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April 24, 2012

The Honorable Tom Harkin Chairman Committee on Health, Education, Labor and Pensions 428 Dirksen Senate Office Building Washington, DC 20510 The Honorable Mike Enzi Ranking Member Committee on Health, Education, Labor and Pensions 428 Dirksen Senate Office Building Washington, DC 20510

Dear Chairman Harkin and Ranking Member Enzi:

On behalf of the over 48,000 physician members of the American Society of Anesthesiologists (ASA), I would like to express our strong support for *Title X – Drug Shortages* of the *Food and Drug Administration Safety and Innovation Act (S.L.C. KER12278)*. We thank and applaud you for introducing and advancing this critical legislation. We would also like to thank you for reaching out to the ASA and other stakeholders.

We would particularly like to thank you for including drugs that are a "sterile injectable product" or "used in emergency medical care or during surgery" in its drug shortage definitional provisions. As you are aware, the Government Accountability Office (GAO) found anesthetic and central nervous system drugs to be among the class of drugs experiencing the highest frequency of shortages at 23% of all shortages. Therefore, we believe it is essential to require manufacturers to notify the Food and Drug Administration (FDA) when there is a shortage of a "sterile injectable product" or a drug "used in emergency medical care or during surgery." We urge you to maintain this language as the bill moves forward. Given that anesthetic and central nervous system drugs are among the class of drugs experiencing the highest frequency of shortages, Congress cannot fully address the drug shortage issue without addressing the anesthetic drug shortage.

As the Institute of Medicine (IOM)-recognized leaders in patient safety, anesthesiologists are seriously concerned about the toll drug shortages are having on our patients. In March of this year, ASA conducted an informal survey of 3,033 anesthesiologists regarding drug shortages. Of those surveyed, 97.6% experienced a drug shortage, 96.3% had to use alternative drugs, 50.2% had to change the procedure in some way, 7.0% had to postpone cases and 4.1% had to cancel cases. Most troubling, those that responded to the informal survey reported that six patients (0.2%) died as a result of a drug shortage.

In addition, as a result of drug shortages, 66.7% of those surveyed reported that patients experienced a less optimal outcome, 52.8% reported that patients experienced longer OR/recovery times and 27.5% reported patient complaints. The informal survey identified the following anesthesia drugs with the highest frequency of reported current shortage: Fentanyl

66.3%, Thiopental 40.3%, Succinylcholine 21.1%, Propofol 19.2% and Pancuronium 15.2%. While anesthesiologists are trained to safely administer multiple drugs, and can often find alternatives for drugs in short supply, these shortages can cause decreased patient satisfaction or adverse outcomes, including death in extreme situations.

We believe the time for action on drug shortages is now, that the bipartisan *Food and Drug Administration Safety and Innovation Act* is an important step forward, and, as written, *Title X* has our full support.

If you have any questions, please feel free to contact Manuel Bonilla, M.S. (m.bonilla@asawash.org), Director of Congressional and Political Affairs or Grant Couch (g.couch@asawash.org), Federal Affairs Associate at (202) 289-2222.

Sincerely,

Jerry A. Cohen, M.D.

President

American Society of Anesthesiologists