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March 14, 2013

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Food and Drug Administration Drug Shortages Task Force and Strategic Plan; Federal Register Volume 78, Number 29; February 12, 2013. Docket No. FDA-2013-N-0124.

Dear Dr. Hamburg:

On behalf of the more than 1,700 members of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), we appreciate the opportunity to respond to questions from which the FDA Drug Shortages Task Force will develop a drug shortages strategic plan.

NASPGHAN is the largest body of experts on pediatric digestive and nutritional health. We are deeply concerned with the national shortage of parental nutrition products and certain trace minerals and vitamins that are medically necessary for many of our most vulnerable patients. We appreciate that FDA shares our concerns about ongoing parenteral nutrition shortages and is working with manufacturers to address quality problems and increase production. Additionally, we strongly encourage the FDA to continue looking for overseas sources.

We know that medical institutions are engaged in conservation efforts to extend the supply of nutrients that are in shortage. Still, most pediatric gastroenterologists are struggling to provide optimal care to their patients, and many patients are going without needed nutrients. Among the products that have been identified as in short supply include: Zinc, IV Fat Emulsion, Calcium Gluconate, Selenium, Copper, Sodium Acetate, Sodium Phosphate, Potassium Chloride, Chromium, Amino Acids, and Vitamin C.

NASPGHAN offers responses to the following questions presented by FDA:

Are there other communication tools that FDA should use or additional information the Agency should share to help health care professionals, manufacturers, distributors, patients, and others manage shortages more effectively? Are there changes to our public shortage Web sites that would

help enhance their utility for patients, prescribers, and others in managing shortages?

We suggest that for vitamin, mineral, and parental nutrition, FDA should seek to partner with professional societies by providing them early information regarding impending or actual shortages and by facilitating changes to treatment paradigms, if appropriate, to help manage scarce resources. In addition to NASPGHAN, we suggest that the FDA engage other health care and medical professional societies on shortages of vitamin, mineral and parental nutrition, including: American Academy of Pediatrics, American Society for Parenteral and Enteral Nutrition (ASPEN), Academy of Nutrition and Dietetics, American Dietetic Association, and American Gastroenterological Association.

We also encourage continued agency collaboration for addressing impending or actual shortages. For example, on February 22, 2013, the Centers for Disease Control and Prevention (CDC) issued a *Morbidity and Mortality and Weekly Report* that alerted providers and institutions to zinc deficiency dermatitis in cholestatic, extremely premature infants when zinc supplementation is not provided. Because of the nationwide shortage of injectable zinc, the CDC directed providers to consult ASPEN's recommendations for conserving and prioritizing trace elements in short supply and recommended that neonatal intensive care units monitor levels of zinc in infants at risk. We believe that these proactive types of communications are important to alleviating unnecessary illness or suffering in pediatric patients due to product shortages.

Another area which warrants FDA and CDC attention and additional communication is reported shortages of Alcohol Dehydrated Injection (Ethanol). A study recently published in *Pediatrics*, found that when the frequency of ethanol lock therapy was reduced for parenteral nutrition-dependent children with intestinal failure, the result was complete failure in preventing catheter-related blood stream infection.[1] As the article notes, while a number of drug shortages have resulted in "work-arounds" for nutrition support, the shortage of ethanol has had significant adverse implications on children with intestinal failure and short bowel syndrome. Because there is significant morbidity associated with rationing of ethanol lock therapy and because of the high number of pediatric patients who rely on central venous devices for parenteral nutrition, we ask that the FDA and CDC make communicating about anticipated and actual dehydrated ethanol shortages a priority and to take whatever steps necessary to allow uninterrupted supply of this critical product.

NASPGHAN can employ its communications vehicles for rapid dissemination of these communications to pediatric gastroenterologists throughout the country and, therefore, ask that

[1] Ralls M, Blackwood A, Arnold M, et al. Drug Shortage – Associated Increase in Catheter-Related Blood Stream Infection in Children. *Pediatrics* 2012; 130-e1369.

the FDA and CDC develop a system of coordination with medical professional societies to allow for most effective and widespread dissemination of critical communications. Furthermore, NASPGHAN offers itself as a resource for working with the FDA to identify substitute products and alternative treatment protocols in the cases of severe vitamin, mineral or parental nutrition shortages.

What other actions or activities should FDA consider including in the strategic plan to help prevent or mitigate shortages?

We ask that the FDA proceed with rulemaking implementing Title X of the FDA Safety and Innovation Act which requires manufacturers of drugs to notify the FDA of a permanent discontinuance in the manufacture of a drug, an interruption of the manufacture of a drug that is likely to lead to meaningful disruption in the supply of that drug, and the reasons for such discontinuance or interruption. We firmly believe that vitamins, minerals and parental nutrition products should all be considered "life-supporting" and "life-sustaining" for the purposes of implementing the law, and that requiring notice from manufacturers at six months prior to the date of discontinuance or interruption will allow the FDA to most effectively maintain a publicly available up-to-date list of drugs in shortage, as specified in the law.

Thank you in advance for your consideration of our comments. We hope you will consider NASPGHAN a resource and a partner in addressing the shortage of nutritional products. Please use NASPGHAN's Washington representative Camille Bonta as the contact for further communications or with requests for additional information. She can be reached at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

Athos Bousvaros

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