American Society of Anesthesiologists

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January 3, 2014

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health & Human Services
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. **FDA-2011-N-0898**; Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products

Dear Commissioner Hamburg:

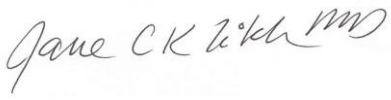
The American Society of Anesthesiologists (ASA), on behalf of its over 51,000 members, appreciates the opportunity to provide comments in response to the Food and Drug Administration's (FDA) November 4, 2013 Federal Register Notice regarding the proposed implementation of drug shortage provisions in the Food and Drug Administration Safety and Innovation Act (FDASIA). The bipartisan passage and enactment of FDASIA was an important step in helping to prevent and mitigate drug shortages, but critical anesthesia drugs are still in short supply. ASA looks forward to the release of the U.S. Government Accountability Office report that will examine the cause of drug shortages and formulate recommendations on how to prevent and alleviate shortages. Below, ASA offers comments on the proposed definitions and specific recommendations on how to improve communication on shortages between the FDA and physicians.

Early manufacturer notification to the FDA is a key component of resolving drug shortages. ASA is a strong advocate for mandatory manufacturer notification, which was one of the five recommendations developed during a November 2010 Drug Shortage Summit co-convened by ASA and other key stakeholders. Specifically, ASA endorses the provision in FDASIA and language in the proposed rule applying the manufacturer notification requirement to drugs used "during surgery" and drugs "intended for use in the prevention or treatment of a debilitating disease or condition." The FDA proposes to define the latter as "a drug product intended for use in the prevention or treatment of a disease or condition associated with mortality or morbidity that has a substantial impact on day-to-day functioning." While the FDA does not list specific drugs that are used "during surgery" or "in the prevention or treatment of a debilitating disease or condition," ASA believes that drugs used in anesthesia and pain medicine fall comfortably within the notification requirement. In addition, ASA endorses the provision in FDASIA and language in the proposed rule applying the manufacturer notification requirement to prescription drugs marketed without an approved application, which have been used by anesthesiologists for decades and are critical to safe anesthesia care.

Finally, as noted by the FDA, communication between the Agency and physicians is an essential component to addressing drug shortages. The FDA has already taken important steps to improve communication by updating the FDA's website so drugs can be sorted by therapeutic category and developing a smartphone application so physicians can instantly access information about shortages. The FDA should also consider establishing a mechanism whereby physicians can receive shortage information about specific therapeutic categories via email updates, an RSS-feed, or through the smartphone application. These targeted communications will allow physicians to only receive the information they need.

We look forward to continue working with the FDA on this important issue. Please feel free to contact Lisa Pearlstein, J.D., Pain Medicine and Regulatory Lobbyist at l.pearlstein@asawash.org or 202-289-2222 if you have any questions or need additional information regarding this issue.

Sincerely,



Jane C.K. Fitch, M.D.
President
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