United States Senate
WASHINGTON, DC 20510

April 21, 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,

The Food and Drug Administration (FDA) plays a critical role in assuring compliance with U.S. laws and regulations to protect the safety of drug and medical device products in the U.S. market. Earlier this month the agency announced that it would postpone foreign and domestic inspections, with limited exceptions. We agree that the health and safety of the FDA's workforce must be prioritized. However, given the need to protect the drugs and devices Americans rely on to maintain their health and wellbeing, we also want to ensure that you have the strongest tools for full and accurate reporting and compliance from manufacturers.

In February, the FDA wrote that all its staff in China, with the exception of the country director, were repatriated back to the United States and that all scheduled inspections in China for February and March were postponed or conducted using other means.[1] The FDA noted that it conducts approximately 500 inspections per year of mostly drugs, food, and medical devices in China. Most of the routine surveillance inspections for March were for medical products and are set to be rescheduled for later this fiscal year. The letter also noted that the agency has a multi-layered compliance process in place despite not being able to conduct inspections in China.

As the spread of the 2019 Novel Coronavirus (COVID-19) expanded to additional countries, on March 10, the FDA announced that it is postponing most foreign inspections through April, effective immediately.[2] The FDA indicated it would employ other tools to ensure safety and apply risk-based approaches, such as denying entry of unsafe products, physical examinations and product sampling, reviewing previous compliance history, mutual agreements between foreign governments to share information, and advance record requests. However, the FDA's Fiscal Year (FY) 2021 budget justification notes the challenges of regulating a market whose volume of imports and number of foreign facilities has grown, where the complexities of products have increased, and the number of countries involved in the supply chain has expanded to include many with less sophisticated compliance requirements than the U.S.[3]

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[1] https://www.murphy.senate.gov/download/murphy-response-letter_--re-coronavirus-supply-chain
[2] https://www.fda.gov/news-events/press-announcements/coronavirus-disease-2019-covid-19-update-foreign-inspections
[3] Food and Drug Administration Fiscal Year 2021 Justification of Estimates for Appropriations Committees. https://www.fda.gov/media/135078/download

In an expansion of the suspension of FDA in-person inspections, on March 18, the FDA announced that it would temporarily postpone all domestic routine surveillance and facility inspections, with exceptions for mission-critical and for-cause inspections.[4] In that release, the agency said it would leverage all available authorities to continue to ensure the integrity of the products it regulates, while noting that in the previous fiscal year, the overall domestic violation rate was roughly 5 percent.

Given the uncertainty surrounding COVID-19, and broader vulnerabilities this pandemic highlights with regard to the volatility of the U.S. drug and device supply chain, we are concerned about the sustained safety of FDA-regulated products if staff are pulled from inspections for a longer length of time or if this becomes a recurrence. With that in mind, we ask you to respond to the below questions so that we can assess whether the agency has sufficient requirements and authorities to support robust assessment of compliance with applicable requirements, including in times of peril, with respect to the supply of drugs and devices in the U.S. market.

1. Please provide more specifics about the tools and available authorities the FDA uses to evaluate compliance of both domestic and international manufacturing establishments with applicable legal and regulatory requirements when in-person inspections are not possible.

2. Are there additional authorities or tools that Congress could provide to help the FDA better oversee these establishments when in-person inspections are not possible?

3. Are there additional resources that the FDA does not have but could use to ensure the safety of investigators in the U.S. and abroad?

4. What steps does the FDA take to ensure the paperwork it receives from foreign and domestic manufacturers in lieu of an on-site inspection is reliable and accurate?

5. Are there authorities you need Congress to provide in order to strengthen requirements from manufacturers in places with less sophisticated compliance systems than the U.S.?

6. What mechanisms or programs does the agency have to leverage third-party research and chemical analysis of drug product safety and quality to help inform agency decision making?

7. The FY 2021 budget justification notes the use of Artificial Intelligence (AI) to detect and predict risk in the food market. Are there applications for AI in the drug and device market? If not, are there any barriers that exist to expanding this work to include a broader range of products FDA oversees?

[4] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-focuses-safety-regulated-products-while-scaling-back-domestic

We look forward to working with you to strengthen the tools of the FDA and support its workforce in order to further secure the U.S. supply chain and protect users.

Sincerely,

Christopher S. Murphy
United States Senator

Patty Murray
United States Senator

Debbie Stabenow
United States Senator

Gary C. Peters
United States Senator

Elizabeth Warren
United States Senator

Richard Blumenthal
United States Senator