

Congress of the United States
Washington, DC 20515

February 25, 2020

Steven Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

We write regarding the safety and security of the drug and personal protective equipment (PPE) supply chains since the outbreak of the Novel Coronavirus (COVID-19) in Wuhan, China. There are over 79,000 Coronavirus cases globally and over 2,500 deaths to date.¹ The epidemic shows no signs of abating. As the outbreak continues, the risk to the medical supply chain is potentially calamitous due to global dependence on Chinese manufacturing. In 2018, the United States imported more than \$13 billion of drugs, devices, and food from China.² As members of Congress from New Jersey, home to 14 of the world's 20 largest pharmaceutical companies, we are concerned about the health and well-being of our own constituents and our nation's ability to access drugs and protective equipment imported from China.³ As such, we request information on the FDA's plan to address the safety and security of our supply chain.

According to the U.S.-China Economic and Security Review Commission, China is the world's largest producer of active pharmaceutical ingredients (APIs) and the U.S. relies heavily on drugs and PPE that are sourced from China or include APIs from China.⁴ About 80 percent of APIs used to produce drugs globally come from China.⁵ However, we have no data on exactly how many APIs are imported from China to the U.S.⁶ While the U.S. Food and Drug Administration (FDA) has indicated it is taking proactive measures to address any disturbances to the drug supply chain to China, we question if these measures are sufficient in light of the epidemic's growth in recent weeks. For example, the FDA has announced implementation of its "risk-based model" to identify Chinese drug firms for proper inspection, but simultaneously the agency has ceased all inspections due to the U.S. State Department's warning against travel to and within China.⁷ This renders the FDA's safety measures useless.

Due to a lack of inspectors and an ineffectual regulatory system in Beijing, the FDA struggles to guarantee the safety of drugs or APIs that are imported from China. Indeed, in 2016, the National Medical Products Administration in China investigated over 1,500 clinical trial programs and canceled 80 percent of drug applications for approval after finding fraudulent data or incomplete data submissions.⁸ As the Chinese government struggles to contain the COVID-19 infections within its borders, the ability of China to conduct full regulatory inspections of drug exports are of concern.

Since the COVID-19 outbreak began, the World Health Organization (WHO) has raised alarm bells on the security of the medical supply chain, noting that stockpiles are already depleted to a four-to-six-month backlog.⁹ These levels are insufficient to meet the current WHO's needs and we remained concerned about further deterioration. Furthermore, the demand of PPE has risen 100 times since the COVID-19 outbreak began.¹⁰ This is relevant because China manufactures most of

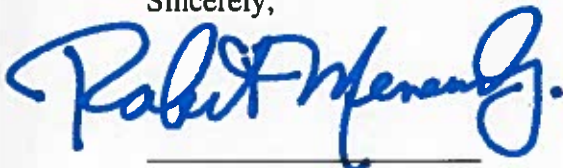
the world's masks, gowns, and respirators, which are essential tools for U.S. hospitals during an infectious disease outbreak.¹¹ As the outbreak of COVID-19 intensifies, we are concerned that the demand will outpace the supply of PPE.

In light of this, we ask that the FDA provide answers to the following questions by March 5, 2020:

1. According to reports that the FDA has compiled a list of 150 at-risk drugs, please provide a breakdown of brand-name and generic drugs available in the U.S. that use APIs produced in China. Please detail which, if any, of these drugs are deemed critical to the health and safety of Americans.
2. Please clarify what other information Commissioner Hahn was referring to on February 14, 2020 when he stated that said that while the FDA is no longer conducting medical product inspections in China, the FDA is still working to use "other information to inform decisions allowing the products to enter the U.S. market."¹²
3. Please detail the FDA's process and any adjustments or changes the FDA has made since the COVID-19 outbreak began.
4. We understand that the FDA has made strides in improving the inventory of registered pharmaceutical manufacturing firms, but gaps remain in the visibility of Chinese drug or API manufacturers that are shipped to the U.S.¹³ Please explain how the FDA has addressed these gaps in inventory. What assurances can the FDA provide that the lack of this information will not cause drug or API shortages? Please detail any additional steps the FDA taking to address possible drug shortages as a result of COVID-19.
5. The WHO has warned of a global PPE shortage. What steps is the FDA taking to ensure that U.S. health care providers have the necessary PPE required to care for patients? What is the Administration doing to boost manufacturing of PPE from sources outside of China?

We believe U.S. reliance on China for drugs and APIs presents a national security risk, in addition to an economic risk, especially during the growing outbreak of COVID-19. We hope that the FDA is doing everything possible to make modifications to protect the drug and PPE supply chain and expand efforts at transparency. Keeping the public updated and informed at all times is essential. We hope the FDA will look to Congress as a partner in ensuring our common goal of eliminating negative impacts to U.S. public health. We await your prompt responses and look forward to working with you on this evolving issue.

Sincerely,



Robert Menendez
U.S. Senator



Bill Pascrell, Jr.
Member of Congress

-
- ¹ World Health Organization. (2020). Novel coronavirus (2019-nCoV) situation reports. Retrieved from https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200223-sitrep-34-covid-19.pdf?sfvrsn=44ff8fd3_2
- ² Karlin-Smith, S. (2020). FDA: No drug shortages reported because of coronavirus but situation 'fluid'. Retrieved from <https://www.politico.com/news/2020/02/07/chinese-drugs-shortage-coronavirus-112049>
- ³ State of New Jersey Business Portal. NJ advantages for pharmaceutical companies. Retrieved from <https://www.nj.gov/njbusiness/industry/pharmaceutical/>
- ⁴ U.S.-China Economic and Security Review Commission. (2019). Report to Congress. Retrieved from <https://www.uscc.gov/sites/default/files/2019-11/2019%20Annual%20Report%20to%20Congress.pdf>
- ⁵ Silverman, E. (2020, January 27). The coronavirus in china could threaten pharma's ingredient source. Retrieved from <https://www.statnews.com/pharmalot/2020/01/27/china-coronavirus-pharmaceutical-ingredients/>
- ⁶ U.S.-China Economic and Security Review Commission. (2019). Report to Congress. Retrieved from <https://www.uscc.gov/sites/default/files/2019-11/2019%20Annual%20Report%20to%20Congress.pdf>
- ⁷ U.S. Food and Drug Administration. (2020). FDA's actions in response to 2019 novel coronavirus at home and abroad. Retrieved from <http://www.fda.gov/news-events/press-announcements/fdas-actions-response-2019-novel-coronavirus-home-and-abroad>
- ⁸ U.S.-China Economic and Security Review Commission. (2019). Report to Congress. Retrieved from <https://www.uscc.gov/sites/default/files/2019-11/2019%20Annual%20Report%20to%20Congress.pdf>
- ⁹ WHO warns of PPE shortage; nCoV pace slows slightly in China. (2020). Retrieved from <http://www.cidrap.umn.edu/news-perspective/2020/02/who-warns-ppe-shortage-ncov-pace-slows-slightly-china>
- ¹⁰ Ibid.
- ¹¹ McKenna, M. (2020, February 4,). Amid coronavirus fears, a mask shortage could spread globally. Wired, Retrieved from <https://www.wired.com/story/amid-coronavirus-fears-a-mask-shortage-could-spread-globally/>
- ¹² U.S. Food and Drug Administration. (2020). FDA's actions in response to 2019 novel coronavirus at home and abroad. Retrieved from <http://www.fda.gov/news-events/press-announcements/fdas-actions-response-2019-novel-coronavirus-home-and-abroad>
- ¹³ U.S.-China Economic and Security Review Commission. (2019). Report to Congress. Retrieved from <https://www.uscc.gov/sites/default/files/2019-11/2019%20Annual%20Report%20to%20Congress.pdf>