AMERICAN SOCIETY OF PLASTIC SURGEONS®
THE PLASTIC SURGERY FOUNDATION™

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October 3, 2016

Robert M. Califf, MD
Commissioner of Food and Drugs - U.S. Food and Drug Administration
10903 New Hampshire Ave
Hillandale Bldg, 4th Floor
Silver Spring, MD 20993

RE: Docket No. FDA-2016-D-2268 DRAFT GUIDANCE "Insanitary Conditions at Compounding Facilities"

Dear Dr. Califf:

The American Society of Plastic Surgeons (ASPS) appreciates the opportunity to provide comments on the draft guidance entitled "Insanitary Conditions at Compounding Facilities."

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.

While we understand the U.S. Food and Drug Administration's (FDA's) desire to secure the pharmaceutical supply chain and ensure the delivery of good-quality prepared medicines, as well as to protect patients from potentially life-threatening contaminated medical products, we are disappointed to see the Agency is moving forward to treat sterile compounding in a physician's office as equally dangerous as those procedures performed in a compounding center.

In addition, we respectfully remind the Agency that every day, patients and family members reconstitute medications provided in the home setting. We do not believe it is the intent of the FDA to restrict patient care, but are concerned that this guidance document may create roadblocks that will forever impact ease of administration, limit access, and drastically increase the cost of care for patients.

As we are sure you are aware, last fall the United States Pharmacopeia (USP) Convention shared a proposal to revise existing compounding rules. Almost 8,000 comments, the majority of which were from health care providers, were submitted in response. The vast majority expressed concern that the proposal was an overreaching one-size fits all approach, developed without scientific evidence to support the overly restrictive proposal. In recognition of the many issues raised, the USP has agreed to table any updates until it has an opportunity to meet with stakeholders to further discuss the unintended consequences the proposal will have on both physicians and patients.

The ASPS respectfully requests that the FDA also table their draft documents, refraining from undermining its own existing standards and currently established USP standards until the USP completes its consideration of comments submitted, holds discussions, and makes any required revisions.

We also request the Agency perform an analysis related to the impact of this draft guidance, in part, to identify how such a proposal might increase healthcare costs. Any analysis should include a thorough review of the economic impacts associated with increased emergency department (ED) utilizations, hospitalizations, outpatient medical visits and well as indirect costs related to lost time at school or work.

Finally, given the potentially broad implications this draft guidance may inadvertently create, we also request a public meeting be held to allow physicians an opportunity to provide additional input to the Agency.

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

Sincerely,

Debra Johnson, MD
President, American Society of Plastic Surgeons