



SHORTAGES OF PARENTERAL NUTRITION PRODUCTS

Shortages of parenteral nutrition products and certain trace minerals and vitamins have increased, putting our country's most vulnerable citizens – infants and children – at risk. The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) believes with support from Congress, the Food and Drug Administration (FDA) must exercise the full extent of its authority to alleviate shortages of parenteral nutrition products.

HOW SEVERE ARE THE SHORTAGES?

The shortage of parenteral nutrition products and certain trace mineral and vitamins have become widespread. According to the American Society of Health-System Pharmacists, 238 drugs are in short supply. Many of the shortages in 2013 have been of intravenous (IV) nutritional products. A primary, but not exclusive, reason for these shortages is the result of a decision by American Regent/Luitpold, a large manufacturer of total parenteral nutrition products, to temporarily shut down in 2012 due to quality issues. Among the products being reported by NASPGHAN members in short supply are Zinc, IV Fat Emulsion, Calcium Gluconate, Selenium, Copper, Sodium Acetate, Sodium Phosphate, Potassium Chloride, Chromium, Amino Acids, and Vitamin C.

WHAT IS THE IMPACT OF THE SHORTAGES?

Pediatric gastroenterologists are struggling to provide optimal care to their patients, and many patients are going without needed nutrients. Shortages have resulted in "work arounds" for nutrition support. Institutions report they must constantly revise their total parenteral nutrition protocols based on accessibility of parenteral nutrition components. However, in the case of some shortages, there are significant adverse implications and no viable alternatives. For example, included among drugs in shortage is Alcohol Dehydrated Injection (Ethanol). Ethanol lock therapy is used to prevent catheter-related blood stream infections. According to a 2012 study published in *Pediatrics*, 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. The shortage of ethanol and the lack a "work around" to accommodate the shortage puts at risk the high number of pediatric patients who rely on central venous devices for parenteral nutrition.

Neonates and pediatric patients who do not receive necessary parenteral nutrition are at significant risk of long-term health implications, including stunted growth and bone malformations. Infants and premature babies are at risk of infection if certain trace minerals and vitamins are not available at recommended doses. For example, when zinc supplementation is not provided to very premature infants, the result can be skin lesions, diarrhea, immunologic impairment, growth failure, and poor wound healing.

ACTION NEEDED TO ALLEVIATE SHORTAGES

NASPGHAN welcomed the FDA's announcement on May 29, 2013 that it would exercise its regulatory discretion for Fresenius Kabi, USA, LLC, to import to the United States trace elements and phosphate injection from its plant in Norway. However, allowing importation of nutritional products in short supply is a temporary solution and may not benefit all patients. Some physicians and health care institutions have decided to not use the trace elements product from Norway because the composition of the product is different than FDA-approved products. For example, the imported product contains fluorine that may be at an unacceptable amount for neonates.

As demonstrated with the shutdown of American Regent/Luitpold and the resulting shortage of parenteral nutrition products, many drug shortages are the cause of quality and manufacturing processes. While NASPGHAN recognizes there is no easy solution to resolving drug shortages, NASPGHAN encourages Congress to continue to look for ways it can assist the FDA in preventing and alleviating drug shortages, including legislating financial incentives that lead to expanded production of drugs that have chronically been in short supply, including investments that reward high-quality manufacturers of drugs.

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