



October 3, 2019

Linda Mundy, MD, PhD
Vice President and Chief Medical Officer
American Regent, Inc.
5 Ramsey Road
Shirley, New York 11967

Dear Dr. Mundy,

We write to echo concerns first raised by the American Society for Parenteral and Enteral Nutrition (ASPEN) regarding the pricing and the limited stability of American Regent's recently released selenious acid injection.

The National Home Infusion Association (NHIA) is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. NHIA members provide total parenteral nutrition to more than 25,000 patients with cancer, Crohn's disease, bowel disease, and other conditions.

For many years, drug shortages have inhibited home infusion providers' ability to provide TPN. The cost of several common PN drug ingredients has gone up considerably in the last several years. Of particular concern is the increase in the price per mcg of selenium, which our members report has increased tenfold.

Because home PN care is reimbursed at a per diem rate (PN formulation, administration supplies, infusion pump, infusion backpack, home delivery, and non-nursing clinical management), a significant price increase may result in this trace element being withheld from patients who require supplementation.

This financial burden will have a significant impact on neonatal and pediatric patients. As you may know, PN admixtures for these populations do not include multi-trace element products, and as such, intravenous selenium must be added separately. Similarly, multi-component products are rarely appropriate for patients requiring long-term PN at home. As such, their formulations must be supplemented by injectable selenium.

The high cost of these products could prompt some providers to look for alternative ways to meet their patient needs. The best way to help vulnerable patients minimize their risk for cardiomyopathy, skeletal muscle myopathy, macrocytic anemia, and abnormalities in hair and nails, however, is to assure access to this important micronutrient.

In addition to price concerns, our members have expressed concerns about the limited stability of injectable selenium in PN admixtures. Specifically, your product insert states that PN admixtures containing selenium should be refrigerated for no more than 24 hours. Patients requiring PN at home



frequently receive a seven-day supply that is compounded in advance. The limited stability of this product would require either daily deliveries of PN admixtures or would require the patient to add selenium to the PN prior to administration. This creates potential safety risks, including touch contamination, measuring and adding an incorrect dose, or failure to add the nutrient/medication. Further, because the current injectable selenium product is available only in a single-dose vial which costs \$200 – 300, patients may attempt to re-use a vial, increasing the risk of cross-contamination and blood stream infection.

We join with ASPEN in requesting that you devise a strategy that allows the product to be used as per best practices, and consider conducting extended stability studies to simulate the addition of selenium to PN used in the home setting; marketing smaller volume presentations that provide the average dose of selenium to the home market; and developing presentations that have a longer “beyond use” time.

In closing, we thank you for your attention to this request. Please contact me if you have further questions or would like to arrange a meeting to discuss this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Connie Sullivan", written in a cursive style.

Connie Sullivan, BS Pharm
President and CEO