American Society of Anesthesiologists

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June 12, 2014

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Bldg. 51, rm. 4171
Silver Spring, MD 20993

Re: Docket No. **FDA-2014-D-0248**; Draft Guidance for Industry on Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products; Availability

Dear Commissioner Hamburg:

The American Society of Anesthesiologists (ASA), on behalf of over 52,000 members, is writing in response to the Food and Drug Administration's (FDA) Federal Register notice regarding the draft guidance for industry on labeled vial fill size in injectable drug products. ASA strongly supports the FDA's recommendation that a drug product's vial fill size be appropriate for the labeled use and dosing of the product. Critical anesthesia drugs are still in shortage, and the availability of appropriately sized vials will help limit waste of drugs in shortage.

Vial sizes appropriate for the labeled use and dosing of the product are imperative to help alleviate drug shortages. Some sterile injectable generics, like propofol, are produced in single dose vials. The Centers for Disease Control and Prevention (CDC) has stated that if single-dose vials are to be used for more than one patient, providers must adhere to USP standards to minimize risk. ASA supports CDC's position, and adopted CDC's Safe Injection Practices in the *Recommendations for Infection Control for the Practice of Anesthesiology* (3d ed.), located here: https://www.asahq.org/For-Members/Standards-Guidelines-and-Statements.aspx . However, many physicians practice in facilities that do not have access to the equipment necessary to repackage drugs pursuant to USP 797 and must discard the unused portion of a drug, which is particularly problematic when the drug is in short supply.

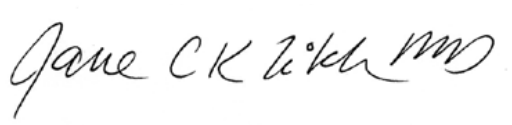
Moreover, vial sizes appropriate for the labeled use and dosing of the product may not be available or may be more expensive per milliliter than larger vials that contain a significant volume beyond a usual or maximum dose for the expected use of the drug product. In particular, contrast is produced in single dose vials and is used in interventional pain management procedures to determine correct needle placement. Vial sizes appropriate for the labeled use and dosing of contrast are not always available and are often priced higher per milliliter than larger vials of contrast that contain a significant volume beyond a usual or maximum dose. Due to these access and cost concerns, physicians are incentivized to purchase vials of contrast that contain a significant volume beyond a usual or maximum dose, which leads to waste of limited resources, increased costs to the health care system, and potentially microbial contamination if CDC infection control standards are not followed.

ASA would appreciate the opportunity to work with the FDA and sponsors to implement guidance on labeled vial fill size, and in particular to identify the usual or maximum dose for a drug product. Physician anesthesiologists have unique knowledge of the typical doses of drug products and how they

are used every day in operating room settings and pain clinics. Working together, we can take significant steps to help mitigate drug shortages and protect patient safety.

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

Respectfully yours,



Jane C.K. Fitch, MD
President
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