinephrine: Stability in Polypropylene Syringes. *The Canadian Journal of Hospital Pharmacy*. 2009;62(5):375-380.

¹⁰ Letter to USP from Christopher Bichakjian, MD, Chair, ACMS Scientific Advisory Committee dated January 27, 2016

buffered lidocaine among Mohs surgeons. This means patient access to Mohs micrographic surgery would be severely hindered. Instead, patients would be directed to hospital outpatient departments (HOPD) for skin cancer care and treatment, significantly increasing costs to patients and insurers, including the Medicare program, unnecessarily. We note that some health plans have attempted to limit Mohs micrographic surgery to the office setting because costs in the HOPD are high, which means some patients may not have access to the procedure at all.

While we remain deeply concerned with this draft guidance, FDA recently announced its 2018 Compounding Policy Priorities Plan¹¹ that the agency will take a step back from the previous position and re-examine these issues. Specifically, FDA stated:

“This guidance will address concerns raised by some providers who compound small quantities of drugs in their offices for patient use, and as part of their routine clinical practice. This came up in the setting of certain dermatological procedures, for example. The FDA plans to better define the circumstances under which we believe drugs are being mixed and applied in a manner that creates negligible patient risk, and therefore wouldn’t be subject to the same compliance policy under the agency’s risk-based approach to implementing these requirements.”

We believe the FDA can help prevent future problems, such as those associated with the New England Compounding Center (NECC), without imposing a one-size-fits-all approach. We have urged FDA to either exclude physician offices from the definition of “compounding facilities” in any finalized guidance or provide a meaningful exemption that does not impede Mohs surgeons’ ability to safely prepare buffered or diluted lidocaine, which is the standard of care and within the scope of Mohs surgical practice. Any exemption would ideally be consistent with the current literature, which demonstrates that prepared buffered lidocaine is safe and effective for patient use for periods not less than two weeks. ACMS is unable to accept an “immediate use” exemption of less than 24 hours given the safe anesthetic preparation practices and long-standing safety record in Mohs micrographic surgery, coupled with the need for patient access.

ACMS is cautiously optimistic that FDA’s forthcoming revised draft guidance will maintain patient access to important, medically necessary medicines prepared in the physician-office setting.

The Role of USP in Physician Office Compounding and Recent Engagement

According to its website, the US Pharmacopeia (USP) is a scientific nonprofit organization that sets public standards for identity, strength, quality and purity of medicines. USP standards are recognized in various provisions of the federal Food, Drug and Cosmetic Act (FDCA), and in laws, regulations and policies promulgated by states. These standards are enforced by the U.S. Food and Drug Administration (FDA), states and other oversight organizations (such as The Joint Commission). Under the DQSA, Congress clarified FDA’s authority over drug compounding and reaffirmed USP’s role under Section 503A. FDA subsequently released guidance specifically referencing USP’s *General Chapter <797> Pharmaceutical Compounding – Sterile Preparations*, including enforcement approaches.

¹¹<https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm592795.htm>

In September 2015, USP proposed revisions to General Chapter <797>. According to USP, based on the nature and significance of the public comments received, the chapter will be revised and is anticipated to be published in the Pharmacopeial Forum 44(5) Sept./Oct. 2018 for a second round of public comment. General Chapter <797> is expected to become official on December 1, 2019.

Recently, USP initiated a process whereby “expert consultants” selected from the physician community have been invited to provide advice and guidance as USP’s Compounding Expert Committee (CEC) continues to revise and refine Chapter <797>, addressing key issues and definitions. ACMS’ nominee, Allison Vidimos, RPh, MD, has been appointed as an expert consultant.

Request for Congressional Oversight to Ensure Patient Access to Medically Necessary Medicines

The unfortunate events associated with tainted intrathecal steroids and the resultant fungal meningitis outbreak in 2012 that prompted significant scrutiny over drug compounding in the United States, including passage of the Drug Quality and Security Act of 2013, is completely unrelated to how Mohs surgeons utilize local anesthetic mixed in their offices. And, while significant progress has been made with the FDA and USP, Congressional oversight is essential to ensure patients have continued access to physician-compounded medicines.

We look forward to working with the Members of this Subcommittee and the Congress, serving as subject matter experts on physician-office compounding, to safeguard the safety and health of our patients.