COMMITTEE on FINANCE
Chairman Chuck Grassley

Grassley at Hearing on Foreign Drug Manufacturing Inspection Oversight

Prepared Opening Statement by U.S. Senator Chuck Grassley of Iowa
Chairman, Senate Finance Committee
Hearing on COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process
Tuesday, June 2, 2020
VIDEO

Good afternoon,

I'd like to welcome everyone to the Finance Committee's oversight hearing on the Food and Drug Administration's (FDA) foreign drug manufacturing inspection process.

This committee has an obligation to ensure drugs paid for by the taxpayer via Medicare and Medicaid satisfy quality standards and are safe and effective for patients.

That responsibility, both of Congress and the FDA, is heightened now that we are living through the COVID pandemic.

Whether we are in the midst of a pandemic or not, these supply chain issues must be shored up and solved.

Starting June of last year, I began my oversight activities on this issue.

I wrote letters to Secretary Azar and then Acting FDA Commissioner, Dr. Sharpless.

I asked a series of questions relating to manufacturing facilities overseas that manufacture final dosage form drugs and active pharmaceutical ingredients (APIs).

I also asked about how the FDA manages its foreign inspections regime.

The Government Accountability Office has said that the FDA does conduct some unannounced inspections overseas but they don't have data on frequency.

However, GAO noted in 2019 that the FDA estimated that they generally provide twelve weeks of notice before the inspection.

Simply said, you're undermining the ability of field inspectors to do their job. Twelve weeks is plenty of time to doctor up a facility to make sure that it passes.

Yet, incredibly, some facilities still get caught. That's how bad it is.

The end result is that the consumer is put at risk.

According to the most recent FDA data, the United States has 46 percent of finished dosage form facilities. That's where APIs are turned into the final form such as a tablet.

That means over 50 percent of sites manufacturing finished drugs are located overseas.

But, that's just part of the story. What we really need to know is where did the API come from?

According to the most recent FDA data, 13 percent comes from China, and 19 percent comes from India. Combined, that's more than any other country. And overall, more than 70 percent of facilities that make APIs are located overseas.

These figures, coupled with the COVID pandemic, have garnered a lot of attention, including what might need to be done from a national security perspective.

But, the figures do make clear what needs to be done from a drug safety perspective – we need to have a robust and aggressive foreign inspections program.

Now, with respect to China and India, both those countries have had serious quality control problems.

We all remember the valsartan recall where that drug was found to contain contaminants used in rocket fuel.

Facilities in China and India produced that drug.

Let's not forget about the Heparin scandal either.

In that case, patients undergoing dialysis began to have severe and life threatening side effects because a manufacturing plant in China introduced a toxin into the production chain.

Hundreds of people died and hundreds were sickened.

Then we have Ranbaxy, an Indian manufacturer.

Ranbaxy's production chain exposed drugs to potential cross-contamination by penicillin and used APIs from facilities that were not approved by the FDA.

Ranbaxy also manufactured Lipitor, and was shut down because it could not explain why some of those tablets had pieces of glass in them.

I fear these examples are just the tip of the iceberg.

They show why the FDA must maintain an aggressive inspections regime to ensure drug quality but also impose a strong enforcement regime on bad actors.

In February of this year, FDA Commissioner Hahn told me that in Fiscal Year 2018 the Center for Drug Evaluation and Research issued almost five times as many warning letters to human drug manufacturers as compared to 2015.

He said that's a sign that FDA is better able to use its resources to identify problems. Good. Stay aggressive and don't hesitate to be more aggressive.

On the front end, though, that process should include unannounced inspections overseas. After all, why would we give manufacturers time to prepare their facility for inspection?

They ought to be looking over their shoulder every day. That keeps them honest.

During the Obama administration, the FDA started what was called the India Pilot Program.

It allowed for no warning inspections or a couple days' worth of warning.

Under it, the FDA issued a 60 percent increase in "Official Action Indicated" findings.

In 2015, the Obama administration shut the pilot program down without explanation.

It sounds like the program was a victim of its own success.

Now, this issue is bipartisan. Republican and Democrat administrations have come up short.

The Government Accountability Office has a body of work from multiple administrations that proves it.

For example, both the Obama and Trump administrations have struggled to fill vacancies in foreign offices.

Today, we have witnesses from the FDA that can speak to all of these issues and how the pandemic has impacted their work.

On the first panel, we have FDA witnesses and a GAO witness.

On the second panel, we have private sector companies.

Thank you for being here.

It's important to note that I plan to follow up with another hearing soon examining another problematic aspect to our medical supply chain, specifically the increase in trade of fake and faulty personal protective equipment.

That is separate from what we will discuss today.

In closing, I want to say two things.

First, thank you to the FDA officials that work tirelessly to inspect facilities overseas.

Second, regardless of party, we must have an honest discussion of the government's shortcomings so that we can better understand what we, as Congress, can do to ensure drug safety for the taxpayer.

After all, we work for them and must always answer to them.

Now, I'll turn to Ranking Member Wyden.

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