American Hospital Association

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February 10, 2012

Margaret A. Hamburg, M.D.
Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
Docket No. FDA-2011-N-0898
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA–2011–N–0898, Applications for Food and Drug Administration Approval to Market a New Drug; Revision of Postmarketing Reporting Requirements – Discontinuance; (Vol. 76, No. 243), December 19, 2011.

Dear Dr. Hamburg:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) interim final rule amending its postmarketing reporting regulations to modify the term "discontinuance" and clarify the term "sole manufacturer" with respect to notification of discontinuance requirements. **The AHA supports the rule and believes it will improve FDA's ability to prevent and mitigate the impact of imminent drugs shortages by increasing the scope of information that the agency receives regarding discontinuances. However, we continue to believe that more must be done to increase FDA's authority to address drug shortages**.

This interim final rule comes at a critical time and is welcome news for hospitals and their patients. The number of drug shortages has tripled in the past six years and the shortages are seriously impacting patient care. Hospitals are committed to providing every patient with the right care, at the right time, in the right setting. Timely access to the right drug is an essential element in that equation. A 2011 AHA survey found that nearly 100 percent of hospitals had experienced a shortage within the previous six months. And most have rarely, if ever, received advance notification of these drug shortages. The FDA and clinicians need more notice from drug manufacturers so they have time to act to ensure that patient care is not disrupted. While hospitals are doing their best to reduce the impact of shortages by increasing inventories, buying alternative drugs and training clinical staff on how to deal with drug shortages, there is more that can and should be done.

The AHA appreciates the FDA's time and efforts, particularly through the Drug Shortage Program, to collaboratively resolve and reduce the impact of shortages. Current FDA regulations, as mandated by section 506C of the *Food, Drug and Cosmetic (FDC) Act*, requires sole manufacturers of certain drug products to notify the agency at least six months before discontinuing the manufacture of certain drug products that are "life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition." Using this information and other resources and tools available under its current authority, the FDA has been able to prevent more than 250 shortages since 2010.

However, FDA's current policy does not require reporting of temporary interruptions in manufacturing, nor does it explicitly require reporting of discontinuances if other manufacturers make the same drug but in different strengths, dosage forms or routes of administration. Experience with the increasing number of drugs in shortage has shown that these reporting exemptions have contributed to the number of shortages and have resulted in harm to patients.

Therefore, this interim final rule, which addresses shortcomings in the current reporting requirements, is an important development that will provide the FDA additional information that the agency can use to work with manufacturers and the clinical community to do even more to address drug shortages. In the interim final rule, the FDA formalizes and expands upon the definitions for two terms related to the agency's existing manufacturer reporting requirement. First, it defines "discontinuance" to include both permanent and *temporary* discontinuances in the manufacture of a drug which could lead to a disruption in supply of the product. The rule also clarifies the term "sole manufacturer" to require manufacturers to report a discontinuance of their drug even if other strengths, dosage forms, or routes of administration of the same drug are still on the market. The AHA believes that this rule will significantly increase the number of manufacturers reporting and the volume of reports submitted, thereby allowing FDA to communicate more and better information to patients, hospitals, and physicians, as well as allow the agency to work in a more informed manner with manufacturers to reduce the impact of drug discontinuances that may lead to a shortage.

While the interim final rule is certainly a step in the right direction, there is more to do to address this public health crisis. The AHA supports the *Preserving Access to Life Saving Medications Act* (H.R. 2245/S. 296), which will strengthen the FDA's ability to respond to drug shortages by establishing an even stronger requirement for manufacturers to report potential or actual supply disruptions to the FDA. The notification requirements call for manufacturers to notify the FDA of any changes, interruptions, or adjustments that could affect the supply of the drugs they manufacture. It would also provide FDA with the authority to seek civil monetary penalties to ensure compliance with this requirement. This legislation also would require the FDA to implement evidence-based criteria for identifying drugs that may be vulnerable to shortages and notify and collaborate with the manufacturers of such vulnerable drugs in order to establish and improve their plans and processes for averting and addressing drug shortages. We believe that this legislation would help to address the issues leading to shortages and provide the FDA with additional authority and information to prevent further drug shortages. But other steps supported by the AHA also should be considered by Congress and the FDA, including removing obstacles so that the FDA is able to streamline approval of drugs in shortage; improving communication among stakeholders, including the extent and timeliness of information; and exploring financial incentives to encourage drug manufacturers to stay in, re-enter or initially enter the market.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President