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Pallone Remarks at Oversight Hearing on FDA Foreign Inspections

Washington, D.C. – *Energy and Commerce Chairman Frank Pallone, Jr. (D-NJ) delivered the following opening remarks at an Oversight and Investigations Subcommittee hearing on ""Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program:"*

Today, the Committee continues its longtime work of conducting oversight of the Food and Drug Administration's foreign drug inspection program. This program is a key piece of our efforts to ensure that the prescription drugs Americans' take every day are safe and effective.

Under the law, any firm – whether it is based domestically or overseas – that seeks approval to market a drug in the United States must comply with FDA's Current Good Manufacturing Practice (CGMP) regulations.

Both foreign and domestic firms are held to the same standards, which lay out the essential quality controls that ensure drugs are safe for use. Those standards also apply equally to both brand and generic manufacturers. While it is up to the manufacturers to take the necessary steps to implement CGMP practices, FDA is tasked with inspecting facilities around the world to verify their compliance.

In the past, the Committee found that FDA was woefully unprepared to take on the challenge of regulating and inspecting foreign drug manufacturers. As part of our ongoing oversight of this program, we found that foreign firms were not being inspected with regular frequency, FDA had no permanent presence overseas, and its databases could not even tell it what firms were actively shipping products to the United States.

As a result of these disturbing issues, in 2012, Congress passed and the President signed the Food and Drug Administration Safety and Innovation Act of 2012. The law changed the way FDA selects firms to inspect, allowing it to focus on more high-risk facilities, including those abroad. It also increased FDA's authorities over foreign manufacturers.

Then, in 2013, the Drug Quality and Security Act provided FDA with "track-and-trace" authority to give the agency more tools to counter potentially dangerous drugs in the supply chain. And, again in 2017, Congress provided more resources to FDA's foreign inspection program through the Generic Drug User Fee Amendments.

Despite these new authorities and resources, FDA's foreign drug inspection program continues to face challenges. For instance, the number of foreign inspections has declined the last two years. This is troubling because FDA had been making progress in inspecting more facilities up until two years ago. FDA also continues to struggle with hiring staff to conduct foreign inspections.

Again, this is all deeply disturbing considering that Congress provided the generic drug user fees, in part, to fund foreign inspections. I am interested in hearing from FDA on why the number of foreign inspections has declined in recent years and what is preventing it from reaching its capacity.

While today's hearing focuses on FDA's efforts, manufacturers have the first responsibility to guarantee their products are safe and effective. We must do what we can to ensure manufacturers continue to produce high-quality drug products, including through innovative methods such as continuous manufacturing. Those methods not only help control quality, but also enable firms to compete in the global market.

One final point to keep in mind is that the issues we will be discussing today affect all kinds of drugs throughout the supply chain. Much of the press coverage has framed these issues as a "generic drug issue" – but the fact is that the majority of active pharmaceutical ingredients or API for both generics and brands come from foreign countries.

Generic drugs have saved Americans billions of dollars and are critical to lowering health care costs across the board. FDA must ensure that any company, whether brand or generic, that wishes to market drug products in the United States adheres to the same quality standards. That provides not only a level playing field, but confidence in American consumers that the drugs they are taking will be safe and effective.

I look forward to hearing from our witnesses about what is being done to ensure that confidence, and what more is needed to secure the nation's drug supply.

I yield back.

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