American Society of Anesthesiologists

1501 M Street, N.W. • Suite 300 • Washington, D.C. 20005 • (202) 289-2222 • Fax: (202) 371-0384 • mail@ASAwash.org

June 8, 2011

Peter Lurie, M.D., M.P.H.
Office of Policy, Office of the Commissioner
Food and Drug Administration
U.S. Department of Health & Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Drug Shortage Recommendations

Dear Dr. Lurie,

The American Society of Anesthesiologists (ASA), on behalf of its over 46,000 members, would like to thank you and the Food and Drug Administration (FDA) for seeking our input and perspective on the importance of addressing drug shortages and considering all viable options to address such shortages, including improving the Agency's internal processes.

As we discussed during our May 16, 2011, meeting, according to the University of Utah Drug Information Services, the number of identified new drug shortages has increased significantly over the past four years from 70 shortages in 2006 to 211 shortages in 2010. Many of these 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 unavailable first-line therapy. Anesthesiologists, in particular, have seen a dramatic increase in the number of shortages of critical drugs such as propofol, succinylcholine, and epinephrine.

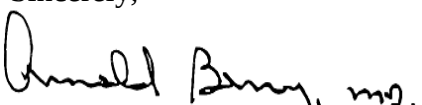
In a recent survey of 1,373 members, the ASA found that 90.4% are currently experiencing a shortage of at least one anesthesia drug. Within the last year, 98.1% of ASA respondents reported experiencing an anesthesia drug shortage. The causes of drug shortages are multifactorial and may include unexpected shortages of raw materials, production line problems (often due to old equipment or packaging shortages), corporate mergers (fewer suppliers), limited manufacturing capacity (multiple products produced on same equipment), FDA regulatory issues (closing a major supplier), cost-containment, smaller 'just-in-time inventories' (manufacturers, distributors, pharmacies) and limited communications between parties. To definitively address the variety of these issues, new regulations, legislation, and agreements with manufacturers may need to be considered.

As we discussed, ASA recommends that FDA consider the following actions to reduce drug shortages:

- Improve communication between supply chain stakeholders (manufacturer, distributor and pharmacy) with patient care providers by notifying when drugs in shortage will be available again.
- Work with provider groups to redefine whether specific drugs are deemed by the FDA as "medically necessary" and therefore require notification.
- Establish drug shortage classification system to stratify the expected duration and intensity of shortage with the intent of minimizing hoarding and allowing FDA to focus its resources on more serious shortages.
- Increase collaboration with industry, DEA, and FDA to establish a process that would more readily modify active pharmaceutical ingredient (API) quotas in response to drug shortages of controlled substances.
- Establish an expedited approval pathway for those unapproved drugs (i.e., pre-1938 therapies) that are deemed critical therapies.
- Incentivize manufacturing redundancies as part of the FDA approval process for drugs that are deemed vulnerable.

We look forward to continuing to work with the FDA on addressing this important issue. Please feel free to contact Traci Bone, JD, Pain Medicine Regulatory Lobbyist, at t.bone@asawash.org or 202-289-2222 if you have any questions or need additional information regarding drug shortages.

Sincerely,



Arnold J. Berry, M.D.
Vice President of Scientific Affairs
American Society of Anesthesiologists

cc: Clarence Lam, M.D.
Donald E. Martin, M.D.
Mark A. Warner, M.D.