

November 7, 2017

Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Gottlieb:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) is writing to strongly urge the Food and Drug Administration (FDA) to take any and all steps possible to expedite the resolution of the worsening shortages of small-volume parenteral solutions that are so fundamental to patient care in hospitals.

We are concerned that the shortages of widely-used and critical products are quickly becoming a crisis and looming threat to the public's health. Therefore, we call on the FDA to both vigorously pursue strategies with the current manufacturers of these products and to seek out new suppliers in order to ameliorate the current shortage, as well as prevent such shortages from occurring in the future. More must be done to resolve the current shortages and secure the supply of these life-saving products moving forward.

The current shortages of small volume parenteral solutions, such as the 50 and 100 milliliter injection bags of sodium chloride 0.9 percent, dextrose 5 percent, as well as intravenous (IV) nutritional products are unacceptable, and must be resolved quickly to prevent a negative impact on patient care. Currently, hospitals are scrambling to manage the shortfall, and have employed strategies including switching patients to appropriate alternative products, such as oral products, changing selected medications from IV piggyback to IV push administration, and prioritizing patients based on clinical factors.

While these strategies have helped mitigate the problem to date, the AHA is concerned that patients could face harm if these shortages are not resolved quickly. To make matters worse, hospitals are struggling to use syringes as a replacement, due to the lack of available syringe pumps and unclear guidance from FDA regarding whether drugs may be stored in syringes. In addition, shortage management and conservation measures, while crucial to extending supplies



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during shortages, put hospitals in the difficult situation of explaining to patients why these seemingly simple products are unavailable, potentially impacting patient confidence in their care when they are at their most vulnerable.

The AHA understands and appreciates that FDA has been working with Baxter and other major manufacturers of these products to address the current shortages. We also appreciate your efforts to obtain alternative sources of the products, including from overseas suppliers. **However, we strongly urge FDA to do more by pushing current manufacturers to not only continue to produce these products at their maximum capacity but also to make investments to ensure an increasing supply for the future. We also encourage FDA to seek out and approve new domestic suppliers of these products in locations that are not prone to natural disasters.** This will help make the market more resilient when there are unexpected interruptions in supply from one or two manufacturers and when sudden increases in demand occur. To help address shortages in the short term, the agency also should consider other options, such as temporarily allowing health systems to provide needed amounts of non patient-specific compounded products to health care facilities they own and control, without consideration of whether the distribution occurs within a 1-mile radius of the health system's compounding pharmacy.

The AHA stands ready to work with FDA on this issue. If you have any questions, please feel free to contact me or have a member of your team contact Roslyne Schulman, director for policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy