AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

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

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Stephen Ostroff, MD
Acting Commissioner
U.S. Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA-2004-D-1525-0002; *Mixing, Diluting, and Repackaging of Biological Products Outside of an Approved Biologics License Application*

Dear Acting Commissioner Ostroff:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on and express our support for the U.S. Food and Drug Administration's (FDA) goals of ensuring the quality and safety of our nation's compounded and repackaged drug supply. While the Drug Quality and Security Act (DQSA) does much to ensure that compounding pharmacies meet the highest possible production standards, the law left the agency with many questions as to where and how certain compounded and repackaged drug treatments would be made available to physicians and patients, if they are made available at all. As many physicians and patients rely on compounded or repackaged drug products to treat a wide range of serious conditions, the AMA has a strong interest in ensuring that the agency's implementation of the DQSA ensures the safety of compounded and repackaged drugs while maintaining access to critical treatment options and not impeding the practice of medicine.

Biological Products

The AMA is concerned that proposals included in the agency's draft guidance for Mixing, Diluting, and Repackaging Biological Products may severely impact physician and patient access to some compounded and repackaged biological products that have been used safely in practice for a number of years. The draft guidance proposed by the agency includes "beyond use dates" (BUDs) that are so short that drug products subjected to them would essentially be unavailable for physicians and patients outside of a hospital setting. While these BUDs may be appropriate for some compounded or repackaged biological products, the AMA is concerned that placing similar restrictions on all biological products may unnecessarily restrict access to critical treatment options that have a history of safe and efficacious use for longer periods of time, even after compounding or repackaging. The AMA recommends that, where the evidence demonstrates that a certain product can be safely compounded or repackaged with a longer BUD, the agency consider this evidence and set a BUD appropriate for that particular drug product instead of one set arbitrarily for an entire class of product.

Short BUDs, such as those proposed in the agency's draft guidance, will be problematic for many physicians and patients. For physicians practicing outside of a hospital setting, or for those treating

patients in a hospital without in-house pharmacy capabilities, the proposed BUDs will make access to certain biological products from compounding facilities nearly impossible, as a facility cannot complete sterility testing, fulfill an order, and ship to a treatment setting within the window provided. This is especially true for physicians treating patients in rural areas, where delivery to clinics takes even longer. The proposed BUDs also run the risk of eliminating viable treatments for patients who do not respond well to other therapeutic options or cannot afford other available treatments.

The AMA understands that, in implementing the DQSA, the FDA has been tasked with balancing many challenging and important interests. While the FDA's primary concern must be ensuring patient safety and integrity of the nation's compounded and repackaged drug supply, the agency must also recognize that physicians frequently serve patients or classes of patients with unique needs that cannot be met through currently-available branded medications. Just as there cannot be a "one size fits all" approach to the practice of medicine, the agency should not apply an across the board "one size fits all" approach to policies that ultimately impact drug availability. While restrictions and limitations may be appropriate in many cases, the FDA should be willing to exercise discretion where exceptions are appropriate and where they have the potential to significantly impact important treatment options for physicians and patients.

Collaboration with Stakeholders

The AMA appreciates the opportunity to participate in stakeholder "listening sessions" with agency staff to present concerns related to DQSA implementation. However, we are very concerned that these sessions do not provide a sufficient opportunity for impacted stakeholders, particularly key national medical specialties, to regularly engage with agency officials who are developing policies that, without critical information, will negatively impact patient care and access. While the agency has offered several opportunities for interested parties to provide written input, it has repeatedly denied requests to meet with the stakeholders whom the DQSA will ultimately impact. Written comments are not a substitute for constructive, in-person dialogue regarding real solutions to the complex issues facing the agency, pharmacies, physicians, and patients. The AMA recommends that the FDA work collaboratively with major stakeholders to discuss implementation activities that potentially affect physician and patient access to important compounded and repackaged drugs and work together with these groups to find solutions that come as close as possible to meeting the goals of all involved.

As the FDA works to ensure the quality and safety of the nation's compounded and repackaged drug supply, we urge the agency to strongly consider the access needs of physicians and patients. It is critical that no patients are harmed by contaminated drugs from compounding facilities. At the same time we must ensure that physicians and patients are able to access the essential treatment options they need, especially when branded drug products do not provide viable treatment options. The AMA looks forward to working with the agency as it continues implementing this important legislation. If you have any questions or need any assistance going forward, please do not hesitate to contact Shannon Curtis, Assistant Director of Federal Affairs, at 202-789-8510 or shannon.curtis@ama-assn.org.

Sincerely,

James L. Madara, MD