AMERICAN SOCIETY OF PLASTIC SURGEONS®
THE PLASTIC SURGERY FOUNDATION™

Executive Office
444 East Algonquin Road • Arlington Heights, IL 60005-4664
847-228-9900 • Fax: 847-228-9131 • www.plasticsurgery.org

November 30, 2018

U.S. Pharmacopeial Convention (USP)
Compounding Expert Committee
12601 Twinbrook Parkway
Rockville, MD 20852

Submitted electronically via: http://www.usp.org/compounding/general-chapter-797

RE: Proposed Revision to USP's General Chapter <797> Pharmaceutical Compounding – Sterile Preparations

Dear Members of the U.S. Pharmacopeial Convention (USP) Compounding Expert Committee,

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to provide comments on the proposed updates to Chapter <797> Pharmaceutical Compounding. The ASPS is the largest association of plastic surgeons in the world, representing more than 7,000 members and 94 percent of all American Board of Plastic Surgery board-certified plastic surgeons in the United States. Plastic surgeons provide highly skilled surgical services that improve both the functional capacity and quality of life of patients. These services include the treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and cancer. The ASPS promotes the highest quality patient care, professional and ethical standards, and supports education, research, and public service activities of plastic surgeons.

We share the USP's concerns about the safety of the medications prepared and administered to patients and appreciate that the Committee has proposed an exemption where the preparation of non-hazardous compounded sterile preparations (CSPs) would be exempt from the standards in this chapter if administered within one hour of beginning the preparation (as written in lines 24-28 of this proposal). We concur that all drugs deteriorate over time in terms of potency and stability and that while a one hour limit may be reasonable for some CSPs, we respectfully point out this time limit will not be workable for medications such as buffered lidocaine, which is a commonly used local anesthetic for office-based procedures, and often pre-mixed prior to the start of patient's procedure to ensure adequate volume is available, should the patient require additional anesthetic beyond the initial injection.

As you may know, buffered lidocaine is created when sodium bicarbonate is added to lidocaine with or without epinephrine using aseptic technique to neutralize the pH of the preparation. The buffering of lidocaine significantly decreases the subjective pain of the injection and increases the onset of the local anesthesia for the patient. After the anesthetic takes effect, a surgeon can perform procedures in the least-expensive place of service – the office.

It's important to note that the FDA has acknowledged that the mixing and application of in-office preparations are of negligible patient risk and physicians should not be subject to the same standards as larger compounding facilities. In its revised draft guidance on Insanitary Conditions for Compounding Facilities, the Agency recognized that physician offices should not be included in its definition of

compounding facilities, and that it generally did not focus enforcement action against physicians who were compounding in the office setting and administering or dispensing to his or her own patients.

We ask that the USP consider the same factors as FDA highlighted – namely: small quantities, office setting, own patient use, routine clinical practice, negligible patient risk – when deciding how to facilitate patient access to CSPs prepared in the clinical setting, especially buffered lidocaine.

Without an exemption or an overall increase in the time-frame for in-office compounding, ASPS believes physicians will be unable to prepare and administer medications such as buffered lidocaine to their patients in the clinical setting without unreasonable burdens, including the additional costs for the procurement of compounded medications from a pharmacy. Additionally, we question the ability for a pharmacy to expeditiously deliver compounded medications, especially to those surgeons who practice in rural settings. As such, we ask that you reconsider the currently proposed one-hour time limit for nonhazardous compounding.

Should you have any questions about our comments, please contact Catherine French, ASPS Director of Health Policy, at cfrench@plasticsurgery.org or 847.981.5401. The ASPS looks forward to working with the USP on this important issue.

Sincerely,

Alan Matarasso, MD, FACS
President, American Society of Plastic Surgeons