American Society of Anesthesiologists

1501 M Street, NW ▪ Suite 300 ▪ Washington, DC ▪ 20005 ▪ Phone: (202) 289-2222 ▪ Fax: (202) 371-0384 ▪ mail@asawash.org ▪ www.asahq.org

Help Ease Drug Shortages

Support increased Congressional and Administration scrutiny of drug shortages
Support S. 296, the "Preserving Access to Life-Saving Medications Act"

ISSUE

Problems caused by the skyrocketing increase in the number of drug shortages have received much public attention in recent months. **Since 2006, the number of identified new drug shortages has increased from 70 to over 211 in 2010. Many of the drugs in shortage are critical drugs used for anesthesia and chemotherapy.** These shortages have caused significant disruptions in patient care including the delay of needed medical treatment, the cancellation of elective surgeries, and in some cases death or less than optimal outcomes. Some of the drugs in shortage have no viable alternatives, while others have alternatives, but those drugs may increase the potential for greater harm than the first-line therapy that is unavailable due to a shortage.

Anesthesiologists, in particular, have seen a dramatic increase in the number of shortages of critical drugs such as propofol, succinylcholine, and epinephrine. Propofol is one of the most commonly used agents for the induction and maintenance of general anesthesia. Succinylcholine is used to induce muscle relaxation and short-term paralysis usually to facilitate tracheal intubation. In addition to its use in cardiac cases, epinephrine is used to prolong the action of an anesthetic agent.

The causes of drug shortages are specific and unique to each drug but fall into four main categories: (1) regulatory and legislative factors such as the absence of Food and Drug Administration (FDA) authority to require notification of anticipated withdrawal from the market; (2) raw materials sourcing and manufacturing factors such as single source suppliers and difficulty in complying with the FDA Good Manufacturing Practice regulations (GMP); (3) business and market factors such as consolidation of firms and reallocation of production lines; and (4) distribution factors such as sole source and bundled purchasing.

Because of the multi-factorial nature of the causes of drug shortages, a variety of solutions will be needed to alleviate drug shortages. For instance, Senator Richard Blumenthal (D-CT) has formally contacted the Government Accountability Office (GAO) requesting an investigation into the causes of drug shortages. In addition, Senator Amy Klobuchar (D-MN) has introduced S. 296, the "Preserving Access to Life-Saving Medications Act." This legislation would increase the FDA's authority to require manufacturers to notify the FDA of an anticipated withdrawal from the market.

PROBLEM

- Physicians are seeing an unprecedented increase in the number of drugs going into shortage, including critical life-saving medications.
- Drug shortages are resulting in the delay of needed medical treatments, the cancellation of elective surgeries, and in some cases death.
- Because of the multi-factorial nature of drug shortages, multiple actions are needed to help prevent future shortages.

CONGRESSIONAL REQUEST

- Support increased Congressional and Administration scrutiny of drug shortages.
- Please co-sponsor and pass S. 296, the "Preserving Access to Life-Saving Medications Act."

Anesthesiologists: Physicians providing the lifeline of modern medicine.
Founded in 1905, the American Society of Anesthesiologists is an educational, research and scientific association with 46,000 members organized to raise and maintain the standards of the medical practice of anesthesiology and improve the care of the patient.

For more information visit the American Society of Anesthesiologists website at **www.asahq.org**.