Drug Compounding
& Mohs Micrographic Surgery

American College of Mohs Surgery
Fellowship trained skin cancer and reconstructive surgeons

Mohs micrographic surgeons compound local anesthetics in their offices using the aseptic technique on the day of Mohs micrographic surgery – a practice that has been proven safe and effective[1,2,3].

Physician-Office Compounding is Safe and Appropriate

Mohs surgeons use buffered lidocaine to ease pain and discomfort during Mohs micrographic surgery. The addition of sodium bicarbonate to commercial 1% lidocaine hydrochloride decreases the burning sensation at the time of injection and speeds up the onset of anesthesia.[4] To ensure appropriate dosing, Mohs surgeons compound the buffered lidocaine in their offices using the aseptic technique -- a practice that has been proven safe and effective. Mohs surgeons only compound buffered lidocaine for use in their offices for their own patients; not for distribution or resale.

The Scientific Advisory Committee of the 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 compounding in the office is safe, appropriate, and consistent with the current literature[5].

Efforts to Eliminate Physician-Office Compounding Lack Scientific Evidence

The United States Pharmacopeia (USP), a scientific nonprofit organization whose drug standards are enforceable in the United States by the US Food and Drug Administration (FDA), proposed to eliminate the aforementioned practice by significantly revising its sterile compounding standards set forth in its General Chapter <797> Pharmaceutical Compounding for Sterile Preparations. These revisions are being proposed without evidence to substantiate that the aforementioned compounding practice poses any harm or adverse impact to patients.

In August 2016, the FDA issued draft guidance -- "*Insanitary Conditions at Compounding Facilities*" -- that sets forth new standards (e.g., requiring physicians that compound drugs in their offices to have engineering control devices capable of maintaining an ISO Class 5 environment or be deemed "insanitary") without scientific evidence to suggest this level of precaution is warranted. Moreover, the process under which these new standards are being established circumvent ongoing deliberations to update USP General Chapter <797>, which FDA currently recognizes as required under statute.

Impact of Eliminating Physician-Office Compounding on Skin Cancer Care

Compounding pharmacies and other outsourcing facilities that might otherwise produce, stock, and distribute compounds needed in Mohs surgical practices find it impractical to do so given the small quantities Mohs micrographic surgeons use and the wide variety needed for Mohs surgery patients. If physician-office compounding is deemed unlawful, access to Mohs micrographic surgery would be reduced and the cost to insurers and patients would be significantly increased as these services would shift to the more expensive hospital outpatient department.

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. ACMS opposes efforts to end in-office compounding using the aseptic technique. Given the rise in skin cancer diagnoses, where more new cases of skin cancer will be diagnosed this year than the combined incidence of cancers of the breast, prostate, lung and colon, **we urge the Congress to protect access to Mohs micrographic surgery – a procedure with a success rate of 99% in curing skin cancer – by preserving physician-office compounding**.

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[1] 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.
[2] Letter to John Albertini, MD, President, ACMS, from Leonard Goldberg, MD, FACMS dated January 26, 2016
[3] Melman, D., & Siegel, D. (1999). Prefilled Syringes: Safe and Effective. *Dermatologic Surgery,* 492-493. Retrieved January 18, 2016, from http://www.ncbi.nlm.nih.gov/pubmed/10469100
[4] 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.
[5] Letter to USP from Christopher Bichakjian, MD, Chair, ACMS Scientific Advisory Committee dated January 27, 2016