



December 23, 2011

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Office of Policy and Planning  
Food and Drug Administration  
U.S. Department of Health & Human Services  
10903 New Hampshire Avenue, Bldg. 32, Rm. 4220  
Silver Spring, MD 20993-002

**ATTN: Docket No. FDA-2011-N-0690, 76 Fed. Reg. 189, 9/29/2011 and 215, 11/7/2011**

Dear Dr. Lurie:

On behalf of the more than 44,000 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 regarding the FDA Center for Drug Evaluation and Research (CDER) approach to addressing drug shortages. The FDA specifically requests comments on the recent FDA report titled *A Review of FDA's Approach to Medical Product Shortages* (the "FDA Report") and its recommendations issued in response to the drug shortage crisis.

These comments address the impact of drug shortages on Certified Registered Nurse Anesthetists (CRNAs) and the patient population they serve, and how the FDA can mitigate the effects of these shortages. In September 2011, the AANA surveyed its membership regarding these issues. We have attached the AANA Drug Shortage Survey Results as Appendix A to these comments.

The AANA believes that given the complex and multifaceted root causes of the drug shortage crisis, the solution to the crisis is similarly complex and multifaceted. The FDA is only one part of the solution, albeit a very significant part. The AANA's comments therefore address the FDA's role in both short and long-term solutions.

These comments highlight recommendations in the FDA Report that address and reflect the CRNA concerns for safe and effective anesthesia care for their patients. The AANA believes that the following actions, which are all reflected in the FDA Report, are necessary for any FDA action plan to effectively address the drug shortage crisis:

- Enhance manufacturer notification of drug shortages
- Improve communication with national healthcare professional associations, including the AANA
- Enhance FDA communication about alternative medications
- Enhance internal FDA data collection and analysis
- Increase FDA resources to address drug shortages

The AANA appreciates the opportunity to comment on the FDA's development of strategies to prevent and mitigate drug shortages and also reaffirms its desire to continue to serve as a resource to the FDA on an ongoing basis. The AANA would like to share its expertise on this critical issue, particularly as it involves shortages of drugs related to anesthesia services, including pain management drugs.

### **Background: The AANA and CRNAs**

The AANA is the professional association for more than 44,000 CRNAs and student registered nurse anesthetists representing over 90 percent of nurse anesthetists in the United States. CRNAs are advanced practice registered nurses who personally administer more than 32 million anesthetics to patients each year in the United States. Nurse anesthetists have provided anesthesia in the United States for nearly 150 years, and high-quality, cost-effective CRNA services continue to be in high demand. 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 pre-anesthetic assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery. CRNAs also provide acute and chronic pain management services.

CRNAs are the primary providers of anesthesia care in rural America. In some states, CRNAs are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities.

### **AANA Supports Enhanced Manufacturer Notification of Drug Shortages**

In September 2011, the AANA conducted a survey of AANA members in order to gauge how drug shortages have affected CRNAs over the past year and to provide a vehicle for CRNA suggestions and comments. The AANA Drug Shortage Survey Results (Appendix A) reveal that a total of 434 members responded to the survey. Most respondents (94.7 %) experienced a drug shortage that affected their practice within 12 months of the survey. Significantly, 6 percent of respondents indicated that they cancelled cases due to drug shortages. Cancellations imperil our healthcare system by increasing costs, inconveniencing patients, and potentially placing patients at risk for adverse healthcare outcomes.

AANA survey respondents strongly indicated that advanced notification of an impending drug shortage and the anticipated duration of the shortage would help them plan to address patient needs. Advanced notice would allow CRNAs, in conjunction with their facilities' pharmacies and other affected health professionals, to develop plans to extend their current drug supply and to facilitate clinical decision making. CRNAs indicated that with the current system of notification their drug supplies often run out shortly after they are informed of a shortage. The FDA report reflects this critical need for advanced notification from manufacturers: "DSP [Drug Shortage Program] staff state that more often than not manufacturers fail to provide notification of actual or potential shortages." (FDA Report, FDA Activities Working with Manufacturers to Help Prevent and Mitigate Medical Product Shortages, p. 1)

Notably and consistent with the FDA Report's recommendations, the AANA supports two bills pending in Congress (S. 296 and HR 224) that seek to remedy the problem of insufficient advance notice of shortages by expanding and increasing the FDA's enforcement authority to require that manufacturers provide early notice of drug shortages of medically necessary drugs.

The AANA also supports and urges the FDA to develop guidance and regulations that clarify the informational content about potential drug shortages that is currently submitted by industry and released to healthcare professionals. Often industry-supplied information about drug shortages that is provided for public release lacks substantive details. (FDA Report, Executive Summary, p.1) We recognize that this recommendation is also consistent with Executive Order 13588, "Reducing Prescription Drug Shortages," issued by President Barack Obama October 31, 2011, which the AANA supports. The AANA Drug Shortage Survey Results indicate that CRNAs recommend that the FDA improve communication and available resources about drug shortages. Many responses noted the need for the FDA to provide additional details, including the cause of drug shortages.

### **AANA Recommends that the FDA Improve its Communication with National Associations of Healthcare Professionals**

A key theme of the AANA Drug Shortage Survey Results also echoed a key theme of the FDA Report: The FDA must increase efforts to communicate with healthcare professionals via their professional associations, including CRNAs via the AANA. The FDA Report states that once the FDA receives an explanation of the reasons for a shortage from a manufacturer, it informs the public of the shortage's existence "via communications with ASHP [American Society of Health-Systems Pharmacists] and other professional organizations, and via its own web site." (FDA Report, FDA Activities Working with Manufacturers to Help Prevent and Mitigate Medical Product Shortages, p. 1) The AANA Drug Shortage Survey results reflect that one-third of respondents were unsure about the amount of FDA assistance provided to them and their facilities regarding drug shortages. Nearly a third also indicated that the FDA had not provided any assistance regarding drug shortages. Several commentators noted that the FDA does not directly communicate with CRNAs. Only 5.1 percent of respondents indicated that the FDA had helped them "well" in handling drug shortages.

The AANA therefore requests that the FDA include the AANA in any and all external communications that address drug shortages affecting anesthesia services, including pain management drugs. Currently, the AANA receives 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. To the extent that the FDA engages in additional communications with professional organizations about drug shortages affecting anesthesia services, the FDA should include the AANA in all communications, including written correspondence and meetings and dialogue affecting anesthesia practice. This strategy will advance the FDA's interest in protecting the public and enable the AANA to better serve its members and their patients. Through better communication with the AANA, the FDA will meet the needs of all anesthesia professionals to plan for drug shortages affecting anesthesia services and lessen the shortages' impact on patient care.

In addition, the AANA reiterates its commitment to serve as an expert resource to the FDA by providing information and answering questions about drugs used in anesthesia services, including pain management drugs, and helping the FDA evaluate proposed measures to respond to shortages. For example, the FDA Report indicates that in certain circumstances the FDA seeks input from outside stakeholders, including specialty societies, on the determination of medical necessity of certain drugs. We request that the FDA include the AANA on its roster of specialty organizations that assist the FDA in answering questions about the medical necessity of drugs involved in anesthesia services, including pain management drugs.

Likewise, the AANA supports the FDA Report's proposed development of a sentinel reporting network that would include the AANA to facilitate early warning of drug shortages. The AANA believes such a network would facilitate the expeditious reporting of higher quality information about drug shortages. The AANA is willing to serve as part of this network to assist the FDA in information collection.

### **AANA Recommends that the FDA Enhance its Communications with Healthcare Professionals about Alternative Drugs**

The FDA should provide additional information about the availability and sources (including distributors) of alternative medications, dosing recommendations, and pharmacologic implications of the alternative medications. CRNAs reported on the AANA drug survey the need for more information about drug equivalents or alternatives. (39 percent of respondents listed information regarding drug alternatives as a resource that CRNAs need to better help them manage drug shortages.)

### **AANA Recommends that the FDA Enhance its Internal FDA Data Collection and Analysis to Prevent and Alleviate the Negative Impact of Drug Shortages**

The FDA Report notes that an FDA database would provide more detailed information about shortages and enable the FDA to analyze the causes, durations, and effectiveness of FDA responses to shortages. The AANA supports development of this database and believes such data analysis could lead to earlier remediation of shortages. The AANA also strongly supports the FDA Report's proposed comprehensive identification of the factors that contribute to success or failure in preventing drug shortages. According to the FDA, "The absence of readily analyzable data limits FDA's ability to assess the adequacy of its responses to shortages, to identify steps it can take to reduce the likelihood of shortages, and, potentially, to predict future shortages." (FDA Report, Review and Discussion of Key Issues, p. 1) Deep analysis of these factors will contribute to the body of knowledge concerning drug shortages and will lead to the development of better prevention and mitigation efforts.

### **AANA Recommends Increasing FDA Resources to Address Drug Shortages**

The AANA supports the FDA Report recommendation that calls for increasing the number of FDA staff responsible for addressing shortages. In light of the vast and increasing scope of drug shortages at least in the near term, the FDA needs additional resources to carry out its responsibilities effectively. The FDA Report states that the number of DSP staff has remained stable over the last several years while the number of shortages has increased substantially. (FDA Report, Review and Discussion of Key Issues,

p. 1) Increasing FDA staff in this area would enable the FDA to more expeditiously review new manufacturing sites, suppliers, and specification changes, thereby leading to increased supplies of medically necessary drugs and contributing to long-term solutions to shortages.

## Conclusion

We thank the FDA for including the AANA in the September 26, 2011 workshop addressing the drug shortage issue. The AANA has valuable input to offer the FDA in addressing this and other issues that affect anesthesia care. We look forward to continuing to serve as a resource to the FDA and we request that the FDA include the AANA in all communication and dialogue with anesthesia professionals on this critical issue. Please do not hesitate to contact AANA Senior Director of Professional Practice Lisa Thiemann, CRNA, MNA, at (847) 655-8876 or [lthiemann@aana.com](mailto:lthiemann@aana.com) if you have any questions or comments.

Sincerely,



Debra P. Malina, CRNA, DNSc, MBA  
AANA President

cc: Wanda O. Wilson, CRNA, PhD, AANA Executive Director  
Lisa J. Thiemann, CRNA, MNA, AANA Senior Director, Professional Practice  
Frank J. Purcell, BS, AANA Senior Director, Federal Government Affairs  
Barbara L. Anderson, JD, AANA Assistant Director, Professional Practice



## Appendix A AANA Drug Shortage Survey Results

### Overview

The purpose of the AANA Drug Shortage Survey was to gauge how drug shortages have impacted CRNAs in the past year and provide additional information, as requested by the U.S. Food and Drug Administration (FDA), regarding CRNAs suggestions and comments related to drug shortages.

The survey was disseminated through a direct email to randomly selected members, as well as posted on the AANA website. The results presented in this report summarize the combined email and web-based survey data.

### Response Rate

Of the 10,000 emails which were sent, 9,804 (98%) were successfully received (e.g., email addresses on file were current and active). Overall, 408 members completed the emailed survey, for a response rate of **4.2%**. Twenty-six members completed the survey through the AANA website. A total of 434 members responded to the survey. Open ended questions were not mandatory; the thematic analysis was only based on the number of responders to each individual question.

### Summary of Results

**1. In the past 12 months, have you experienced drug shortages that have affected your clinical practice?**

**94.7%** (n=411/434) of respondents reported that a drug shortage affected their practice in the past 12 months.

**2. Have you experienced shortages of any of the following medications? Check all that apply.**

Of the drugs listed on the survey, the most common drug shortage indicated was **Propofol** (82.0%, n=356/434), followed by **Neostigmine** (49.8%, n=216/434), **Vecuronium** (28.6%, n=124/434), and **Phenylephrine** (18.2%, n=79/434). Responders were able to make multiple selections when answering this question. The top 5 drug shortages experienced for those responders who selected "Other" are:

- 1. Succinylcholine**
- 2. Dexamethasone**
- 3. Sodium Thiopental**
- 4. Labetalol**
- 5. Ephedrine**

### 3. Have drug shortages caused you to cancel cases?

Of the responders to this question, **6.1%** (n=25/409) reported having to cancel cases due to drug shortages.

### 4. What drug shortage information do you need to make sure your patients get the care they need?

The top five pieces of drug shortage information that CRNAs reported needing are:

1. **Advanced notice of shortage** (41.7%, n=80/192)
2. **Duration of shortage** (31.8%, n=61/192)
3. **Information regarding drug alternatives** (18.8%, n=36/192)
4. **Information regarding cause of the shortage** (7.8%, n=15/192)
5. **How much inventory is currently available** (7.3%, n=14/192)

The most common theme was the need for advanced notice of an impending shortage. Responders indicated that this information would allow them to better plan how to extend their current drug supply. They indicated that often by the time they were informed of a shortage, their drug supply had quickly run out. CRNAs report the need for more information about drug equivalents or alternatives. This information includes the availability of alternative medications, dosing recommendations, and pharmacologic implications/concerns of the alternative medications.

Other points made, at a lower frequency, included a need for increased/more effective communication dissemination at both national and local levels. Additionally, there was some interest expressed in finding out what other suppliers or drug sources exist outside of the U.S.

### 5. Besides drug shortage information, what other resources would help you better manage drug shortages?

The top five resources that CRNAs reported would better help them manage drug shortages are:

1. **Information regarding drug alternatives** (39.2%, n=62/158)
2. **Advanced notice of shortage** (12.7%, n=20/158)
3. **Improved information dissemination** (12.7%, n=20/158)
4. **Information on the duration of shortage** (8.2%, n=13/158)
5. **Information on alternate sources of drug** (5.7%, n=9/158)

CRNAs reported the need for more information regarding drug equivalents or alternatives. This information includes the availability of alternative medications, dosing recommendations, and pharmacologic implications/concerns of the alternative medications. As seen with Question 4, CRNAs would find advance notice of drug shortages, information on the anticipated duration of the shortage and information on alternate sources (e.g., distributors) of drugs useful resources in

helping them manage a drug shortage. The need for improved information dissemination is also highly suggested. The suggestions for better information dissemination includes having one source of all information, better communication via emails or websites, better communication from the FDA and professional organizations, and better information dissemination within a facility (e.g., between pharmacy and providers).

## 6. How well has the FDA assisted you or your facility with drug shortages?

The top five responses to this question were:

1. **Unknown** (34.3%, n=68/198)
2. **Not at all** (30.3%, n=60/198)
3. **Very little / Poor** (8.6%, n=17/198)
4. **FDA only communicates with pharmacy rather than directly with providers** (7.1%, n=14/198)
5. **Well** (5.1%, n=10/198)

Of the responders, one-third was unsure about the amount of FDA assistance provided to them and their facility regarding drug shortages. One-third of the responders indicated that the FDA had not provided assistance at all regarding drug shortages. Several responses also stated that the FDA only communicated with the facility's pharmacy and not directly with providers. An inconsistency in communication between local pharmacy and providers has been a common theme noted throughout this survey for multiple questions. CRNAs noted that they received drug shortage information directly from their professional association, rather than the FDA. Only 5.1% of respondents indicated that the FDA had helped them "well" with respect to drug shortages.

## 7. What recommendations do you have to improve this assistance from the FDA?

The top 5 recommendations for improvement of FDA's assistance were:

1. **Improve communication and available resources** (26.1%, n=37/142)
2. **Regulate / work more closely with manufacturers to produce critically needed drugs** (21.1%, n=30/142)
3. **Provide advanced notice of drug shortages** (16.9%, n=24/142)
4. **None / Unknown** (16.9%, n=24/142)
5. **Make alternative drugs available / provide information and assistance with alternative drugs** (7.0%, n=10/142)

The top recommendation to improve FDA assistance was noted as improving communication and available resources regarding drug shortages. Many responses noted the need for the FDA to communicate directly with providers and provide more detailed information regarding drug shortages. Additionally, multiple suggestions included working more closely with manufacturers to anticipate and attempt to mitigate drug shortages. As noted in previous responses, there is a need for providers to have advanced warning of drug shortages and information regarding availability and sources of alternative drugs.

Other suggestions to note, although reported less frequently, include providing access to foreign drugs, providing help with cost containment of available stocks of drugs, and including anesthesia provider, such as CRNAs, in drug shortage related discussions.

**8. What do you recommend that other stakeholders do regarding drug shortages (i.e., Industry, distributors, group purchasing organizations, or government agencies)?**

The top 5 recommendations for other stakeholders regarding drug shortages were:

1. **Increase regulation of manufacturers / Provide more incentives for or "force" manufacturers to produce drugs in shortage** (18.4%, n=26/141)
2. **Work on controlling drug costs** (15.6%, n=22/141)
3. **None / Unknown** (11.3%, n=16/141)
4. **Address issues before drug shortages occur** (9.2%, n=13/141)
5. **Obtain foreign drugs / drugs from other sources** (7.8%, n=11/141)

The top recommendation was to increase oversight and regulations of drug manufacturers. Many responders suggest providing incentives for manufacturers to continue to produce off-patent or generic drugs, which may not be as profitable for manufacturers but are still required for regular patient care. Additionally, many individuals provided comments relating to increases in drug cost and profitability for manufacturers. Many individuals indicate that they feel that drug shortages are artificially created to drive up drug costs. Additionally, they feel that drug discontinuations are purely profit-based decisions on the part of the manufacturer. Many individuals feel that regulatory bodies and other stakeholders need to be proactive about identifying potential drug shortages and address issues before they lead to levels where a drug shortage is necessary. There was also interest expressed in finding out what other suppliers or drug sources exist outside of the U.S.

Although not reported in the top five recommendations, there are several individuals who suggested establishing local/regional networks for pharmacies or facilities to aid in drug exchange if certain facilities have ample supply of a drug.

**9. Please provide us with any comments, opinions, or suggestions regarding drug shortage issues that you would like to share with us.**

The top six comments, opinions, or suggestions regarding drug shortage issues were:

1. **Shortages are profit driven** (22.9%, n=22/96)
2. **None / Unknown** (20.8%, n=13/96)
3. **Need for information regarding drug alternatives** (8.3%, n=8/96)
4. **Need to identify / communicate the cause of the shortage** (8.3%, n=8/96)
5. **Advanced notice of shortage** (7.3%, n=7/96)
6. **Concern about patient care during shortage** (7.3%, n=7/96)

The comments provided to this question had a wide range of themes. The main theme was the perception that shortages and drug discontinuations are profit driven. As seen with other previous questions, additional themes that emerged included an increased need for information regarding drug alternatives, identification and communication regarding causes of drug shortages, and a need for advanced notice of drug shortages. CRNAs also expressed concern over patient safety due to drug shortages.