

ONE HUNDRED SIXTEENTH CONGRESS
Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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March 9, 2020

The Honorable Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

As the U.S. Food and Drug Administration (FDA) and other United States health agencies work to respond to the ongoing outbreak of the novel coronavirus (COVID-19), we write to you today regarding the impact of the virus on the supply of safe drugs and other medical products. Even before the outbreak, we noted our concerns about drug and medical device shortages, and the impact they can have on Americans' access to safe and effective medical products. As FDA and our other health agencies respond to this global emergency, we want to ensure that FDA is equipped to maintain its commitment to protecting and promoting public health by addressing potential shortages and minimizing harm for patients.

FDA plays a central role in ensuring the safety and effectiveness of medical products sold in the United States, and Americans should take comfort in the knowledge that drug products approved by the FDA are among the most rigorously reviewed in the world. This authority is not limited to medical products manufactured in the United States. As Dr. Janet Woodcock, the Director of the Center for Drug Evaluation and Research, noted in a recent hearing before our Committee, drug manufacturing, particularly manufacturing of active pharmaceutical ingredients (APIs), has moved overseas in recent decades, with 13 percent of API manufacturing facilities now located in China.¹ In addition to API, other products, including personal protective equipment (PPE), such as surgical masks, gowns, and gloves, are manufactured in China. FDA has the authority and responsibility to ensure that these products remain safe, effective, and available for American health care workers and patients.

While we understand the immediate risk of the COVID-19 outbreak to most people in the United States remains low, the level of risk to any individual community varies based on the

¹ House Committee on Energy and Commerce, *Hearing on Safeguarding the Pharmaceutical Supply Chains in a Global Economy*, 116th Cong. (Oct. 30, 2019).

circumstances. The potential public health threat posed by COVID-19 is very high to the United States and globally, and the situation and our knowledge about the virus is constantly evolving. The disease has already proven to be contagious in China, where over 80,000 have been infected, and we are now seeing documented cases of community transmission in the United States and sustained or widespread community transmission in other countries. It is imperative that the international public health community work to assist the Chinese people while addressing potential vulnerabilities in the global public health ecosystem, including the supply of medical products.

In your recent statement on this issue, you noted that while there are no vaccines, gene therapies, or blood derivatives licensed by FDA currently manufactured in China, the outbreak will likely impact the medical product supply chain, including disruptions to supply or shortages of critical medical products in the United States.² Already, FDA has reported that at least one human drug was added to the drug shortage list related to a site affected by coronavirus due to an issue with manufacturing an API used in the drug. We are also concerned that we could face shortages of PPE due to supply chain problems just when increased response and preparedness efforts are leading to increased demand.

To better understand FDA's efforts to mitigate supply chain problems, we ask that you provide Committee staff a briefing regarding these challenges. Specifically, we would like to know how many manufacturers, distributors, and importers might be affected by supply chain issues as a result of the COVID-19 outbreak. We are also interested in FDA's ongoing work to combat shortages, including what the Agency is hearing from potentially affected manufacturers, distributors, and importers, and what steps it is currently considering or taking to reduce potential shortages. Specifically, for the drug that has been added to the shortage list, we would like to know how many alternatives are available for this drug, and whether you anticipate those alternatives may also be affected by supply chain issues related to the COVID-19 outbreak. FDA has stated that it cannot name the specific drug that is in shortage due to the COVID-19 outbreak because it is confidential commercial information. We are interested in understanding how FDA intends to weigh conflicting priorities regarding the timely notification of shortages related to COVID-19 with its need to protect confidential commercial information.

To ensure safety, we would also like to receive an update on the impact the COVID-19 outbreak has had on FDA's risk-based inspections. To ensure the agency remains responsive and prepared, we would like to know more about FDA's resources, specifically, how existing resources are being used to account for this new challenge, how this will affect other vital operations at FDA, and whether the agency will need additional resources to meet supply chain demand. Finally, we would like to know what data systems FDA is using to track potential shortages resulting from the COVID-19 outbreak.

² U.S. Food & Drug Administration, *FDA's Actions in Response to 2019 Novel Coronavirus at Home and Abroad* (Feb. 14, 2020).

The world is counting on our public health agencies to respond quickly and effectively to address this outbreak. We appreciate your attention to this matter and request that briefing be scheduled no later than March 23, 2020. If you have any questions, please contact Stephen Holland of the Majority Committee staff at (202) 225-2927 or Kristin Seum of the Minority Committee staff at (202) 225-3641.

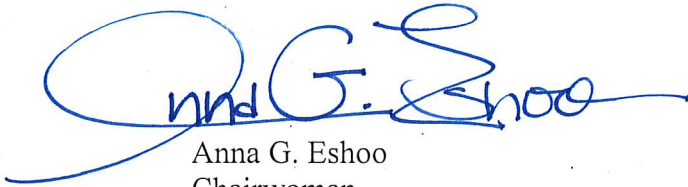
Sincerely,



Frank Pallone, Jr.
Chairman



Greg Walden
Ranking Member



Anna G. Eshoo
Chairwoman
Subcommittee on Health



Michael C. Burgess, M.D.
Ranking Member
Subcommittee on Health



Diana DeGette
Chair
Subcommittee on Oversight
and Investigations



Brett Guthrie
Ranking Member
Subcommittee on Oversight
and Investigations