



March 3, 2020

Stephen M. Hahn, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

## RE: Lack of full transparency regarding coronavirus-related drug shortages

## Dear Commissioner Hahn:

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. The agency, however, has refused to identify the medication. Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, is dismayed by the refusal of the FDA to identify the medication. We are writing to strongly urge your agency to immediately disclose on its website and in a press statement the specific drug involved in the shortage and to include such disclosures in all future announcements of shortages of drugs (or other medical products) that are linked to the COVID-19 epidemic, which are widely expected.

As you are aware, full transparency by all government agencies involved in the response to the COVID-19 epidemic is essential for maintaining the public's trust. Any hint that the government is hiding important information sows distrust. At a press conference last week, Secretary of Health and Human Services Alex Azar assured the public that his department will maintain a policy of "radical transparency" with respect to the COVID-19 epidemic.<sup>2</sup> The FDA's refusal to identify the specific medication that is in shortage because of the COVID-19 epidemic falls far short of the level of transparency promised by Secretary Azar.

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

<sup>&</sup>lt;sup>2</sup> Morse M. COVID-19 is spreading rapidly abroad while immediate threat to Americans remains low, says Alex Azar. February 25, 2020. <a href="https://www.healthcarefinancenews.com/news/covid-19-cases-abroad-are-spreading-rapidly-while-immediate-threat-american-public-remains-low">https://www.healthcarefinancenews.com/news/covid-19-cases-abroad-are-spreading-rapidly-while-immediate-threat-american-public-remains-low</a>. Accessed March 1, 2020.

An FDA spokeswoman asserted that the name of the drug involved in the shortage is considered "confidential commercial information." 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

cc: The Honorable Alex Azar, Secretary of Health and Human Services

<sup>&</sup>lt;sup>3</sup> Silverman E. The FDA identifies its first drug shortage due to coronavirus but won't name the medicine. *STAT*. February 28, 2020. <a href="https://www.statnews.com/pharmalot/2020/02/28/fda-coronavirus-shortage-confidentiality/">https://www.statnews.com/pharmalot/2020/02/28/fda-coronavirus-shortage-confidentiality/</a>. Accessed March 1, 2020.