Chair Rodgers Opening Statement
Hearing on FDA's Foreign Drug Inspection Program
February 6, 2024

INTRODUCTION

Thank you, Chair Griffith.

The FDA's mission statement states that it is responsible for "the safety, efficacy, and **security**" of items including pharmaceutical drugs.

The "FDA approved" stamp on a drug or generic drug has long stood as the gold standard that allows Americans to trust in the safety and effectiveness of their medication.

This means trusting that the science behind an approved drug is sound.

But equally as important is the ability to trust that the drug was manufactured in a safe and secure facility before it reaches the patient.

This has become even more important as our drug supply chain becomes increasingly globalized and our health care system relies more on foreign-manufactured generic drugs.

I'm concerned that the FDA is failing in its mission. It is not adequately executing its foreign inspection program...

...which was questionable at best before the pandemic... became non-existent during the pandemic... and has seen little improvement since.

This poses major risks to the integrity of medicine and drugs on the market in the United States.

U.S. DEPENDENCY ON FOREIGN DRUG MANUFACTURERS

China and India combined manufacture the active pharmaceutical ingredients used to make nearly 70 percent of generic drugs on the US market.

In some instances, the quality of drugs manufactured in foreign facilities that enter the US market is highly questionable or dangerous.

Last May, eye products manufactured overseas introduced a never-before-seen strain of infectious bacteria in the U.S.

The outbreak affected 81 patients in 18 states...

… causing 18 individuals to lose their eyes or vision, and 4 others to lose their lives.

After this tragic incident, the FDA's site-inspection of the facility found unsanitary conditions...

...including a failure to clean equipment and failure to perform adequate batch testing.

In China the situation is dire as the FDA has a single investigator—just one—based full time in the country.

It was in China where a whistleblower warned—despite FDA resistance—that a commonly used blood pressure medication was contaminated...

...leading to a widescale recall in 2018.

What makes all of this even more disturbing is that in practice we hold domestic manufacturers to much higher standards than we do foreign manufacturers, including those from countries that are our adversaries like China.

We need a level playing field that encourages domestic manufacturing.

FDA's RESPONSIBILITY AND LONGSTANDING ISSUES

Unfortunately, the issues with FDA's foreign inspection program go back decades.

In 1998, the Government Accountability Office reported the FDA had problems with:

- the timeliness with which investigators submitted inspection reports...
- the frequency of routine inspections...
- and delays in taking prompt enforcement action against foreign drug manufacturers.

In 2007, GAO highlighted the FDA didn't know how many foreign manufacturers were subject to inspection...

...that the agency inspected relatively few foreign manufacturers...

...and the agency could not provide the exact number of uninspected foreign establishments.

In 2019, GAO raised questions about the adequacy of FDA's foreign inspections compared to domestic inspections.

While domestic inspections are almost always unannounced, the FDA has a practice of preannouncing foreign inspections—up to 12 weeks in advance.

This massive disparity is one of the reasons why companies manufacture drugs abroad rather than here in the United States.

In 2022, yet another GAO report found the FDA was still struggling to hold foreign drug manufacturers accountable.

It is past time that FDA address these issues. People's lives depend on it.

FDA INSPECTIONS DURING COVID

The COVID-19 pandemic made an already bad situation worse.

In March 2020, FDA postponed almost all of its foreign inspections.

Although domestic inspections resumed in July 2021, most foreign inspections conducted were still limited only to those deemed "mission critical."

The agency instead resorted to alternative tools, like virtual inspections and record reviews, and relying on inspections conducted by conflicted home country regulators.

These tools are no substitute for in-person inspections given the risk of cover-up and fraud.

As long as foreign facilities remain uninspected, they pose a risk to the quality and safety of life-saving medications that many Americans rely on.

CONCLUSION

It is completely unacceptable that FDA refused to participate in today's hearing under any circumstances, but especially given their long history of challenges in fulfilling their mission.

Their absence will not stop us from continuing to hold them accountable and ensuring the safety of the American people.

I thank our witnesses for being here today and look forward to hearing your testimonies.

I yield back.