May 6, 2013

Dr. Margaret Hamburg  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Hamburg:

We appreciate the efforts of the Food and Drug Administration to address the severe shortage of several products that are commonly used at children’s hospitals, including those used in total parenteral nutrition for critically ill infants. However, the ongoing shortage of these products, including sodium phosphate, potassium phosphate, calcium gluconate, calcium chloride, zinc, trace elements, and several others, is deeply concerning. Without steady doses of total parenteral nutrition, critically ill infants are at risk of serious negative health outcomes such as painful skin lesions, poor bone health, or vitamin deficiencies. We understand that at least one manufacturer of these products is currently offline and is working with you to get back on the market. We ask that you do everything in your power to get these products back on the market quickly and safely.

Shortages of products required for total parenteral nutrition are already disrupting treatment for infants. At one hospital in the Midwest, providers have been forced to reduce doses of electrolytes in children greater than 1500g in order to protect doses for neonates. At other hospitals, rationing of intravenous phosphate has forced neonates in the Cardiac Intensive Care Unit to go without this critical product, and some of these seriously ill infants are also beginning to show signs of phosphorous deficiency. Several hospitals have reported that they are within one or two weeks of running out of these products completely.

It is essential that we do all we can to prevent shortages in products that compose total parenteral nutrition so that children’s hospitals can again focus on providing the best care to their patients. Thank you for your attention to this urgent and critical matter.

Sincerely,

Al Franken  
United States Senator

Pat Roberts  
United States Senator
Tom Harkin  
United States Senator

Sherrod Brown  
United States Senator

Michael F. Bennet  
United States Senator

Amy Klobuchar  
United States Senator

Elizabeth Warren  
United States Senator

Mark Kirk  
United States Senator

Lamar Alexander  
United States Senator

Rob Portman  
United States Senator

Tim Scott  
United States Senator

Mike Johanns  
United States Senator

Johnny Isakson  
United States Senator

Robert P. Casey, Jr.  
United States Senator

CC: American Regent, Hospira, APP
Richard Blumenthal
United States Senator