

**Congress of the United States**  
**Washington, DC 20515**

October 25, 2019

The Honorable Alex Azar  
Secretary  
The Department of Health and Human Services  
200 Independence Ave SW  
Washington, DC 20201

Dear Secretary Azar-

As Co-Chairs of the House of Representatives Cancer Caucus, we write today to express our concerns regarding ongoing reports of drug shortages facing the childhood cancer community, and to inquire as to how the Department of Health and Human Services (HHS) is responding to these shortages and may play a larger role in addressing these shortages.

As you know, one drug currently facing a shortage is vincristine, a chemotherapy drug used to treat numerous kinds of childhood cancer. The shortage comes after one of only two manufacturers of the drug, Teva Pharmaceuticals, made a "business decision" in July to discontinue the drug.<sup>1</sup> Meanwhile the remaining supplier of vincristine, Pfizer, has been experiencing manufacturing issues, further reducing the available supply of the drug.<sup>2</sup> This has forced providers and patients into an untenable position, as there is no alternative drug for pediatric patients that can be substituted for vincristine.<sup>3</sup>

In light of this shortage, the Children's Oncology Group has issued revised recommendations for clinical trial treatment protocols where vincristine is in use, including reducing or skipping doses and even stopping use of the drug entirely.<sup>4</sup> While new doses of the drug are expected to ship at the end of October, and the shortage is expected to be resolved by January 2020,<sup>5</sup> any amount of time without a reliable supply of this drug is unacceptable for children undergoing cancer treatment and their families.

Drug shortages are not a new problem, nor are they unique to pediatric cancer medications. The U.S. Food and Drug Administration's (FDA) database of drug shortages lists 131 medications currently experiencing a shortage.<sup>6</sup> Drug shortages have been a significant and persistent threat

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<sup>1</sup> U.S. Food and Drug Administration, "Current and Resolved Drug Shortages and Discontinuations Reported to FDA." Online at [https://www.accessdata.fda.gov/scripts/drugshortages/dsp\\_ActiveIngredientDetails.cfm?AI=Vincristine+Sulfate+%28VINCASAR+PFS%29+Injection%2C+USP&st=d&tab=tabs-2](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Vincristine+Sulfate+%28VINCASAR+PFS%29+Injection%2C+USP&st=d&tab=tabs-2).

<sup>2</sup> Roni Caryn Rabin, The New York Times, "Faced With a Drug Shortfall, Doctors Scramble to Treat Children With Cancer" (October 14, 2019). Online at <https://www.nytimes.com/2019/10/14/health/cancer-drug-shortage.html>.

<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

<sup>5</sup> U.S. Food and Drug Administration, "Current and Resolved Drug Shortages and Discontinuations Reported to FDA." Online at [https://www.accessdata.fda.gov/scripts/drugshortages/dsp\\_ActiveIngredientDetails.cfm?AI=Vincristine%20Sulfate%20Injection.%20USP%20\(Preservative-Free\)&st=c](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Vincristine%20Sulfate%20Injection.%20USP%20(Preservative-Free)&st=c).

<sup>6</sup> U.S. Food and Drug Administration, "Current and Resolved Drug Shortages and Discontinuations Reported to FDA." Online at <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

to public health for a number of years, and while progress has been made to reduce the number of shortages, too many drugs still remain in short supply today.<sup>7</sup>

The lack of a reliable drug supply puts unnecessary strain on health systems, health care providers, and patients. Shortages delay care, increase the burden on hospitals and pharmacists who must scramble to find available doses, and often force providers to rely on other treatment options that may not be as effective or that carry more risk.<sup>8</sup> The dangers of shortages of drugs like vincristine are further exacerbated when pediatric patients are affected, as there are often fewer alternative medications that are approved for use in children that can be substituted.<sup>9</sup>

Congress has taken several actions in recent years to address the issue of drug shortages, and to enable the FDA to better respond when shortages occur. Title X of the FDA Safety and Inspection Act of 2012 empowered FDA to fast-track inspections of drug manufacturing facilities and product applications that could help resolve or guard against a shortage, broadened manufacturer reporting requirements regarding drug shortages, and directed FDA to establish a drug shortages task force.<sup>10</sup> As part of the 21<sup>st</sup> Century Cures Act of 2016, FDA was also authorized to establish a grant program for institutions of higher education and nonprofits to facilitate the study of innovative manufacturing techniques like continuous manufacturing that may help reduce drug shortages.<sup>11</sup> However, drug shortages continue to pose a threat to public health, and it is clear that there is still more work to be done to protect patients from the consequences of a shortage.

In light of this current life-or-death situation facing too many children with cancer, we would like to know more about what is currently being done to mitigate these kinds of drug shortages. To that end, we would appreciate your prompt answers to the following questions:

1. We understand that the primary agency within HHS that responds to drug shortages is the FDA. What tools and authority does the FDA currently have to monitor and respond to drug shortages?
2. Are there other agencies or offices within HHS that play a role in responding to drug shortages outside of the FDA?
3. To what extent does HHS communicate or coordinate with other departments or agencies within the federal government to respond to drug shortages?
4. What information are drug manufacturers required to report to HHS regarding a drug shortage, and on what timeline are they required to report that information?
5. To what extent does HHS require drug manufacturers to communicate with and disseminate information to patients, pharmacists, health care providers, hospitals, and other supply chain stakeholders regarding a drug shortage, and on what timeline are they required to report that information?

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<sup>7</sup> Congressional Research Service, "Drug Shortages: Causes, FDA Authority, and Policy Options" (December 27, 2019). Online at <https://fas.org/spp/crs/misc/IF11058.pdf>.

<sup>8</sup> Katie Thomas, The New York Times, "Drug Shortages Persist in U.S., Harming Care" (November 16, 2012). Online at <https://www.nytimes.com/2012/11/17/business/drug-shortages-are-becoming-persistent-in-us.html>.

<sup>9</sup> Rabin.

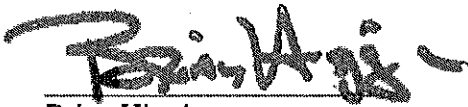
<sup>10</sup> Congressional Research Service.

<sup>11</sup> Ibid.

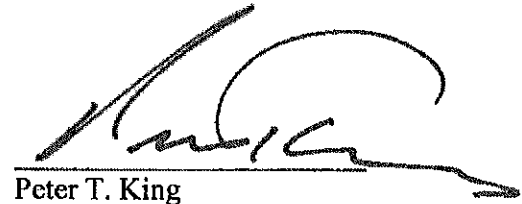
6. How does HHS communicate with and disseminate information to health care providers, patients, the general public, and other stakeholders regarding drug shortages?
7. What steps does HHS currently take to work with drug manufacturers to prevent drug shortages from occurring in the first place?
8. What additional tools or authority would be useful to the Department in order to strengthen HHS's ability to prevent and respond to drug shortages? Specifically, how might HHS take additional action to ensure that the existing supply of drugs with pediatric indications and without pediatric alternatives are prioritized for pediatric patients when shortages occur?
9. How can Congress be helpful to the Department and its efforts to respond to drug shortages?

Children with cancer and their families face too many challenges as it is; they should not also have to bear the worry, fear, and frustration that comes with knowing a drug that could help their child exists, but is inaccessible due to a shortage. Thank you for your attention to this important issue, and we look forward to your response.

Sincerely,



Brian Higgins  
Member of Congress



Peter T. King  
Member of Congress



Derek Kilmer  
Member of Congress



Brian Fitzpatrick  
Member of Congress