



Help along the way

Joan Bishop, Executive Director
Albany Medical Center, MC-28
99 Delaware Avenue
Delmar, NY 12054
(518) 262-5079, FAX (518) 262-5528
bishopj@amc.edu / www.oley.org

March 30, 2020

Ed Weinstein, MD, PhD, Clinical Team Leader
Division of Anti-Infective Agents
Food and Drug Administration

Dear Dr. Weinstein

I am pleased to learn that the FDA plans to review applications with thoughts of emergently approving products to fill the void left by the unavailability of ethanol. Ethanol has been successful in preventing and treating catheter related complications for years. The sudden absence of supply has invoked tremendous fear and helplessness among this patient population. As one of our members wrote: "I am a nurse and sustain myself on home parenteral nutrition. I had been hospitalized seven times in two years before I began using ethanol lock therapy. I have been infection free since (2+ years). With my homecare company telling me that ethanol will not be available in the near future, I fear for my health." Another member writes, "My ten year old son is home nutrition support dependent. He had been hospitalized many times for central line infections until we began using ethanol locks. He has not been hospitalized since implementing this change in his routine. We worry about his future without it." As one home care company dietitian asks, "Can the FDA push Belcher to lower the cost or allow other manufacturers to start making it again?" It's that important!

[Prevalence of Home Parenteral and Enteral Nutrition in the United States.](#)

[Mundi MS](#)¹, [Pattinson A](#)¹, [McMahon MT](#)², [Davidson J](#)², [Hurt RT](#)^{1,2,3,4}.

[Nutr Clin Pract.](#) 2017 Dec;32(6):799-805. doi: 10.1177/0884533617718472. Epub 2017 Jul 17.

Results: For 2013, there were 6778 Medicare beneficiaries for HPN and 114,287 for HEN. The ratio of Medicare to non-Medicare was 0.271 for HPN and 0.261 for HEN, leading to an estimated prevalence of 25,011 patients receiving HPN (79 per million U.S. inhabitants) and 437,882 patients receiving HEN (1385 per million U.S. inhabitants). **There are an estimated 4129 pediatric patients and 20,883 adult patients receiving HPN;** for HEN, 189,036 pediatric patients and 248,846 adult patients.

I urge you to consider all of the options and if suitable ones are found, please approve before the current supply of ethanol is exhausted. A treatment is critical to the prevention of Catheter Related Bloodstream Infections (CRBSIs) and catheter occlusions. Central venous access in the Oley Foundation patient population is essentially their "lifeline" and life sustaining for many years and, often, a lifetime.

Thank you! Good luck and God Speed.

Joan Bishop
Executive Director