Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Ranking Member Frank Pallone, Jr.

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

February 6, 2024

FDA's foreign inspection program is essential to making sure that the food and medical products that Americans rely on are safe. But this program faces many inherent challenges due to the complexity of foreign manufacturing and limited transparency from foreign manufacturers. That is why today's hearing is important. We need to understand what more the agency can do to ensure Americans are consuming safe products regardless of where they come from.

The issue of food and drug safety has been a longstanding, bipartisan issue for this committee. Last Congress, in this Subcommittee, we held a hearing with private industry and top FDA officials on the infant formula crisis, which stemmed from an unsanitary manufacturing plant producing contaminated formula. In 2019, we held a similar bipartisan hearing to the one we're having today, looking specifically at FDA's foreign drug inspection program.

Since then, the issues facing FDA's foreign inspection program have become even more pronounced. Our food and drug supply chains are increasingly global, and FDA cannot and does not rely on foreign regulators to consistently meet the high safety bar that Americans expect for our food and drugs.

That is why FDA has stepped in several times over the past year to coordinate national safety responses linked to contaminated products, including those imported from abroad. Working within its limited authorities, FDA has implemented national responses to protect Americans from contaminated drugs, eyedrops, hand sanitizer, applesauce, and fresh fruit.

However, the agency still lacks critical tools that it could use to better prevent public health threats linked to our global market. For example, FDA has consistently told us that it lacks important authorities to prevent children from consuming potentially contaminated products. Specifically, the agency does not currently have the authority to require companies marketing food to young children to conduct toxic element testing and grant the agency access to testing records.

There are also significant gaps in the agency's authorities when it comes to monitoring the drug supply chain. FDA still lacks critical insights into the sourcing of key active pharmaceutical ingredients for important drugs. In addition, the agency faces longstanding structural challenges in its foreign drug inspection program including staff retention, translation issues, and the need for advance coordination with foreign governments and companies to inspect a plant's operations.

I hope Congress can be a partner to FDA as it explores how to reinvigorate its foreign inspections program in the aftermath of COVID-19, when travel restrictions impeded its ability to work abroad. At the same time, we should also recognize that new tools will be required to keep tabs on our growing global market and keep Americans safe.

For example, FDA has requested additional authorities to conduct remote inspections, which could include livestreaming videos of plant operations, teleconferences, and screensharing technologies. These proposals would allow FDA to protect public health when its capacity for in-person inspections is stretched thin, like during public health emergencies. I hope Congress can come together and figure out how to support FDA as it explores new tools to address the challenges of a global market.

As we explore FDA's foreign inspection program today, I hope we can continue this Subcommittee's historically bipartisan approach to oversight of food, drugs, and other medical products. That way, we can come together as partners to the agency, giving it the tools and resources it needs to protect Americans in our global market for these products.

Thank you, Mr. Chairman. I yield back.