

United States Senate

WASHINGTON, DC 20510

February 28, 2020

The Honorable Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hahn:

We write to inquire about the steps the Food and Drug Administration (FDA) plans to take if potential shortages or disruption of medical products occurs due to the outbreak of a new coronavirus, COVID-19, first identified in Wuhan City, Hubei Province, China. This morning the FDA reported that the United States has its first COVID-19 related drug shortage. The FDA has been a key partner in working with our offices in creating policy proposals to address domestic drugs shortages, and we would like that partnership to continue. Like you, we are concerned that the current COVID-19 outbreak may worsen domestic drug shortages and risk the health of our constituents. We ask that you provide us with a briefing on FDA's administrative and regulatory actions to mitigate new, potentially devastating shortages due to the COVID-19 outbreak.

News outlets have reported that FDA has identified a list of 20 drug products at risk of shortage if the COVID-19 outbreak in China worsens.¹ These drugs are either solely manufactured in China or contain an active pharmaceutical ingredients (APIs) solely made in China.² As you know, the majority of prescription drugs Americans consume are manufactured abroad. This is particularly true for manufacturers of API. Though data is limited, FDA testified before the House Energy and Commerce Subcommittee on Health on October 30, 2019 that more than 70 percent of API manufacturers are located overseas.³ While only 13 percent of API manufacturers are located in China, these manufacturers are the primary producer of ingredients found in common generic drugs like antibiotics, blood pressure medicine, and hundreds of other

¹ Michael Mezher, "FDA Monitoring 20 Drugs at Risk of Shortage due to Coronavirus," *Regulatory Affairs Professional Society*, <https://www.raps.org/news-and-articles/news-articles/2020/2/fda-monitoring-20-drugs-at-risk-of-shortage-due-to>

² Sarah Karlin-Smith, "FDA identifies 20 drug products made only in China," *Politico*.

³ Janet Woodcock, "Testimony: Safeguarding Pharmaceutical Supply Chains in a Global Economy," *Food and Drug Administration*, <https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019>

generic drugs.⁴ If the COVID-19 outbreak decreases China's production capability, the drugs Americans take, which are about 90 percent generic, may be at risk.

While we appreciate FDA proactively reaching out to more than 180 manufacturers of drug and medical device manufacturers to identify potential vulnerabilities in the drug supply chain, Americans have already experienced diminished access to their medications, and cannot afford additional impacts due to additional or prolonged drug shortages. To better understand FDA's efforts to address drug shortages, particularly around the current COVID-19 outbreak, we request answers to the following questions:

1. How is FDA working to identify potential vulnerabilities of US medical products stemming specifically from the outbreak?
2. What tools are available to FDA to reach swiftly and mitigate the impact to US patients and health professionals?
3. FDA may lack complete information around the prescription drug supply chain such as the source country of raw materials, source country of APIs, or which facilities manufacture particular drugs.
 - a. How did FDA develop its COVID-19-specific drug shortage list?
 - b. What information or criteria was used to develop the list?
4. FDA reported that the United States has its first COVID-19 related drug shortage. Please provide more details on the type of drug now in shortage and the steps FDA is taking to mitigate the shortage.

We would appreciate FDA's prompt response to this inquiry. We look forward to reviewing FDA's actions to ensure that patient care is not impeded, and to working with the Agency to find solutions to prevent drug shortages.

Sincerely,



Benjamin L. Cardin
United States Senator

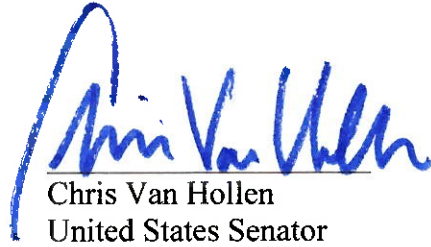


Tina Smith
United States Senator

⁴ Anna G. Eshoo and Adam B. Schiff, "China's grip on pharmaceutical drugs is a national security issue," *Washington Post*, https://www.washingtonpost.com/opinions/we-rely-on-china-for-pharmaceutical-drugs-thats-a-security-threat/2019/09/10/5f35e1ce-d3ec-11e9-9343-40db57cf6abd_story.html



Richard Blumenthal
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Chris Van Hollen
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