

United States Senate

WASHINGTON, DC 20510

February 28, 2020

Dr. Stephen Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hahn,

We write today to request information about your agency's plans for FDA inspections in China in light of the outbreak of a new coronavirus, COVID-19, first identified in Wuhan City, Hubei Province, China, and the serious potential health risk the outbreak could pose to FDA's compliance and inspection personnel. Additionally, we strongly urge you to establish open lines of communication with your workers and their union representatives now, as you make plans to resume inspections in China. FDA employees deserve a seat at the table as agency leadership has discussions and develops policies related to inspections in China.

As you know, FDA's workers, including its compliance and inspection personnel, play a critical role in carrying out the agency's mission to protect the public health. FDA's compliance and inspection personnel are on the front lines ensuring that our food is safe and properly labeled and that our pharmaceuticals and medical devices are safe and effective. Inspection activities in China have been suspended but pose a potential risk to FDA workers when activities resume.

The FDA must protect the health and safety of its workers while carrying out its important mission. In order to better understand your agency's plans around future inspections and efforts to protect the health and safety of your workers in China, we ask that you provide responses to the below questions by March 13, 2020:

1. Are there any near-term plans to resume sending any FDA employees, including compliance or inspection personnel, to China?
 - a. If yes, when does FDA plan to resume sending those employees and when does it plan to resume inspections? Please detail the scope and frequency of inspections that will be resumed.
2. FDA has stated that inspection-related travel to China that is deemed to be mission-critical will be assessed on a "case-by-case basis."¹ Does FDA have any established protocol for those decisions? If so, please provide details on that protocol.

¹ FDA Statement, FDA's Actions in Response to 2019 Novel Coronavirus at Home and Abroad (Feb. 14, 2020), available at <https://www.fda.gov/news-events/press-announcements/fdas-actions-response-2019-novel-coronavirus-home-and-abroad>.

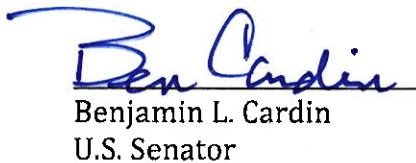
3. How much notice does FDA plan to give compliance and inspection personnel before resuming inspections in China? Has FDA done any work, on its own or in coordination with the Centers for Disease Control and Prevention (CDC), the Occupational Safety and Health Administration (OSHA), or any other agency, to begin developing health and safety protocols for FDA inspectors once inspections in China resume?
 - a. If yes, please detail this work.
 - b. If no, please detail why such work has not been initiated and when FDA plans to begin this work.
4. How is FDA communicating information and/or policies related to inspections in China to its workers and/or union representatives? Please provide any such communications (including written and electronic communications), the date of the communication, how the communication was distributed, and to whom it was distributed.

Thank you in advance for your attention to this important matter. We look forward to hearing from you.

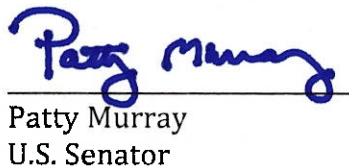
Sincerely,


Chris Van Hollen
U.S. Senator


Sherrod Brown
U.S. Senator


Benjamin L. Cardin
U.S. Senator


Mazie K. Hirono
U.S. Senator


Patty Murray
U.S. Senator