The Honorable Christopher Murphy
United States Senate
Washington, D.C. 20510

Dear Senator Murphy:

Thank you for your letter of February 6, 2020, cosigned by your colleague, Senator Marco Rubio, regarding coronavirus and supply chain questions. We appreciate your interest in ensuring that the Food and Drug Administration (FDA or the Agency) has the necessary tools to ensure the safety and supply of pharmaceuticals, food and medical supplies from China. As you are aware, the U.S. Government is accelerating response efforts to the Coronavirus outbreak (COVID-19). I appreciate your support, and that of Congress, as we all work together toward the shared goal of controlling this outbreak and protecting the health of our fellow citizens.

To that end, we offer responses to your specific questions as follows:

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 FDA need?**

FDA is working closely with the Department of Health and Human Services (HHS) to assess our resource needs. We will continue to work with the Administration and Congress to identify and prioritize any additional funding needs to ensure we have the resources necessary to protect the public health.

Manufacturers of drugs and biologics are required to notify FDA of manufacturing discontinuances or interruptions, while medical device manufacturers are not. This authority has facilitated FDA's information gathering activities, as FDA continues to remind manufacturers of drugs and biologics of the applicable requirements to notify the FDA of manufacturing discontinuances or interruptions due to the coronavirus situation.

Device manufacturers, on the other hand, are not required to report when they become aware of a circumstance, including discontinuation of a device, that could lead to a device shortage, and are also not required to respond to FDA inquiries about such disruptions. Voluntary reporting of medical device shortages does occur, but in this outbreak, as in prior emergencies, FDA has had to contact companies to request information. This is time consuming, resource intensive, and inefficient – particularly in an emergency. With no mandatory reporting requirement, it is difficult for the FDA to get the information it needs to perform accurate shortage assessments. This is why, for the past two years, as part of the President's budget, FDA has recommended a legislative proposal to provide FDA with authorities for medical devices comparable to those that are already in place for drugs and biologics.

FDA has requested funding in its FY 2021 budget to support much needed modernization of outdated IT systems within the Center for Devices and Radiological Health (CDRH). Without an integrated knowledge management system, staff collects information from manufacturers, health care providers, and others in the supply chain, analyzes the information manually and navigate many fragmented systems. This hampers their ability to access and use data efficiently, including in response to the coronavirus outbreak. The FY 2021 budget also requests an increase of $5 million across FDA to advance key vaccine modernization activities including providing scientific and technical support to new vaccine manufacturing technologies, expanding the domestic vaccine manufacturing capacity and supporting the development and availability of other medical countermeasures – including antiviral drugs, therapeutics, and diagnostic tests.

FDA recommended three other legislative proposals, also in the President's budget, to better enable the Agency to prevent or mitigate drug shortages, including a proposal to improve the Agency's ability to assess critical manufacturing infrastructure by allowing the collection of more accurate supply chain information.

FDA would welcome the opportunity to work with Congress to advance legislation to provide FDA with these enhanced authorities.

b. If so, does the FDA anticipate a shortage in resources should this pandemic not subside in the near future?

As mentioned above, FDA is working closely with the Department to assess the Agency's financial resources and funding needs. We will work with Congress and the Administration to take all the necessary steps to protect the public health. Should a specific need arise into the future, we will be sure to communicate it to Congress, including you and your staff.

This remains an evolving situation, and FDA, along with the entire Department, continues to take a proactive and vigilant approach. We continue to monitor this situation closely and communicate with manufacturers of drugs and biologics to remind them of the applicable requirements to notify FDA of manufacturing discontinuances or interruptions due to COVID-19.

We have also been actively reaching out to manufacturers of devices critical for response efforts—such as personal protective equipment (PPE)—and health care facilities to encourage them to report supply disruptions to FDA and to increase production if possible. CDRH does not have a dedicated shortages group. The Center has shifted significant resources to the COVID-19 outbreak, but this is not sustainable in the long term.

It is critical to underscore that this remains a very dynamic situation that continues to evolve. FDA is prepared to utilize all the tools we have available to help mitigate any disruption, including working with manufacturers and expediting review of alternate sources of supply to help prevent or mitigate shortages.

2. Last month, the federal govt. ordered all nonessential personnel to leave China.

a. 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?

On January 30, the Department of State (DOS) issued a Do Not Travel to China advisory and on January 29 authorized departure for certain federal government staff in China, including FDA staff in our China office. All FDA travel to China is canceled until further notice as a result of the State Department travel restrictions. All FDA staff in China—except for the Country Director who is part of the Embassy Beijing's Emergency Team working alongside HHS colleagues—have been repatriated to the U.S.

b. How many personnel are typically in China to conduct these inspections?

FDA's in-country China office has 25 total employees. Of those, 18 are trained investigators who conduct inspections. In addition, FDA sends investigators from the U.S. on a three-week temporary duty (TDY) to conduct inspections. On any given week that could result in up to 12 additional investigators in China conducting inspections.

3. How has the coronavirus impacted the FDA's inspection schedule for the 2020 calendar year?

FDA is committed to maintaining its scheduled inspections around the globe to the maximum extent possible, while maintaining the safety of the staff involved. FDA staff and investigators will continue to carefully assess the situation in locations affected by COVID-19. Any mission critical travel will be assessed on a case-by-case basis in coordination with HHS and DOS. This remains a very dynamic situation, which continues to evolve, and the full impact to FDA's inspection schedule for the 2020 calendar year will depend on how the outbreak unfolds.

FDA conducts approximately 500 inspections per year in China with the majority of these inspections being for drugs, foods and medical devices. FDA is not currently conducting inspections in China due to the State Department warning advising against travel to China. All scheduled inspections in China for the months of February and March were either postponed or the Agency was able to utilize other information to determine whether to allow the product to enter the U.S. market. Of these inspections,[1] approximately 90 percent were routine surveillance inspections. The for-cause inspections scheduled for February were postponed after reviewing all available information and a case-by-case analysis. Routine surveillance inspections have a different public health consideration than a for-cause inspection in which a serious concern has been identified requiring more timely follow up by the agency, and the timing of these inspections is further determined on a case-by-case basis as informed by the risks the issue poses to American patients and consumers. The majority of routine surveillance inspections in China scheduled for March are for medical products and at this time are expected to be rescheduled for later this fiscal year. We will continue to closely monitor the situation in China so that as the situation improves, we will be prepared to resume inspections as soon as feasible.

The robust and multi-layered compliance process at FDA is continuing to protect American patients and consumers even though we are not able to conduct inspections in China at this time.

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[1] *https://www.fda.gov/about-fda/fda-basics/what-does-fda-inspect*

Inspections are one of many tools that the Agency uses to inform our risk strategy for imported FDA-regulated products and to help prevent products that do not meet FDA's standards from entering the U.S. market. Other tools include: import alerts; increased import sampling and screening; requesting records, in advance or in lieu of an inspection[2]; evaluation of previous FDA inspections history to determine if this information would suffice in lieu of an inspection; and relying on a firm's previous compliance history and information from foreign governments with which we have mutual recognition agreements. These are all part of our Agency's risk-based approach to ensuring quality and compliance with applicable FDA requirements. This process is not solely reliant upon on boots on-the-ground inspections. Firms and individuals who manufacture and sell FDA-regulated products are responsible for ensuring the quality of their products. FDA can pursue regulatory and enforcement action, such as warning letters, seizures, or injunctions, against products on the market that are not in compliance with the law, or against firms or individuals who violate the law.

4. How is the FDA coordinating with companies to monitor the safety and supply of products manufactured in China?

There is no evidence that COVID-19 has been transmitted through imported goods and we know of no cases of COVID-19 in the United States linked to exposure to imported food or medical products.

As noted above, FDA has been in contact with manufacturers of drugs and biologics to remind them of the applicable requirements to notify FDA of manufacturing discontinuances or interruptions due to the coronavirus situation. Since the start of the outbreak, FDA has been in direct communication with manufacturers of medical human drug products, finished drug product as well as active pharmaceutical ingredients (API), approved for the U.S. market to determine the outbreak's impact on supply chain.

As previously noted, unlike manufacturers of drugs and biologics, medical device manufacturers are not required to report to FDA manufacturing discontinuances or interruptions and are not required to reply to FDA inquiries about such disruptions. However, we have been reaching out to manufacturers of devices critical for response efforts and encouraging them, as well as health care facilities, to report supply disruptions to FDA. Similarly, staff has been in contact with the makers of animal pharmaceuticals to help anticipate and mitigate any supply chain issues.

FDA staff also participate in many working groups focused on assessing inventories of U.S. supplies and potentials disruptions or shortages—supporting U.S. government partners, industry, as well as our international regulatory authority counterparts around the world—to maintain situational awareness of medical product supply chain issues.

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?

FDA has an established reporting process for medical drug product shortages. Manufacturers are required to report on the FDA website: 1) information about shortages to FDA, 2) the reasons for

[2] Firms may elect to provide this voluntarily to allow FDA to make approval decisions.

shortages, and 3) the expected duration of shortages. Section 506C of the Federal Food, Drug, and Cosmetic Act (FDCA), as amended by Title X of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, lists the mandatory reporting requirements for manufacturers. For more information on FDA's efforts to monitor and prevent drug shortages, including the latest Report on Drug Shortages[3] required by FDCA Section 506C-1, please visit this website: *https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages*.

And, as noted, medical device manufacturers are not required to report circumstances that could lead to shortages to FDA, but the Agency has encouraged manufacturers and healthcare facilities to report any supply disruptions to the device shortages mailbox, *deviceshortages@fda.hhs.gov*. This mailbox has proven to be a valuable resource and the information submitted is instrumental to FDA's efforts to detect and mitigate potential supply chain disruption.

This issue is of the highest priority for FDA and we will continue to monitor and assess the evolving situation and be in communication with manufacturers, our interagency partners, and the public.

As noted, if a supply chain disruption is identified FDA will utilize all tools we have available to help mitigate any disruption, including working with manufacturers and expediting review of alternate supply to help prevent or mitigate shortages.

6. Has the FDA coordinated with other companies in an effort to potentially fill any supply shortages?

As in the past, if a potential shortage of a critical medical product is reported FDA will take steps to quickly share that information with the public.

We're closely coordinating with partners across the U.S. government as we all work to prepare, mitigate, and respond to this outbreak.

I would like to reiterate that the United States can't do this alone. The whole of the American Government is actively working to contain the disease and limit further spread of the outbreak in collaboration with the WHO, the ministries of health of the affected countries, the international community, and non-governmental organizations.

Thank you, again, for your concern and contacting us regarding this matter. If you have any questions, please let us know. The same letter has been sent to Senator Rubio.

Sincerely,

Karas Gross
Associate Commissioner for
Legislative Affairs

[3] *https://www.fda.gov/media/130561/download*