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RULES AND ADMINISTRATION

United States Senate

WASHINGTON, DC 20510

October 22, 2019

The Honorable Norman Sharpless, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

I write to express my serious concern about the recent shortage of Vincristine, a critical drug used to treat many childhood cancers—including more than 1,000 patients at Children’s Minnesota each year.¹ An October 14, 2019 news report indicated that the drug’s limited supply is forcing physicians across the country to consider rationing, lowering, or skipping doses for patients.² Since there is no appropriate substitute for the drug available in the U.S., the current lack of Vincristine could jeopardize the health and well-being of vulnerable children across the country unless the shortage is swiftly resolved.

According to reports, the Vincristine shortage is linked to a Pfizer manufacturing delay following Teva Pharmaceuticals’ withdrawal from the market earlier this year. Previously, just two drugmakers manufactured the drug in the U.S. until Teva stopped production. Teva has indicated that it informed the Food and Drug Administration (FDA) that it would stop manufacturing the drug in March 2019,³ and in July 2019, the FDA posted a statement that, “Teva made a business decision to discontinue the product.”⁴

While Pfizer is working to expedite production of Vincristine to meet the full market need by January at the latest, the next shipment is not planned until later this month, and notably, this is not the first time that patient demand of Vincristine has been met with a limited supply.⁵ As recently as the spring of 2018, hospitals warned that their stockpiles of Vincristine were exceptionally low.⁶ If Pfizer’s current barriers to production extend beyond the anticipated

¹ Erdahl, Kent. (2019, October 15) *Doctors Seeing Shortage in Critical Drug Used in Cancer Therapies*. KARE NBC, Minneapolis. Retrieved from <https://www.kare11.com/article/news/health/doctors-seeing-shortage-in-critical-drug-used-in-cancer-therapies/89-42860cc0-06ec-45c2-8d42-ce955c0c9e3f>.

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

³ Frazin, Rachel. (2019, October 15). *Doctors Warn of Possible Rationing on Critical Childhood Cancer Drug*. The Hill. Retrieved from <https://thehill.com/policy/healthcare/465813-doctors-warn-of-possible-rationing-on-critical-childhood-cancer-drug>.

⁴ FDA Drug Shortages. (2019, July 5). Retrieved from [https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Vincristine+Sulfate+\(VINCASAR+PFS\)+Injection,+USP&st=d&tab=tabs-2](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Vincristine+Sulfate+(VINCASAR+PFS)+Injection,+USP&st=d&tab=tabs-2). (Accessed on October 21, 2019)

⁵ FDA Drug Shortages. (2019, October 18). Retrieved from [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). (Accessed on October 21, 2019)

⁶ Crow, David. (2018, May 9) *Hospitals in US Sound Alarm on Impending Chemotherapy Shortages*. Financial Times. Retrieved from <https://www.ft.com/content/83ad5334-52f1-11e8-b3cc-41e0209208ec>.

December timeline, then doctors and patients without a suitable substitute drug may need the FDA to step in to ensure that children with cancer can continue to obtain the product.

The FDA has previously taken action to help resolve drug shortages, including allowing for the temporary importation of foreign drugs with appropriate safeguards—for example, four medications to fight cancer in 2011.⁷ In a May 2018 statement about drug shortages, the agency reiterated a willingness to “explore importation of a product from a foreign manufacturing source until the shortage is resolved.”⁸

It is crucial that Vincristine’s current drug shortage is quickly addressed. Accordingly, I respectfully request answers to the following questions:

1. What actions will you take to mitigate the Vincristine shortage should the drug remain in limited supply after December 2019? Have you looked for other manufacturing sources outside of the country? If not, why not? If so, will the FDA explore temporary importation of the drug? What actions will you take to prevent future drug shortages of Vincristine once the current shortage is resolved?
2. Did the FDA contact Teva and Pfizer to ask about the status of their Vincristine supplies after reports surfaced in the spring of 2018 to ensure the companies could continue to meet demand? If not, why not? If so, please provide a copy of any responses you received.
3. Did Teva notify the FDA of its plan to discontinue production of Vincristine in March 2019? If so, why is the FDA notice dated July 5, 2019? What strategic planning and communication occurred between the FDA, Pfizer, hospitals, physicians, and patients between March 2019 and July 2019 in anticipation of potential market disruption?

Thank you for your prompt attention to this important matter.

Sincerely,



Amy Klobuchar
United States Senator

⁷ Ventola, C Lee. (2011). The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies. *US National Library of Medicine, Pharmacy & Therapeutics*. 36(11), pp. 740-742, 749-757. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278171/#b15-ptj3611740>.

⁸ Gottlieb, Scott. (2018, May 31). *Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's Work to Mitigate Shortages of Intravenous Drugs, Shorten Supply Disruptions and Better Predict Vulnerabilities*. U.S. Food and Drug Administration. Retrieved from <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-work-mitigate-shortages-intravenous-drugs-shorten>.