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RE: Need for full transparency regarding coronavirus-related drug shortages

Dear Sirs:

On February 27, the Food and Drug Administration (FDA) announced the first medication shortage caused by the rapidly expanding novel coronavirus (COVID-19) epidemic that originated in China.¹ The agency, however, has refused to identify the medication. Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, was dismayed by the refusal of the FDA's refusal to identify the medication. Because hiding such information from the public sows distrust in the government agencies, as well as private organizations, involved in the response to the COVID-19 epidemic, your organizations must encourage your member companies to publicly disclose the names of their specific drugs or biological products that are involved in any shortage resulting from the COVID-19 epidemic.

¹ Food and Drug Administration. FDA statement: Coronavirus (COVID-19) supply chain update. February 27, 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-supply-chain-update>. Accessed March 1, 2020.

Today, we also have sent a letter to FDA Commissioner Stephen M. Hahn urging that his agency make the same types of disclosures to the public.

An FDA spokeswoman asserted that the name of the drug involved in the shortage is considered “confidential commercial information.”² However, we believe such information should not be considered confidential commercial information because disclosure of such information would not reasonably be expected to cause substantial competitive harm and because publicly traded pharmaceutical companies already have an obligation to disclose such information to their shareholders. Moreover, important public health interests must take precedence over any purported industry interest in keeping such information secret. For example, knowing which drug shortages are due to the COVID-19 epidemic will help the medical community better understand the evolving adverse impacts of the epidemic and take actions to mitigate those impacts.

We look forward to a favorable response to our request regarding this important public health matter.

Sincerely,



Michael A. Carome, M.D.
Director
Public Citizen’s Health Research Group

² Silverman E. The FDA identifies its first drug shortage due to coronavirus but won’t name the medicine. *STAT*. February 28, 2020. <https://www.statnews.com/pharmalot/2020/02/28/fda-coronavirus-shortage-confidentiality/>. Accessed March 1, 2020.