American Hospital Association

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March 20, 2014

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Dr. Hamburg:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, 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 long-standing and severe shortages of normal saline and other IV fluids that are so fundamental to patient care in hospitals. We call on FDA to 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 again in the future.

The current shortages of IV fluid 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 using smaller IV bags, switching patients to appropriate alternatives and prioritizing patients based on clinical factors. While these strategies have somewhat mitigated the problem to date, the AHA is concerned that patients could face harm in the future if these shortages are not resolved quickly. In addition, conservation measures, while crucial to extending supplies during shortages, put hospitals in the difficult situation of explaining to patients why these seemingly simple products are unavailable, potentially eroding patient confidence in their care when they are at their most vulnerable.

The AHA understands and appreciates that FDA has been working with the four major manufacturers of IV fluids to address the current shortage and is engaged in efforts to obtain alternative sources of the products, including from overseas suppliers. However, given the extended duration of the shortages and their impact on the provision of patient care in the nation's hospitals, we strongly urge FDA to do even more to end this shortage 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 new domestic suppliers of saline in order to make the market more resilient

when there are unexpected interruptions in supply from one or two manufacturers and when sudden increases in demand occur.

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

Sincerely,

/s/

Rick Pollack
Executive Vice President