Remarks of Mark Abdoo, Associate Commissioner for Global Policy and Strategy,
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Panel on Global Supply Chain Resilience: The Role of Government and Stakeholders
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Good morning. It's a pleasure to be here with all of you, with our moderator Lowell, and with my co-panelists Brian, Tammy and Fatemeh. I'm Mark Abdoo, Associate Commissioner for Global Policy and Strategy at the FDA. My office, the Office of Global Policy and Strategy, is a hub for information gathering, analysis, and dissemination to aid in the Agency's decision-making and for integrating global considerations into the agency's policies, programs, and strategies.

Since OGPS includes the FDA's four foreign offices with posts in six countries - the agency's eyes and ears on the ground in critical locations around the globe – we have a unique perspective on the global dynamics that shape FDA's work. And, as nearly all the critical supply chains FDA regulates have a global component, we have a unique perspective on the recent progress the agency has made in understanding supply chain vulnerabilities and supporting resilience and redundancy in manufacturing and production.

Today, I'd like to cover:

- Some of the challenges that continue to impact supply chains,
- FDA programs and authorities that have strengthened our ability to support supply chain resiliency,
- Where FDA fits within the whole-of-government approach to strengthening critical supply chains.

The fact is every industry we regulate is at risk from supply chain issues, deeply embedded in "just in time" manufacturing methodology and sole sourcing to maximize profit, leading to low inventories, and offshoring of key elements to reduce costs. In the face of international strife and economic distortions, these risks have resulted in real world consequences, for example related to availability of certain drug products and infant formula. The FDA has a patchwork of authorities that are helpful, and which Congress has expanded over the last few years, but they in

no way match the public expectations that for essential products there will be a plentiful supply readily available. As we've learned in the past few years, supply chains can be disrupted by quality defects, public health emergencies, weather events, transportation disruptions, changes in how healthcare is provided or simply changes in consumption habits. The result of such disruptions is often shortages of critical products.

Here are a few illustrations of these supply chain challenges: Last year's nationwide shortage of infant formula occurred due to manufacturing challenges and quality control problems at a facility that is one of the dominant producers of this essential product.

While quality systems can help strengthen supply chains, the variety of root causes of supply chain disruptions are complex and can occur without warning. You also may have heard of Texas ice storms that disrupted the petroleum industry. This disruption impacted the availability of raw materials used in medical device manufacturing.

The pandemic is another example that we're all familiar with. It triggered unprecedented demand for N-95 masks and ventilators. Toward the end of the pandemic, the United States experienced increases in demand for treatments for concurrent outbreaks of influenza, COVID-19, and Respiratory Syncytial Virus (RSV), which led to supply issues for pediatric ibuprofen, acetaminophen, and amoxicillin.

The havoc that the COVID-19 pandemic played on medical product and food supply chains started a shift in how the agency evaluates the effects of manufacturing conditions on shortages and product availability. This relationship between manufacturing quality and product availability was brought into sharper focus during the nationwide shortage of infant formula due to the adulteration of formulas produced at one specific manufacturing facility. For the next few minutes, I'm going to speak about how some of FDA's authorities and programs have evolved from the start of the pandemic to the present day.

In March of 2020, Congress passed the bipartisan Coronavirus Aid, Relief, and Economic Security (CARES) Act. The CARES Act provided FDA with new authorities intended to identify and mitigate shortages of medical products by, among other things, enhancing FDA's visibility into drug and medical product supply chains. The Act requires certain manufacturers of drugs or

active pharmaceutical ingredients to create and implement a manufacturing facility specific risk management plan which evaluates the risks to the supply of the drug for that establishment. FDA's raft guidance for industry on Risk Management Plans to Mitigate the Potential for Drug Shortages was published in May of 2022.

Next, the CARES Act requires the annual reporting by each person registered with FDA under Section 510 of the FD&C on the amount of the drug that it manufactured, prepared, propagated, compounded, or processed for commercial distribution. To support the reporting requirement, FDA developed the NextGen Portal and issued both a guidance for industry and a technical conformance guide to help industry use the portal to accurately report their production amounts.

Lastly, the CARES Act expands the requirements for manufacturers of certain drugs to notify FDA about permanent discontinuances in manufacturing or interruptions in manufacturing that are likely to lead to a supply chain disruption. The draft guidance for industry on Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Product or Active Pharmaceutical Ingredients (under Section 506C of the FD&C Act) was published by FDA in April of this year, and the agency is still taking comments on the document at regulations.gov. This guidance will replace a March 2020 guidance on this topic when finalized.

In January of this year, as part of the Consolidated Appropriations Act, Congress passed the Food and Drug Omnibus Reform Act (FDORA) of 2022. FDORA includes a host of interesting new authorities and requirements for FDA, some of which strengthen our oversight and understanding of critical supply chains. On the foods side, the Act includes a provision requiring that critical food manufacturers put in place a risk management plan that will be subject to review during inspection; and also requires the agency to create a new Office of Critical Foods that will be responsible for oversight and coordination related to the supply of products such as infant formula.

On the medical products side, the Appropriations Act directs FDA to review policies related to drug or biologic expiration dates and develop recommendations for sponsors to establish and label products with the longest feasible expiration date supported by stability testing data (Section 2512). The Act clarifies that FDA may receive from certain device manufacturers

voluntary notifications of disruptions or discontinuations of specific devices critical to public health (Section 2514). For biologic products FDORA includes requirements for industry to report a change in marketing status within 180 days (Section 3201). These kinds of authorities help FDA and industry work together to better anticipate and prevent supply chain disruptions before they happen.

Building on the authorities that FDA has received in CARES and FDORA, the Agency put forward a series of FY 2024 legislative proposals in the President's Budget which would enhance the agency's understanding of critical supply chains. These proposals include amending section 510(j)(3) of the FD&C (CARES Act) to require registrants to provide data identifying suppliers they relied on manufacture the listed drug, an amendment to section 502 to require original manufacturer and unique facility identifier information on API labels, and a proposal to amend section 506C(a) of the FD&C to require drug manufacturers to notify FDA of an increase in demand.

FDA has also implemented some innovative programs using existing authorities to bolster our oversight and understanding of supply chains. In 2022, when the country faced an infant formula shortage, FDA staff worked daily with clinicians and hospitals to address availability of specialty and medically necessary formula supply for infants with serious metabolic diseases who were dependent on highly specialized formulas. The agency also helped to expand access to infant formula by temporarily exercising enforcement discretion for certain infant formula requirements on a case-by-case basis. Last fall, the FDA announced a new approach called "Prevention Strategies to Enhance Food Safety." These strategies are affirmative, deliberate approaches undertaken by the agency in partnership with stakeholders to help limit or prevent future outbreaks and illnesses linked to certain FDA-regulated foods, like infant formula.

With respect to medical devices, FDA developed a Resilient Supply Chain Program, which has enhanced the agency's capacity to prevent and mitigate supply chain interruptions and promote resiliency and redundancy. The program's goals include identifying supply chain risks and developing strategies to prevent and mitigate medical device shortages. My colleague Tammy Beckham who leads the resilient supply chain program for CDRH will have a lot more about this program later.

Despite all of the efforts FDA has put into supply chain oversight and resiliency, FDA cannot work in a vacuum. To further strengthen supply chains, we partner with other agencies within the U.S. Government, and with foreign counterparts.

Within the federal government, we strive for a whole-of-government approach to assessing supply chain vulnerabilities and strengthening their resilience. Shortly after taking office in 2021, President Biden issued Executive Order (EO) 140175 on America's Supply Chains, which aimed to design, build, and sustain a long-term capability to manufacture supplies for future pandemics and biological threats in the United States. The Administration recognized that close cooperation on resilient supply chains can foster collective economic security and strengthen our capacity to respond to international disasters and emergencies. To contribute to this government-wide effort, a year later, HHS followed up with a series of reports:

- The Supply Chain and Industrial Base One-Year Report identified practical strategies the U.S. Government should implement to address public health supply chain and industrial base vulnerabilities.
- A separate "100-Day" Review6 of Pharmaceuticals and Active Pharmaceutical Ingredients, in which the FDA played a critical role, followed the one-year report.
- HHS also issued the Essential Medicines report, with the FDA's assistance. It lists 86 essential medications that would need to be followed more closely to ensure a stable supply.

Beyond the Executive Order implementation, the FDA also collaborates on supply chain issues with our U.S. government partners in interagency efforts to support supply chain resilience, including the HHS and Department of State led International Supply Chain Working Group, the National Strategy for a Resilient Public Health Supply Chain, and White House medical product supply chain resiliency efforts.

The United States needs resilient, diverse, and secure supply chains to ensure our economic prosperity and national security. This kind of coordination across the Federal government and with partner governments is one step toward implementing policy frameworks that support a

resilient supply chain, build redundancy, and address risks. Resilient American supply chains can also revitalize and rebuild domestic manufacturing capacity.

In closing, I want to emphasize FDA's commitment to keeping our supply chains secure, robust, and resilient. Both industry and government have important responsibilities in managing supply chain risks. FDA not only has an important role, along with industry, but the agency sustains several important longer-term efforts to harmonize guidelines, reduce regulatory burdens, and collaborate effectively with industry and other partners. I look forward to hearing from my fellow panel members and addressing your questions. Thank you.

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