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March 14, 2013

Margaret Hamburg, MD  
Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Food and Drug Administration, Docket No. FDA-2013-N-0124

Dear Commissioner Hamburg:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide recommendations to the Food and Drug Administration's (FDA) Drug Shortages Task Force on its Strategic Plan. Physicians have expressed both concern and frustration with ongoing shortages, particularly of sterile injectables. Unfortunately, the recent tragic events reportedly caused by a compounding pharmacy have further complicated the ongoing difficulties in addressing shortages of sterile injectables. The AMA welcomes the opportunity to provide comments on a number of the questions presented by the FDA and looks forward to working with the FDA to promote effective communication of shortages to physicians.

*To what extent do purchasers and prescribers use information about manufacturing quality when deciding how to purchase or utilize products?*

The mandate of the FDA has been and should continue to be ensuring that regulated products are safe and efficacious. It should not be within the purview of the FDA to establish metrics for purposes of promoting one product over another as superior to prescribers. First, the approval standard should be properly rigorous to ensure that substandard products are not on the market in the first place. The proposal to use quality measures for purchasers and prescribers would likely greatly expand the resources needed by the FDA in order to make quality assessments.

Furthermore, broad agreement exists that a fundamental cause of shortages involving generic sterile injectables is limited production capacity and lack of redundancy. Creating a system whereby certain manufacturers may experience declining sales because of a lower "quality"

score (even though their product is approved for marketing) will do little to address drug shortages and could in fact exacerbate the situation. This approach could only be contemplated in the presence of excess production capacity.

*Is it possible to design a qualified manufacturing partner program that would have a positive impact on shortages?*

The AMA supports the concept of developing a qualified manufacturing partner program. This holds the potential to have the most immediate impact on production capacity and redundancy while awaiting construction and/or expansion of existing facilities to produce sterile injectables.

*In our work to prevent shortages of drugs and biological products, the FDA regularly engages with other U.S. Government Agencies. Are there incentives these Agencies can provide, separately or in partnership with FDA, to prevent shortages?*

The Drug Enforcement Administration (DEA) and FDA could further expedite communications and coordination beyond those mandated deadlines contained in the Food and Drug Administration Safety and Innovation Act to identify drugs subject to a quota that are likely to go into shortage and, move rapidly to re-assign quota balances a manufacturer is unlikely to meet due to manufacturing or other problems.

*To manage communications to help alleviate potential or actual shortages, FDA uses a variety of tools, including posting information on our public shortage websites and sending targeted notifications to specialty groups. Are there other communication tools that the FDA should use or additional information the Agency should share to help health care professionals, manufacturers, distributors, patients, and others manage shortages more effectively? Are there changes to our public shortage websites that would help enhance their utility for patients, prescribers, and others in managing shortages?*

The AMA strongly supports targeted notification to physician medical specialty organizations.

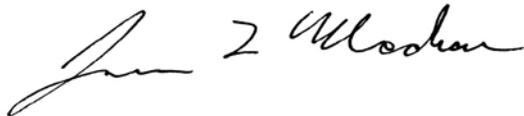
Health care providers may not learn about a shortage until they need to administer the product or a patient informs the physician. This is often too late and could lead to significant disruption in clinical care and may also undermine the health status of otherwise stabilized patients. If the FDA has not already done so, the agency should convene a well-publicized meeting of vendors of prescriber decision support and electronic health records (EHRs) to identify any technical requirements that could be addressed by the agency to ensure that this information is provided directly to physicians through smart phone and tablet applications, EHRs, or other portals regularly accessed by physicians.

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Physicians and patients often will need help identifying local or reputable online pharmacies where products may still be available, the length of time it will be available, and when products are in short supply. The FDA website should include website links, phone numbers, as well as a cautionary message to patients about internet pharmacy sites that tout availability of shortage drugs. Also, the FDA website could link to medical specialty sites or other clinical resources that provide information on alternate medication and dosing.

Should you have questions, please contact Sandy Marks, Assistant Director, Federal Affairs at (202) 789-4585 or [sandy.marks@ama-assn.org](mailto:sandy.marks@ama-assn.org). We appreciate the opportunity to comment.

Sincerely,

A handwritten signature in cursive script, appearing to read "James L. Madara".

James L. Madara, MD