

November 9, 2017

The Honorable Morgan Griffith
1108 Longworth House Office Building
Washington, DC 20515

The Honorable Diana DeGette
2335 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Griffith and Congresswoman DeGette:

The United States and the world continue to experience serious and critical drug shortages. Recent natural disasters, most notably Hurricane Maria, have heavily compromised pharmaceutical manufacturing in Puerto Rico and now leave the U.S. healthcare system on the brink of a significant public health crisis. We appreciate your leadership of the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee on this issue.

Of most immediate concern are the potential patient care implications of the shortage of small-volume parenteral solutions (SVPs). Intermittent shortages of SVPs are emerging as a serious problem for hospitals, healthcare systems, and ambulatory care infusion centers.

These solutions – such as saline or dextrose – are typically 100 mL or less and are used in every healthcare setting that administers intravenous medications in the United States to further dilute hundreds of medications each and every day. Larger institutions use hundreds of these bags per day. Hospitals and other healthcare settings have reported that they are running critically low on product and are unclear as to when their supplies will be replenished. Some of these products were on the Food and Drug Administration's (FDA's) drug shortages list prior to Hurricane Maria, but the storm has exacerbated the situation.

Given the small number of producers, we anticipate that this situation will not be resolved quickly and will likely worsen. While we appreciate action by the FDA to approve importation of SVPs from plants in Ireland, Australia, Mexico, and Canada, we do not know when these drugs will arrive and if there will be sufficient quantity to meet high demand.

We are working closely with officials in the FDA's Drug Shortages Program to help assess the situation and provide perspectives on the impact of these shortages on patients and providers. ASHP collaborates with the University of Utah Drug Information Service to track drugs in short supply and maintains an online resource center that features updates about product availability, recommendations for managing current inventory, and, when available, recommendations for alternative therapies.

According to a report by *USA Today*, pharmaceuticals represented 72 percent of Puerto Rico's exports and 25% of total U.S. pharmaceutical exports in 2016. At this time, most pharmaceutical companies have not shared detailed status about their products, potential shortages, or availability/release dates. Baxter is one of the few companies that we are aware of that has had contact with the FDA, which prompted the FDA to allow importation of small-volume IV solutions from Ireland and Australia. However, we believe that this importation may meet only 10–15% of hospital and health system demand. In view of this, we believe immediate action is needed to assure patients can get the care they need. We are eager to work with Congress and the

Administration to address both this near-term crisis as well as a more comprehensive strategy to manage such situations moving forward

Beyond the immediate need to rectify the SVP emergency, Congress should examine how the pharmaceutical industry communicates information about what drugs are manufactured at which plants and where those plants are located. To date, no state or federal law requires that this information be disclosed. This lack of transparency puts healthcare systems at a significant disadvantage when trying to take a proactive approach to handling a potential drug shortage. The current system results in a reactive approach, which is usually short-notice and has a rapid downstream effect, leaving hospitals at a loss to meet patient needs. As we have seen with Hurricane Maria, the current pharmaceutical infrastructure allows for a significant number of manufacturers to be geographically located in an area that is at high risk for natural disasters.

While there is no single solution to the problem, we ask that Congress consider the following questions as members work to address the ongoing issues that result in drug shortages:

- Should manufacturers be required to disclose to the medical community their manufacturing sites and the products produced in those sites, in terms of volume and percentage of product line?
- Should sole-source products be allowed to be produced in a single plant?
- Should there be redundancy in production of critical products?
- Should the FDA identify a list of “critical medications” that would require manufacturers to develop a reasonable contingency plan in the event of a production interruption or shutdown?
- What incentives could be developed for other manufacturers to increase production when drug shortages occur?
- What can be done to determine the best locations of pharmaceutical plants in addition to ensuring that backup systems can quickly accommodate needs in the event of a disaster, given there are several types of natural disasters that can occur?

Again, we thank you for your leadership on this issue and look forward to working with your office and other stakeholders as you investigate the continuing shortages of critical pharmaceuticals.

Sincerely,

American Hospital Association
American Society of Anesthesiologists
American Society of Clinical Oncology
American Society of Health-System Pharmacists
American Society for Parenteral and Enteral Nutrition
Institute for Safe Medication Practices

cc: The Honorable Greg Walden
The Honorable Frank Pallone