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

I have to start out by saying I hear all these criticisms of the Food and Drug Administration (FDA), and sure we could use more in-person inspections, sure we could have a lot more inspection. However, in order to do that you need money, you need staff, and yet Republicans continue to try to cut back on the funding for FDA and other federal agencies. If they have challenges, the way to deal with it is to give them more tools and more money so they can hire more staff.

The FDA foreign inspection program is essential to ensuring that the food and medical products Americans rely on are safe. But this program faces 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 make sure 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 this one where we, looked specifically at FDA's foreign drug inspection program.

Since then, the issues facing the 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's 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.

But, 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. The agency also 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.

It is important that we work together to give FDA the resources and authorities it needs to strengthen its foreign inspections program to protect Americans.

We understand FDA has challenges. We understand that they have limited resources and staff, but the answer is to provide them with more resources, more staff, and more authority. And not to say that we should scrap them or cut back on their funding.

Thank you, Mr. Chairman. And I yield back the balance of my time.