American Society of Anesthesiologists

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Full Committee Hearing - Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions

United States Senate Committee on Health, Education, Labor and Pensions
Thursday, December 15, 2011

Statement for the Record by
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On behalf of the over 48,000 members of the American Society of Anesthesiologists (ASA), we would like to thank Chairman Harkin and Ranking Member Enzi for holding a hearing regarding drug shortages on December 15, 2011, and allowing ASA the opportunity to submit a statement for the record. We greatly appreciate your willingness to bring this important topic before the Senate Committee on Health, Education, Labor and Pensions and for your efforts to address this issue.

As the recognized leader in patient safety, anesthesiologists are seriously concerned about the toll drug shortages are having on our patients. In April of 2011, ASA conducted a survey of 1,373 anesthesiologists to quantify the impact of drug shortages on our patients and practices. Our survey results demonstrated that as a result of drug shortages, 51% of anesthesiologists altered a procedure in some way, 48% felt shortages resulted in a less optimal patient outcome, 48% reported longer operating room or recovery times and 10% postponed or cancelled procedures. While these numbers may be alarming they pale in comparison to the 98% of anesthesiologists who experienced a drug shortage during the past year, or the 90% of anesthesiologists that reported a shortage of 1 or more drugs at the time of the survey.

One of the most common drugs for which anesthesiologists reported a shortage is propofol. In fact, 88% of anesthesiologists reported experiencing a shortage of this drug. For anesthesiologists, propofol is one of the most commonly used drugs for the induction of anesthesia or for providing sedation. Other drugs used for these purposes may result in less than optimal patient outcomes including prolonged awakening, longer stays in recovery prior to discharge and increased nausea and vomiting. While anesthesiologists are trained to safely use multiple drugs, and can often find alternatives for drugs in short supply, these shortages can cause decreased patient satisfaction (prolonged awakening, delayed discharge, nausea) or adverse outcomes, including death in extreme situations (e.g., trauma patients, unstable hemodynamics, airway emergencies).

In November of 2010, ASA along with the American Society of Clinical Oncology, the American Society of Health-System Pharmacists, the Institute for Safe Medication Practices and the American Hospital Association co-convened a Drug Shortage Workshop Summit. This Drug Shortage Summit Steering group, consisting of the co-conveners, manufacturers, distributors and group purchasers, released initial findings and continued to meet over the course of the next 10 months producing a series of five recommendations for regulatory and legislative action. The work group made the following recommendations.[i]

1) Reallocate resources within FDA and for the Congress to authorize and appropriate funding for FDA activities that prevent or mitigate shortages;

2) Require manufacturers to report product discontinuations and manufacturing interruptions 6 months in advance or upon determining that determining that production will not meet average historical demand. Establish communications methods to provide accurate and timely information to health care providers. Establish methods to better predict the seriousness and duration of drug shortages;

3) Establish criteria for determining whether a drug is vulnerable to shortage. Designate drugs that are vulnerable to shortage as part of the FDA approval process. Establish appropriate incentives for manufacturing redundancies or other means of producing emergency supplies for drugs that are deemed vulnerable to shortages. The pharmaceutical industry should collaborate with regulatory and legislative entities to identify these incentives;

4) Require collaboration between the FDA Center for Drug Evaluation and Research divisions and the Attorney General to establish a process that would expedite the increase in manufacturing production quotas when needed in response to drug shortages of controlled substances;

5) Leverage current FDA pathways to expedite the approval process for medically necessary unapproved drugs that are vulnerable to shortages without compromising the safety of the drug.

While drug shortages are an issue for patients and physicians, shortages also negatively impact health care costs. Drug shortages have resulted in significant price increases and have often caused providers to search alternative sources to obtain critically necessary drugs. In a recent study, Premier found that the average markup on a drug sold in the grey market is 650%. However, for propofol the average markup is a startling 3,161%.[ii] Anesthetic drug shortages can increase procedure and recovery times as a result of anesthesiologists being forced to select alternative therapies, as well as increase societal and health system costs for cancelled or postponed cases. At a time in which Congress and the Administration are focused on reducing health care expenditures and maximizing patient safety, quality and satisfaction, drug shortages present a considerable obstacle to these important objectives.

Anesthesiologists are end users of drugs and need to be better informed about drug shortages and the duration of the shortages. We are pleased to see that Congress and the Administration recognizes the need for provider notification and has taken steps to address this issue.

Recently, the Administration has taken a number of steps to combat drug shortages. On October 31, 2011, President Obama issued an Executive Order that would quicken the review process for applications to start or change production of drugs in shortage, widen the reporting of shortages and expand notifications of shortages and sharing relevant information regarding possible price gouging with the Department of Justice. We commend the Administration for their efforts. These are important steps to address drug shortages, and we fully support them.

Also, we fully support and thank Senator Amy Klobuchar for introducing the bipartisan Preserving Access to Life-Saving Medications Act (S.296), which would require drug manufacturers to notify the Food and Drug Administration if there is an interruption in manufacturing that could lead to a drug shortage. Currently, the Senate version has 20 cosponsors and continues to gain support. We strongly urge Congress to pass this legislation during the 112th Congress.

In addition, ASA looks forward to working with Senator Hatch as he develops legislation to address drug shortages, and we look forward to working with all members of the Senate Committee on Health, Education, Labor and Pensions to address this issue.

Again, thank you for holding such an important hearing on an issue that if addressed properly can improve quality of care for our patients.

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[i] *Regulatory and Legislative Recommendations from the Drug Shortages Summit Steering Group*. Drug Shortage Legislative-Regulatory Work Group: American Society of Anesthesiologists et al. November 5, 2011. http://www.ashp.org/drugshortages/summitreport.

[ii] Cherici, Coleen; Patrick McGinnis and Wayne Russell. *Buyer Beware: Drug Shortages and the Gray Market*. Premier Inc. August 2011. http://www.premierinc.com/about/news/11-aug/Gray-Market/Gray-Market-Analysis-08152011.pdf