Today's hearing is an opportunity to examine the FDA foreign drug inspection program.

I would be remiss if I did not note that I am disappointed the FDA declined to provide a witness after being invited to participate in this hearing.

Regular reviews of the current state and effectiveness of the agency's foreign drug inspection program is an important oversight function.

It is an area where this Committee has been able to work on a bipartisan basis for many years.

More and more of our drugs and their bulk active pharmaceutical ingredients (API) come from foreign countries. This is especially true of generic drugs where manufacturers in China and India comprise a majority of facilities supplying the U.S. market.

Also, India is heavily reliant on China for their bulk API when manufacturing medicines.

Unfortunately, we do not know the true number of medicines and the bulk API that come from foreign manufacturers. FDA has even admitted this themselves.

Congress passed a provision in the 2020 CARES Act that requires any manufacturer who is registered with the FDA to annually report drug substance and volume data, including API. Only about 50 percent of manufacturers are in compliance.

When this Subcommittee last held a hearing on this issue in December 2019, before the known start of the COVID-19 pandemic, there were reasons for cautious optimism that the FDA was taking action to increase the number of foreign inspections and to expand the foreign inspections program to better meet the demands of our global pharmaceutical supply chain.

FDA's team of inspectors was almost up to full strength. The number of foreign inspections conducted in India increased from 207 in 2016 to 305 in 2019 with about 70% of those inspections being surveillance inspections.

The FDA was implementing mutual recognition agreements with European regulatory agencies that would reduce overlapping inspections and improve inspection record sharing, freeing up resources to focus on high-risk facilities.

However, there were still serious shortcomings. Foreign inspections were all pre-announced.

Prior to 2020, the FDA would notify foreign facilities ten to twelve weeks in advance, compared to zero advanced notice for US facilities.

It's alarming that – given this advanced warning – the FDA still found deficiencies during 66% of foreign inspections, including serious deficiencies in 16% of those inspections.

FDA was also too slow to act, in 2019 it took the agency on average 136 days to issue an import alert.

Whatever fitful, halting progress the FDA made towards strengthening its foreign inspection program has been undone by the COVID-19 pandemic and, to date, the FDA has been slow or unable to get foreign inspections back on track.

From March 2020 through February 2022, the FDA's foreign inspection program essentially ceased functioning. FDA conducted only 21 foreign inspections in the 12 months after the March 2020 pause was announced, as compared to 977 foreign inspections in 2019. Pre-announced inspections were replaced by alternatives, such as zoom tours.

Currently, according to the FDA, there is only one investigator **solely** based in China and five **solely** based in India. This workforce shortage presents a huge problem when trying to comb through the backlog of foreign facilities.

It is little wonder that in the absence of regulatory inspections and actions, that we've seen numerous quality control failures in imported drugs.

It is promising to see the FDA implement their Foreign Unannounced Inspection Pilot program with both China and India. The goal of this pilot program is to increase the unannounced surveillance inspections of foreign drug facilities.

Since March 2022, the FDA has completed 35 unannounced and short-term notice inspections in India. I hope they continue implementing this program and that it will lead to changes within the FDA for foreign inspections.

China on the other hand is a completely different story. The FDA has not completed **any** unannounced or short notice inspection since the pilot program was initiated.

FDA has even stated sometimes when their inspectors arrive at the facility, they are prevented from inspecting firms in China.

This is unacceptable.

Further, China's new interpretation of its national security law criminalizes the dissemination of routine business records, including information the FDA needs for meaningful inspections.

We need to begin thinking about whether we should continue to rely on medicines and/or API coming from such a closed regime.

Without a functioning foreign inspection program, one with unannounced inspections and that imposes real consequences for failing to maintain good manufacturing practices, we've lost the ability to deter negligent actors thus putting Americans at risk.

Again, I'm disappointed not to have the FDA here.

We will have additional hearings on this issue. And at future hearings, if the FDA does not come willingly, we have other means to secure their attendance.