Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Subcommittee on Oversight and Investigations Chair Diana DeGette

Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program

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Today's hearing focuses on an area of longstanding concern to the Committee that has taken on increased importance: the safety and effectiveness of pharmaceutical products made in foreign countries.

Between 70 and 80 percent of active pharmaceutical ingredients ("API") and 40 percent of finished drugs are made outside the United States. In particular, China and India produce a significant portion of the U.S. drug supply.

Because the Food and Drug Administration (FDA) cannot possibly test every drug that comes into the U.S., FDA inspections of drug manufacturers abroad are a critical way to ensure that manufacturers around the world are following quality standards and producing drugs that are safe and effective for the American public.

However, the history of FDA's foreign drug inspection program is one of challenges and incremental progress. As far back as 1998, the Government Accountability Office (GAO) has been raising concerns with FDA's foreign inspections.

This Committee has a long history of oversight in this area. For instance, in 2007, we held a hearing about weaknesses in FDA's foreign inspections program. At that time, FDA was not conducting frequent inspections abroad, and did not have reliable data to even know how many firms it needed to inspect. FDA also struggled to hire inspectional staff, and its inspectors did not have reliable translators to help them conduct inspections in foreign-language countries.

The year after that hearing, the world was reminded why securing the global pharmaceutical supply chain is critical, when it was discovered that tainted ingredients were used to produce heparin—a critical drug used in surgery and during dialysis.

As a result of that mishap, Americans died, drug shortages occurred, and many lost confidence in FDA's ability to regulate drugs manufactured abroad.

GAO's reports over the years have also noted vulnerabilities in how FDA regulates foreign drug manufacturing. For example, in 2010, GAO found that FDA may have never inspected most foreign firms. FDA was also struggling to staff up its foreign offices, which were intended to make foreign inspections more efficient and effective.

Because of these and other issues, GAO placed FDA's foreign inspections program on its High Risk list over 10 years ago.

In response to these challenges, Congress increased FDA's resources to conduct foreign inspections and granted FDA new authorities over foreign firms. As a result, FDA increased the number of inspections it conducted, and implemented a risk-based approach to select firms for inspection, regardless of whether they were foreign or domestic.

These were significant improvements. But despite that progress, we are back here today because FDA's foreign drug inspection program still has unresolved challenges. In its written testimony today, GAO reports on the results of its recent travel overseas to evaluate FDA's work. GAO found some of the same issues that have been hindering FDA's foreign inspection program for years.

GAO reports that the number of foreign inspections dropped in the last two years, after years of increases. Furthermore, when FDA conducts inspections in foreign language-speaking countries, it still largely relies on the firm itself to provide a translator, raising concerns about impartiality. And despite getting new resources, FDA continues to struggle to hire enough inspectors, including in its foreign offices.

These challenges take on real meaning when we see reports of potentially unsafe products in the market. Over the past year and a half, FDA has been announcing widespread recalls of popular medications used by millions of Americans to treat blood pressure and heartburn, because of trace amounts of carcinogens identified in multiple versions of these drugs.

While I understand each of these recalls involves its own particular causes and factors, taken together, they raise larger issues and concerns that FDA has not fully addressed longstanding vulnerabilities in its foreign inspections program.

Before I close, I would like to emphasize a couple final thoughts. First, the issues we will be discussing today affect both brand and generic drugs. Many foreign firms provide the active pharmaceutical ingredients used in both brand and generic versions of drugs, so these issues can affect drugs throughout the supply chain – which is all the more reason why they must be addressed.

Finally, this hearing should not be interpreted as an indictment of foreign drug manufacturing generally. Americans should not feel that they cannot trust medicines made abroad, nor should we swear off foreign-made drugs. In fact, we are increasingly reliant on foreign manufacturers.

But if drugs are going to be made abroad, then Americans must have confidence in the ability of FDA to effectively regulate foreign suppliers. It is critical that FDA have the resources and the capability to do this job and ensure that every American can trust the safety and effectiveness of the drugs they take.