

United States Senate

WASHINGTON, DC 20510

February 6, 2020

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

Dear Commissioner Hahn:

In light of the growing epidemic of the novel coronavirus (2019-nCoV), we are writing to ensure the Food and Drug Administration (FDA) has the necessary tools to ensure the safety and supply of pharmaceuticals, food, and medical supplies imported from China.

In 2018, the U.S. imported more than \$12.7 billion worth of pharmaceuticals and antibiotics, medical devices, and food products from China, and these numbers do not even include certain organic chemicals used to create pharmaceutical products. Experts also estimate that roughly 80 percent of the active pharmaceutical ingredients used to make medications come from China. As well, nearly ten percent of medical devices were imported from China in 2018 and, according to the U.S. International Trade Commission, the sale of orthopedic implantable devices grew by 189 percent from 2011 – 2016. While the Centers for Disease Control and Prevention stated it's unlikely the 2019-nCoV will spread to the United States from these products, we are concerned that the pandemic could impact the FDA's ability to monitor compliance with good manufacturing standards and the ability for Chinese manufacturers to maintain supplies to meet demand in the United States and the growing demands in China.

To date, more than 28,000 people in China have confirmed cases of 2019-nCoV – a number that jumps with each passing day – and the death toll has now surpassed that of the SARS outbreak in 2003. There are also widespread reports of shortages of medical supplies, hospital beds, and testing kits in China to confirm potentially more cases of 2019-nCoV. Additionally, the pandemic has forced schools and businesses throughout China to close. These closures, combined with the possibility of infected workers, could limit the ability of Chinese manufacturers to maintain the production capacity needed to keep pace with global demand. Given the strain this virus has placed on China's healthcare system, we are concerned there could be reduced resources available to U.S. healthcare providers that rely on products manufactured in China.

Given the speed with which the 2019-nCoV is spreading, we respectfully request a response to the following questions by February 18, 2020.

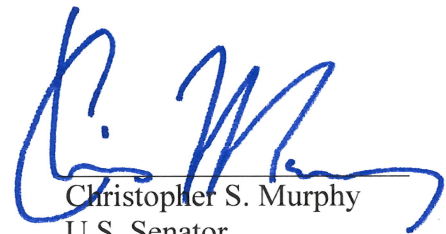
1. Does the FDA have the resources necessary to ensure the 2019-nCoV pandemic does not impact America's supply of pharmaceuticals, medical devices and food imported from China?
 - a. If not, what resources does the FDA need?
 - b. If so, does the FDA anticipate a shortage in resources should this pandemic not subside in the near future?
2. Last month, the federal government ordered all nonessential personnel to leave China. How many FDA personnel are still in China to conduct inspections of facilities producing pharmaceuticals, medical supplies and food for export to the United States? How many personnel are typically in China to conduct these inspections?
3. How has the coronavirus impacted the FDA's inspection schedule for the 2020 calendar year?
4. How is the FDA coordinating with companies to monitor the safety and supply of products manufactured in China?
5. What steps has the FDA taken to ensure that there is not a shortage of essential pharmaceuticals or medical supplies, should the supply of these products from China be disrupted? Has the FDA coordinated with other companies in an effort to potentially fill any supply shortages?

Thank you for your attention to these important matters, and for the FDA's continued efforts to protect Americans from this epidemic. We look forward to hearing from you.

Sincerely,



Marco Rubio
U.S. Senator



Christopher S. Murphy
U.S. Senator