AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

November 20, 2018

The Honorable Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

I am writing on behalf of the physician and medical student members of the American Medical Association (AMA) to thank the U.S. Food and Drug Administration (FDA) for its diligent work to implement the Drug Quality and Security Act (DQSA). As you know, the AMA has been carefully monitoring implementation of the DQSA, specifically sections governing drug compounding. Many of our members and their patients rely on sterile preparations as part of the standard of care for many conditions. This is particularly true for those drug products routinely prepared by physicians in office settings.

For physicians across specialties, in-office preparation of sterile drug products for administration to patients represents the long-held standard of care and preferred method of treatment for a number of conditions. Activities such as buffering lidocaine, drawing up sterile injectables with a local anesthetic, preparing personalized allergy injections, and others represent a critical part of medical practice for a number of physicians and patients. In recent years, the AMA has raised a number of concerns with the FDA and other stakeholders involved in implementation of the DQSA about the potential impact of overly burdensome regulatory restrictions on these physician in-office activities on both patients and medical practice.

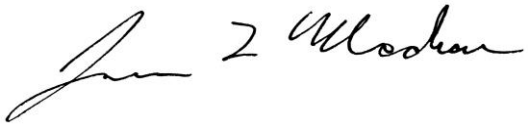
In the recently released revised draft guidance "Insanitary Conditions at Compounding Facilities," the AMA was pleased to see that the FDA has removed references to physician offices as compounding facilities for purposes of the guidance. Physician offices differ greatly from compounding pharmacies or outsourcing facilities compounding complex products in large quantities for retail sales. Physician offices typically are engaged in the low-risk preparation of sterile drug products for administration directly to their patients. Sterile drug preparation by physicians is also typically only done where that practice represents the standard of care for certain conditions and is widely accepted across those specialties. As physician preparation of sterile drug products presents a very different risk profile from other facilities, physician offices should not be considered compounding facilities by the FDA, and should not be subject to the same requirements as those facilities.

The AMA is also pleased to see that the FDA noted it does not intend to take enforcement action against physicians preparing sterile drug products in an office setting for administration to patients in that same office. While the AMA supports enforcement actions taken when egregious, unsafe actions are observed, it does not support FDA enforcement against physicians engaged in low-risk activities that constitute the practice of medicine and represent an appropriate and widely-accepted pattern of practice for the specialty

in question. Generally, physician conduct of this nature should continue to be regulated by state boards of medicine. To subject physician offices to the stringent requirements of higher-risk facilities would undoubtedly result in reduced access to critical treatment for patients.

The AMA appreciates the opportunity to have worked with the FDA on this issue in recent years. We look forward to continuing to work with the FDA to ensure that the sterile preparations our patients require are safe while maintaining access to the critical treatments our patients need most. If you have any questions or would like to discuss this matter further, please contact Shannon Curtis, Assistant Director, Federal Affairs at shannon.curtis@ama-assn.org or 202-789-8510.

Sincerely,



James L. Madara, MD