



National Home Infusion Association  
1600 Duke St. Suite 410  
Alexandria, VA 22314

January 13, 2021

The Honorable Alex M. Azar, II  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

**RE: Termination of the Food and Drug Administration’s Unapproved Drugs Initiative;  
Request for Information Regarding Drugs Potentially Generally Recognized as Safe and  
Effective**

Dear Secretary Azar:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the notice: *Termination of the Food and Drug Administration’s Unapproved Drugs Initiative; Request for Information Regarding Drugs Potentially Generally Recognized as Safe and Effective* published by the Department of Health and Human Services (HHS) in the *Federal Register* on November 25, 2020 (the Notice).<sup>1</sup> NHIA is a trade association that represents home infusion therapy providers, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion community, we write to share our feedback on the Food and Drug Administration’s (FDA) decision to terminate the Unapproved Drugs Initiative (UDI).

The UDI was launched through a guidance document that was issued in 2006 and updated in 2011, without notice and comment rulemaking. The program’s objective was to reduce the number of unapproved drugs on the market. It allowed the first company to receive approval of a previously unapproved drug to have a period of de facto market exclusivity, which the FDA stated, “allowed manufacturers to raise prices in an environment largely insulated from market competition.”<sup>2</sup> In the Notice, the FDA stated that it was withdrawing the guidance documents for both evidence-based and legal reasons.

NHIA agrees with the FDA that the UDI had the unintended consequence of markedly increasing the cost of the drugs subject to the program without providing a corresponding benefit of

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<sup>1</sup> 85 Fed. Reg. 75331 (Nov. 25, 2020).

<sup>2</sup> Id. at 75332.

improved safety or quality. Below is an example of the consequences to the element Selenium, which is a critical component of parenteral nutrition (PN), used to treat pediatric and adult patients who are unable to sustain health through oral or enteral intake. As a result of the UDI, providers have had to endure unreasonable price increases, as well as changes to the formulation making it more challenging to use in pediatric patients.

In 2019, American Regent, the manufacturer of a reformulated version of intravenous selenium, introduced the reformulated version with a price tag more than twelve times greater than the previous formulation, which had been used safely for decades. The recommended daily dose of selenium for an adult is usually 60-100 mcg, and 1-3 mcg/kg/day for neonatal and pediatric patients. Patients requiring long-term PN at home often require individually dosed trace elements including selenium because the trace element profile of multi-component products is rarely appropriate for long-term use. According to the Average Wholesale Price (AWP), the previous selenium product was \$0.05 per mcg, and the new selenious acid product AWP was \$0.69. For a typical adult dose of 60mcg, the price increased from \$3 per dose to \$41.40. In addition, the packaging of the product prompted additional waste when preparing doses for pediatric PN.

NHIA thanks the FDA for revisiting the UDI program and fully supports the FDA's decision to withdraw the UDI guidance documents and terminate the program. We believe this decision will ensure that safe drugs that have been in use for decades will be available to consumers at competitive prices. We thank the FDA and HHS for making this decision, which will have a positive impact on consumers.

NHIA appreciates the opportunity to provide these comments. For questions or additional information, please contact me at [connie.sullivan@nhia.org](mailto:connie.sullivan@nhia.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'Connie Sullivan', with a stylized flourish at the end.

Connie Sullivan, B.S. Pharm  
President and Chief Executive Officer