



March 30, 2020

Michael A. Carome, M.D.  
Director  
Public Citizen's Health Research Group  
1600 20<sup>th</sup> Street, NW  
Washington, DC 20009

Dear Dr. Carome:

Thank you for your letter of March 3, in which you raise concerns regarding the first medication shortage caused by the novel coronavirus (COVID-19), and in particular, that FDA has not identified the medication at issue. The U.S. Food and Drug Administration (FDA or the Agency) understands the significant impact that drug shortages have on patient care and does everything within its authority to help prevent and alleviate shortages.

Drug shortages pose a significant public health threat that can delay critically needed care for patients. Whenever a shortage occurs, FDA actively works with manufacturers and other U.S. federal agencies to try to address supply issues for the drug product in shortage. FDA determines how best to address each shortage situation based on the shortage's cause and the public health risk associated with the shortage. Although FDA works to find ways to mitigate drug shortages, there are multiple factors that can cause or contribute to drug shortages that are outside of FDA's control. FDA cannot require a pharmaceutical company to make a drug or make more of a drug, even if the drug is medically necessary, and FDA cannot control how much of a drug is distributed or which purchasers will be given priority.

As part of FDA's drug shortage efforts, the Agency has identified about 20 drugs that solely source their active pharmaceutical ingredients or finished drug products from China. FDA has been in contact with those firms to assess whether they face any drug shortage risks due to the coronavirus outbreak, and none of these firms have reported any shortage to date. Also, these 20 drugs are considered non-critical drugs. FDA will remain in contact with manufacturers so that the Agency can continue to assist them quickly with any potential issues.

As you know, the Agency maintains a list of drugs that are in shortage and provides related information on its website, including information about the shortage that you referred to in your letter. Although manufacturers are legally required to report many drug supply disruptions to FDA, these manufacturers generally are not required to provide the kind of detailed information about conditions within their supply chain that FDA has needed to monitor the drug supply since the onset of the outbreak. There are also limits on FDA's ability to publicly disclose confidential commercial information that the manufacturers voluntarily provide the Agency. FDA relies on the cooperation of drug companies to obtain accurate information as the Agency proactively takes steps to mitigate drug shortages. Companies will be less willing to provide voluntary

information if they cannot trust FDA not to disclose both commercial confidential information (such as the names and locations of facilities where supply issues are occurring) and the status of production within those facilities.

FDA will continue to do all it can within its authorities to address shortages, working together with industry and other partners to promote a return to production levels that meet the needs of patients. Please see FDA's website for the most up-to-date information regarding COVID-19.<sup>1</sup> Thank you for bringing your concern to our attention. Please let us know if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Hahn".

Stephen M. Hahn, M.D.  
Commissioner of Food and Drugs

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<sup>1</sup> <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update>.