AMA
AMERICAN MEDICAL ASSOCIATION

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

Dear Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide our comments on the U.S. Food and Drug Administration's (FDA) draft guidance, "Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act." The AMA applauds the FDA's steadfast commitment to ensuring the safety of the nation's compounded drug supply and its efforts to implement the Drug Quality and Security Act. The AMA is committed to working with the FDA to promote the safety and sterility of compounded drug products while ensuring patients maintain access to essential treatment options.

The AMA is pleased to see the FDA providing further guidance regarding products compounded by 503B outsourcing facilities. The AMA supports FDA's position that, when appropriate, drug products prepared by outsourcing facilities should be compounded from FDA-approved products. However, there are certain patients for which an FDA-approved product may be available, but may not be appropriate, such as when a patient needs a different concentration from the commercially available form. In these situations and for these patients, a drug product compounded from a bulk substance is clinically necessary and medically suitable.

While the AMA supports compounding from FDA-approved products when appropriate, for those patients for whom a compound from a commercially-available product is not appropriate, the AMA strongly encourages the FDA to engage with relevant medical specialty societies in making determinations of clinical necessity and medical suitability. Determinations of this type are only appropriate when made by treating clinicians and should not be made solely by regulators who may or may not have the relevant expertise in appropriate clinical standards or treatment guidelines. As such, the AMA strongly urges the FDA to work with the physician community to establish a system for engaging with the physicians and their specialty medical societies regarding determinations of medical necessity for certain compounded products. To make these types of determinations without full engagement from the physician community would constitute an overreach on the part of the FDA and would potentially constitute an impermissible intrusion into the practice of medicine. It may also potentially risk access to certain essential treatments for patients without suitable FDA-approved options.

The AMA understands the challenges that appropriate regulation of drug compounding poses and appreciates FDA's work on this important issue. We look forward to continuing to work with you to ensure continued access to safe compounded drug products and stand ready to engage as necessary to

assist with the evaluation of bulk drug substances for use by 503B outsourcing facilities. Should you have any questions or wish to engage on this issue further, please contact Shannon Curtis at 202-789-8510 or shannon.curtis@ama-asssn.org.

Sincerely,

James L. Madara, MD