American Society of Anesthesiologists®

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May 11, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Submitted via email

Dear Secretary Azar:

On behalf of the American Society of Anesthesiologists® (ASA) and our 52,000 members, I am writing to share our concerns regarding severe shortages of injectable anesthetic drugs and to request that the department facilitate an interdepartmental or interagency task force to work with stakeholders, like ASA, for permanent solutions to this serious problem.

In recent months, the United States has experienced unprecedented drug shortages. Of particular concern to our members are shortages of local anesthetics and injectable opioids, both of which are critical to ensuring anesthesia is administered safely to patients under our care. Although strides have been made by the Department of Health and Human (HHS) Services and the Food and Drug Administration (FDA) since the height of the shortages crisis in 2012, physician anesthesiologists are experiencing an increase in shortages. ASA respectfully requests that you facilitate a federal response to this issue and explore permanent solutions to ensure patients receive the best care possible. Formation of a national task force or other federal body to examine drug shortages and recommend solutions will provide the federal government with the information and tools necessary to successfully mitigate drug shortages.

In 2012, legislation known as the Food and Drug Administration Safety and Innovation Act (FDASIA), was enacted and set forth the requirement that manufacturers notify the FDA of a permanent discontinuance or interruption in the production of certain prescription drugs that are "life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, including any such drug used in emergency medical care or during surgery." ASA was pleased to strongly support this provision of the law. While early notification from manufacturers has enabled the FDA to work more effectively with manufacturers and better prevent or mitigate shortages, drug shortages remain a recurring public health concern.

Clinicians continue to experience supply challenges of certain medications. These medications are typically injectable products that are off-patent and have few suppliers. Causes of these shortages remain consistent—drug shortages are largely the result of quality problems during the manufacturing process, which give rise to a halt in production in order to address the problem. In the case of a product with few competitors, this disruption in production cannot be absorbed by

other companies, and demand outpaces supply, resulting in a shortage. In the case of a sole-source manufacturer, no alternatives for production exist, and clinicians must either struggle to obtain a supply of the drug, compound a drug when possible, or recommend an alternative therapy if one exists.

Over the last several months hospitals and other providers have been facing shortages of a number of injectable medications, including local anesthetics and injectable (IV) opioids. Existing production challenges have been exacerbated by manufacturing delays affecting Pfizer, the primary maker of these products, following its acquisition of Hospira. In a letter to customers, Pfizer indicated that the "anticipated full recovery dates for prioritized prefilled syringes have moved to 1Q19 and deprioritized syringes have moved to 2Q19." On January 31, 2018, Pfizer sent customers a further update informing them that, due to a third-party supplier issue, none of these prefilled syringes of injectable opioids are currently being produced or released.

Shortages of these drugs are most alarming because intravenous opioids, such as morphine, hydromorphone, and fentanyl, are used in a variety of practice settings within hospitals and ambulatory surgical centers for the treatment of acute, acute on chronic, or chronic pain. They are also utilized in patients that cannot be managed with oral opioids for medical reasons. Some opioids, such as fentanyl, also have sedation and anesthesia indications.

Having diminished supply, or no supply at all, can cause suboptimal pain control or sedation for patients in addition to creating complex workarounds for healthcare staff, leading to potential errors. In addition, local anesthetics are used on nerves for surgical incisions, epidurals, spinal anesthesia, and peripheral nerve blocks which numb large regions of the body, so surgery can be performed safely and without pain. These agents are essential to the fight against the opioid epidemic as they are a vital part of multimodal analgesia used to reduce opioid use in acute care and surgical settings.

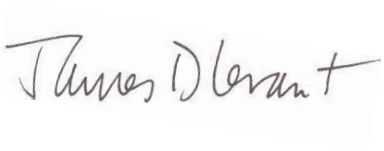
These drug shortages are far reaching and affecting patients across the nation. In a recent survey by ASA, more than 98 percent of respondents noted that they now regularly experience drug shortages at their institutions and more than 95 percent of respondents said the shortages impact the way they treat their patients. While some shortages cannot always be prevented due to natural disasters wiping out supply, others can be foreseen and prepared for in advance. We urge HHS to form a national task force dedicated to discovering the myriad of reasons for shortages, as well as ways to prevent recurrence of the current unparalleled level of medication shortages in the United States. Key questions and issues for consideration by the task force could include:

- What regulatory and legislative remedies are needed under current law (FDASIA) to better address the factors contributing to drug shortages?
- Can best practices to limit waste be established for hospitals/providers utilizing widely used and critical drugs?
- Should manufacturers provide the FDA with more information on the causes of the shortages and their expected duration?
- Should manufacturers be required to be more transparent about the location of production, including situations where a contract manufacturer is used?

- Should (and can) manufacturers be required to establish contingency plans and/or redundancies in the event of a shortage?
- Can HHS and the Department of Homeland Security (DHS) examine drug shortages as a national security initiative to prepare and respond to future disasters and/or supply disruptions?
- Can potential risks for drug shortages be examined when drug company mergers and acquisitions are expected? Can the Federal Trade Commission implement certain requirements?
- What policy recommendations are needed to incentivize and bolster the market?

ASA thanks you for your time and consideration of this important issue. As leaders in patient safety, physician anesthesiologists are ready and willing to work with HHS to address drug shortages and explore solutions that positively impact patient care. If we may be of assistance in anyway, please do not hesitate to contact Manuel Bonilla, ASA's Chief of Advocacy and Practice at m.bonilla@asahq.org or Ashley Walton, J.D., ASA's Pain Medicine and Federal Affairs Manager at a.walton@asahq.org or by phone at (202) 289-2222.

Sincerely,



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