March 12, 2013

Captain Valerie Jensen, RPh
Associate Director
Center for Drug Evaluation and Research
Food and Drug Administration
U.S. Department of Health & Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993-002


Dear Captain Jensen:

On behalf of the more than 45,000 members of the American Association of Nurse Anesthetists (AANA), the AANA welcomes the opportunity to submit these comments in response to the U.S. Food and Drug Administration’s request for comments on its strategic plan to address drug shortages.

Our comments recommend communication components that should be included in the strategic plan to prevent and mitigate the effects of drug shortages. In early 2013, the AANA conducted a survey of AANA members to determine the impact of drug shortages on Certified Registered Nurse Anesthetists (CRNAs) and patient care. Previously, in September 2011, the AANA conducted a similar survey. On December 23, 2011, the AANA submitted the results of the 2011 survey to the FDA. Our comments today reflect preliminary findings from our 2013 survey. We will submit our final report to the FDA when it is complete.

Our preliminary findings reveal that CRNAs and their patients continue experiencing harsh effects of drug shortages in anesthesia and pain management practice. Despite expanded FDA efforts to combat drug shortages since 2011 and enactment of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), significant shortages and concomitant work-arounds continue to plague anesthesia and pain management practice, resulting in risk to patient safety and increasing healthcare costs without adding value.

The AANA recommends that the FDA Strategic Plan include the following components:

- Enhanced communication regarding possible alternative medications, alternative suppliers, anticipated duration of shortages, and reasons for the shortages
- Inclusion of the AANA in targeted alerts regarding drug shortages and on the list of specialty organizations that provide guidance to the agency
Background: The AANA and CRNAs

The AANA is the professional association for CRNAs and student nurse anesthetists. AANA membership includes more than 45,000 CRNAs and student registered nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 34 million anesthetics to patients each year in the United States, according to the 2012 AANA Practice Profile Survey. CRNAs are Medicare Part B providers and since 1989, have billed Medicare directly for 100 percent of the physician fee schedule amount for services.

CRNA services include providing a preanesthetic assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient’s vital signs, managing the patient throughout the surgery, and providing chronic and acute pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities.

According to a 2007 Government Accountability Office (GAO) study, CRNAs are the predominant anesthesia provider where there are more Medicare beneficiaries and where the gap between Medicare and private pay is less. Nurse anesthesia predominates in Veterans Hospitals, the U.S. Armed Forces and Public Health Service. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management facilities and the offices of dentists, podiatrists, and all types of specialty surgeons.

The FDA Should Provide More Detailed Information about Anesthesia and Pain Management Drug Shortages

Our preliminary survey results indicate that critical information concerning drug shortages is still not reaching the anesthesia professionals serving patients in all types of facilities across the United States. The reasons for the lack of helpful information range from poor pharmacy communications concerning shortages the facility is experiencing to the overall lack of general information regarding the causes of drug shortages, anticipated duration, alternative drug suppliers, and alternative drug uses.

The AANA urges the FDA to develop guidance and regulations that direct the pharmaceutical industry to provide specific and complete information to the FDA and to purchasers about potential drug shortages that is useful to providers in mitigating the impact of shortages in the clinical area. The FDA should post and disseminate the additional information as soon as possible. Drug companies should be required to request feedback from providers as to whether or not their notification was helpful in the clinical setting in order to evaluate and improve the notification process. According to the AANA’s preliminary 2013

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survey results, CRNAs find that communication and resources about drug shortages are inadequate. Many CRNAs learn of shortages for the first time when they are ordering drugs and learn that the drugs are not available. CRNAs are often given no information about the duration of the shortage.

The FDA should provide additional information about alternative drug choices and the anticipated duration of drug shortages, as well as continue to provide advance notice of drug shortages. CRNAs report in the 2013 AANA drug shortage survey that they highly value information that offers alternative drug choices or techniques (64.4 percent of respondents), advance notice of shortages (77.7 percent), and anticipated duration of shortages (76.3 percent). Although the FDASIA requires that manufacturers provide advance notice of anticipated shortages, many CRNAs report that they receive little or no advanced notice of anesthesia drug shortages in their facilities. Frequently, they discover that the drug is not available immediately prior to a case. Survey respondents also requested that information regarding alternative suppliers be readily available.

The FDA Should Include the AANA in Targeted Alerts Regarding Drug Shortages and List the AANA as a Specialty Organization that Provides Guidance to the Agency

The AANA requests that the FDA include the AANA in all external communications related to drug shortages impacting anesthesia and pain management services. Although the FDA has indicated that it sends targeted alerts to specialty groups, the AANA has not received FDA targeted communications despite our previous requests. The AANA, as the professional association representing CRNAs who administer more than 34 million anesthetics each year in the United States, has multiple communication vehicles to reach CRNAs in all practice settings throughout the country. Dissemination of targeted information about anesthesia and pain management drug shortages to the anesthesia professional will improve CRNAs' ability to manage the crisis at the facility level. Currently, the AANA obtains information about drug shortages from the FDA’s website and disseminates such information to AANA members via the AANA website with appropriate links to the FDA’s website. The AANA 2013 drug shortage survey results reflect that only 27.3 percent of CRNA respondents found the FDA drug shortage website a valuable resource. Through improved communication with the AANA, the FDA will support the partnership of CRNAs with their facility to reduce the impact of drug shortages on anesthesia and pain care services, reducing their negative effects on patient safety.

The AANA emphasizes its commitment to serve as an expert resource to the FDA in providing the frontline clinical perspective and assisting the FDA in developing meaningful and effective measures to respond to shortages. We request that the FDA include the AANA on its roster of consultative specialty organizations so that we may share our expertise relative to anesthesia and pain management drugs as well as adjunct medications for the betterment of patient care.

Conclusion

Thank you for the opportunity to provide comment to the FDA on the critical topic of drug shortages. We look forward to working with the FDA on solutions to this vexing public health problem. Please do not hesitate to contact AANA Senior Director of Professional Practice Lynn Reede, CRNA, DNP, MBA at (847) 655-1136 or lreede@aana.com if you have any questions or comments.
Sincerely,

Janice J. Izlar, CRNA, DNAP
AANA President

cc:

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