AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

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

December 27, 2013

Margaret A. Hamburg, MD
Commissioner
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 Commissioner Hamburg:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Food and Drug Administration's (FDA) proposed rule that would require manufacturers to notify the agency of a permanent discontinuance or manufacturing interruption of a product that is likely to lead to a meaningful disruption in supply. This FDA notification would be required to be submitted at least six months prior to the discontinuance or interruption, unless a six-month advance notice is impossible. The proposed rule also would require the FDA to issue a public noncompliance letter to a manufacturer for failure to notify the agency.

Drug shortages are a serious problem for patient care. The AMA strongly supported the provisions of the FDA Safety and Innovation Act that are the basis for the FDA's proposed strategy to prevent imminent shortages of drugs and biologicals from having a negative impact on patient care, and the AMA welcomes the proposed rule.

Physicians often do not learn about a shortage until they need to administer the product or a patient informs them that the drug is unavailable, leading to significant disruption in clinical care with potential adverse consequences for health status or treatment outcomes. Obtaining early notice from manufacturers will allow the FDA to inform physicians, who will in turn have an opportunity to identify alternatives so that their patients' care is not disrupted. While the FDA's actions to date have been very successful in preventing or mitigating new drug shortages, they still remain a major problem. Drug shortages can delay or disrupt care and force physicians to turn to less effective or higher risk alternatives.

The AMA also strongly supports the FDA's proposal to use its discretionary authority 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 the law mandated notification for prescription drugs, it allowed the agency to apply the requirements to biological products only if it determines that their inclusion would benefit public health. The AMA supports the proposal to extend the notification requirements to biologicals.

The regulations that the FDA has set forth in this proposed rule will significantly increase the number of manufacturers reporting drug and biological product shortages before they occur, allowing better communication and planning between the FDA, physicians and manufacturers in order to avoid disruptions in patient care. We urge the FDA to finalize the proposed requirements and we thank you for considering the AMA's comments.

Sincerely,

James L. Madara, MD