

August 13, 2019

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Dr. Woodcock:

On behalf of our members, the undersigned organizations write to thank the U.S. Food and Drug Administration (FDA) for its continued efforts to ensure the safety of our nation's compounded drug products. Our organizations strongly support the FDA's goals of ensuring that the compounded drug products our patients receive meet high standards for safety and sterility. However, we remain concerned about the possibility that actions taken by the FDA in finalizing compounding-related guidance documents may significantly hinder our physicians' ability to provide critical treatments to patients in office settings.

At a recent "Listening Session" on compounding topics, it was noted that FDA officials may be interested in finalizing certain guidance in a manner that could potentially restrict physicians' ability to prepare sterile drug products for administration to their patients in the office setting. The guidance in question—Insanitary Conditions at Compounding Facilities—was released as an updated draft document in September 2018. This updated draft guidance reflected the concerns the physician community raised with the initial draft guidance, and indicated that the FDA proposed to exercise enforcement discretion with respect to physician offices preparing sterile drug products for administration to their own patients in office settings. Our organizations were pleased to see this shift from the earlier, overly-restrictive proposals that would have undoubtedly limited patient access to critical treatments performed in physician offices. However, following the Listening Session, we have increasing concern that any final Insanitary Conditions guidance may once again place onerous restrictions on physician practices, threatening patient access to necessary and timely treatments.

As you may know, a significant number of physicians across a number of different specialties prepare sterile products in office settings for administration to their patients. In many cases, in-office preparation and administration of these products represents the long-held standard of care for a certain condition or disease state within a certain specialty. In almost all cases, the preparation of these products in-office has been a preferred pattern of practice for years. Further, preparation of these products generally presents an extremely low risk to patient safety and there has been little evidence of increased sterility issues associated with the act of preparation in the physician office.¹

Patients of many specialists rely on the ability of their physicians to prepare these drugs in-office to avoid certain increased risks, avoid follow-up appointments for treatment, and to avoid receiving treatment in

¹ The physician community is aware of the tracking of outpatient infections by the Centers for Disease Control and Prevention (CDC). However, review of these reports appears to show, at best, anecdotal evidence frequently without a determination of the root cause of infection. In instances where the root cause of infection could be determined, most of publicly available reports appear to be due to failure to follow safe injection practices, and not linked to the compounding of sterile drug products. While the physician community does not wish to minimize the risks associated with failure to follow safe injection practices, we would also urge the CDC and FDA to ensure the reports are not being mischaracterized as a large body of evidence of unsafe compounding practices when they indeed are not.

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higher-cost care settings. For example, allergy and immunotherapy patients receive patient-specific treatments prepared by their physician in that physician's office, where treatment dilutions, can be carefully controlled to avoid potential life-threatening complications, such as serious allergic reactions. Dermatology and plastic surgery patients rely on in-office preparation of buffered lidocaine for use during outpatient procedures. Other specialists provide treatments, such as joint injections, to help patients deal with pain, and these are drawn up with a local anesthetic immediately prior to administration. In the majority of cases, acquiring these products in a ready-to-use form from a compounding pharmacy is not a viable option, either due to stability issues with the drug, increase in potential risks to patients, delay in treatment, or significant increased cost of treatment.

As you can see, our patients rely on the ability of our members to prepare critical sterile treatments in the office setting for administration to their patients. Restricting the ability of our members to offer these necessary services would likely result in a significant increase in access issues and costs, and overall worse health outcomes for our patients. Physicians are simply unable to retrofit practice facilities with new equipment/clean rooms or undergo other structural facility changes to meet safety and sterile requirements akin to those in compounding pharmacy facilities. In addition, as mentioned above, there is a significant lack of evidence showing risks to patients that warrants further change or restrictions on practice.

The health and safety of our patients is, and has always been, the first priority of our members. We share the FDA's goals of ensuring the nation's compounded drug supply is safe and that sterility is maintained. However, reducing access to necessary treatments also presents increased risk to the health status of patients nationwide—a problem we hope FDA also seeks to avoid. As FDA works to finalize the draft guidance for Insanitary Condition in Compounding Facilities, we urge you to work closely with the physician community to determine the most appropriate path forward that both ensures sterility of drug products prepared in office settings and maintains access to critical treatments for patients. Representatives of the physician community welcome further discussion in follow-up to the Listening Session at any time. Please do not hesitate to contact Shannon Curtis, shannon.curtis@ama-assn.org, who can help facilitate dialogue with the broader community as needed. We look forward to working with you on this important issue for our patients.

Sincerely,

American Medical Association
American Academy of Allergy, Asthma and Immunology
American Academy of Dermatology Association
American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Family Physicians
American Academy of Otolaryngic Allergy
American Academy of Otolaryngology–Head and Neck Surgery
American Academy of Physical Medicine & Rehabilitation
American Association of Orthopaedic Surgeons
American College of Allergy, Asthma and Immunology
American College of Rheumatology
American Osteopathic Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Clinical Oncology

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American Society of Colon and Rectal Surgeons

American Society of Hematology

American Urological Association

American Academy of Ophthalmology

Heart Rhythm Society

Spine Intervention Society