**Opening Statement of Chair Diana DeGette**
**Subcommittee on Oversight and Investigations**
**Hearing on "Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program"**
**December 10, 2019**

Today's hearing focuses on an area of longstanding concern to this 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 FDA cannot possibly test every new drug that comes into the U.S., 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 the FDA's foreign drug inspection program is one of challenges and incremental progress. As far back as 1998, the GAO has been raising concerns with FDA's foreign inspection's.

This committee has had a long history of oversight in this area. For example, in 2007 we held a hearing about weaknesses in FDA's foreign inspections program. At that time, the agency was not conducting frequent inspections abroad and did not have reliable data, even to know how it needs to inspect. The FDA also struggled to hire inspection staff and its inspectors did not have reliable translators to help them conduct inspections in foreign language countries. I remember that hearing because I was there, and it was shocking.

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, which is 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 never have inspected most foreign firms. FDA was 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.

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

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

The number of foreign inspections has dropped over the last two years, after years of increases. Furthermore, when FDA conducts inspections in foreign language-speaking countries, it still relies on the firm itself to provide a translator, raising questions about impartiality. And despite the new resources, FDA continues to struggle to hire enough inspectors, including in the foreign offices. And frankly there are still barriers to being able to do that.

These challenges take on real meaning when we see reports of potentially unsafe products in the market. Over the last 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.

Now, I understand each of these recalls involves its own particular causes and factors, but taken together, they raise larger issues and I'm really, Dr. Woodcock I am really happy you are here today because I look forward to hearing what the agencies response is to these new GAO findings.

Before I close, I just want to emphasize a couple final thoughts. First, the issues 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 this can happen throughout the supply chain.

And finally, I want to emphasize this hearing should not be interpreted as an inditement 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 we do need to make sure that all of these issues which have been persistent for many, many years, continue to be addressed. And with that I want to thank both of our witnesses for being here today.