



**American Hospital
Association**

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

December 17, 2013

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, Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products (Vol. 78, No. 213), November 4, 2013.

Dear Dr. Hamburg:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed rule that would amend its regulations to implement certain drug shortage provisions enacted in the *Food and Drug Administration Safety and Innovation Act (FDASIA)*. Specifically, the proposed rule would require manufacturers of certain drugs and biological products to electronically notify FDA of a permanent discontinuance or manufacturing interruption of a product that is likely to lead to a meaningful disruption in supply. Notification to the FDA would be required at least six months prior to the date of the permanent discontinuance or manufacturing interruption; or, if six months' advance notice is not possible, as soon as practicable thereafter, but in no case later than five business days after the permanent discontinuance or manufacturing interruption occurs. The proposed rule also would require the FDA to issue a public noncompliance letter to a manufacturer for failure to notify the agency. **The AHA supports the notification and compliance requirements included in the proposed rule as they will improve FDA's ability to prevent and mitigate the impact of imminent shortages of drugs and biological products.**

The proposed rule is welcome news for hospitals and their patients. 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 drug shortage within the previous six months. Most hospitals reported that they rarely, if ever, receive advance notification of these shortages. The FDA and clinicians need more notice from manufacturers so they have time to act to ensure



Margaret A. Hamburg, M.D.

December 17, 2013

Page 2 of 2

that patient care is not disrupted. While the number of drugs in shortage has decreased over the past two years, due in large part to FDA actions, shortages still represent a significant challenge to hospitals' and physicians' ability to provide appropriate care to patients. Shortages of critical drugs, such as those used to treat cancer or to provide required parenteral nutrition, can delay or prevent needed care and can result in clinicians prescribing second-line alternatives, which may be less effective or of higher risk.

In particular, the AHA strongly supports FDA's decision to use the discretionary authority it was granted under FDASIA to apply the notification requirements to all biological products, including recombinant therapeutic proteins, monoclonal antibody products, vaccines, allergenic products, plasma-derived products and their recombinant analogs, blood or blood components, and cellular and gene therapy products. While FDASIA mandates that the notification requirements apply to prescription drugs, the law allows FDA to apply the requirements to biological products only if the agency determines that their inclusion would benefit public health, taking into account other existing supply reporting programs and aiming to reduce duplicative notifications.

Like drug shortages, shortages of biological products can have serious negative consequences for patients who rely on these products for their treatment. Therefore, we agree with FDA's determination that early notification of discontinuances or manufacturing interruptions of biological products would greatly benefit public health by facilitating prompt FDA action to address, prevent or mitigate shortages of these critical products. The AHA also agrees that the existing reporting programs that apply to some of these biological products do not serve the same purpose, nor do they have the same scope as the notification required under the proposed rule. Therefore, the requirements in the proposed rule would not duplicate existing reporting programs or create redundant reporting.

The AHA believes that this rule will significantly increase the number of manufacturers reporting drug and biological product shortages and the volume of reports submitted, thereby allowing FDA to communicate more and better information to patients, hospitals and physicians. It also will allow the agency to work with manufacturers in a more informed manner to reduce the impact of drug and biological product discontinuances and manufacturing interruptions that may lead to shortages.

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