Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Subcommittee on Oversight and Investigations Ranking Member Kathy Castor

Hearing on "Protecting American Health Security: Oversight of Shortcomings in the FDA's Foreign Drug Inspection Program"

February 6, 2024

Americans rely on a strong FDA to protect their health and safety, especially from the myriad of drugs that are manufactured overseas. FDA has strong reputation for food and drug safety internationally, and its foreign inspections help ensure that our neighbors' food and drugs meet high-quality standards—whether those products are made here or abroad. We need to keep it that way.

We know that FDA cannot, and does not, have total control over the global supply chain. That is why it's so important that its ability to conduct foreign inspections is well-funded, well-staffed, and well-equipped with the authorities it needs to maximize its mission.

As we'll learn today, FDA's foreign inspections work with limited authorities and face real structural challenges. I'm pleased, though, that the agency is taking steps to accelerate inspections and develop new tools to keep our neighbors safe. Thanks to funding in the Fiscal Year 2023 omnibus, FDA now has $10 million in funding to conduct a pilot program for *unannounced* inspections that show promise.

FDA has made changes after the 2022 infant formula shortage to better prevent and prepare for future shortages, and FDA is implementing a proposal to overhaul its human foods program and better incorporate inspections into its larger food safety agenda. For the first time, FDA now has a Deputy Director for Human Foods charged with managing a new, unified human foods program. This will be critical as FDA does the important work of learning lessons from past challenges and preventing mishaps in the future.

Getting foreign inspections right is critical to addressing the wide swath of issues affecting our neighbors' access to drugs, including the harmful shortages we've seen in some parts of the drug market.
When foreign manufacturers know that America's inspections regime is strong, they are pressured to invest in clean, sanitary, and safe facilities. This can help reduce the supply fluctuations on the drug market and the potential for safety recalls.

Americans, rightfully, have high expectations for FDA. I am concerned, however, that Republicans across Congress have routinely asked our public health agencies to do more work without providing the resources to get the job done. Foreign drug inspections are costly, requiring frequent international travel and an international workforce. Improved foreign

inspections require robust, continued, flexible appropriations to address the real challenges we'll hear about today facing our food and drug supply.

There is lots of room for us to work together on this. Food and drug safety has been a longstanding area of bipartisan concern for this Committee. Just last Friday, FDA briefed Committee staff on its response to children's applesauce pouches imported from abroad that were found to contain lead and chromium. Thanks to FDA's efforts, the products were voluntarily recalled by the manufacturer and removed from store shelves around the country. This is just one example of the crucial work that FDA does and must continue to do to keep us safe and healthy.

I hope we can continue to approach this issue in a bipartisan way. By supporting FDA in its reform efforts, we can help keep Americans safe and prevent harmful drugs and products from reaching store shelves.

I look forward to the panel today and I yield back.