Opening Statement of Republican Leader Brett Guthrie
Subcommittee on Oversight and Investigations

"Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program"
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As Prepared for Delivery

Thank you, Chair DeGette, for holding this very important hearing. The adequacy of FDA's oversight of the U.S. drug supply has been a longstanding issue for this Committee.

This Committee has long been at the forefront of increasing access to and reducing the price of drugs in the United States, particularly in our efforts to expand access to generic drugs.

Over the last three decades, the pharmaceutical industry has become globalized and drug manufacturing has shifted significantly from the United States to overseas. Today, about 80 percent of ingredients for America's drug supply are manufactured overseas, and roughly 40 percent of drugs in the finished form are imported.

FDA has the responsibility to monitor the safety and effectiveness of drugs through inspections of drug manufacturing. Over the years, the Government Accountability Office (GAO) has reported that the FDA has been slow to make recommended changes to the foreign drug inspection program in response to a globalized environment.

In 2012, this Committee bolstered FDA's foreign drug inspections with additional authorities in the Food and Drug Administration Safety and Innovation Act, and funding through the Generic Drug User Fee Act. With this support, the FDA has increased the number of foreign drug inspections from 333 in 2007 to 935 in 2018. Through a recent agreement with the European Union on greater cooperation on drug inspections, the FDA has even more resources to focus drug inspections in high-risk facilities.

While important improvements have been made, FDA has persistent challenges. Past GAO reports and investigative reporting have raised concerns about the ability of FDA to oversee a globalized supply chain when 80 percent of inspections involve only one inspector, translation is often provided by the firm to be inspected, and most of the inspections are pre-announced, with firms getting two to three months advance notice. In contrast, domestic facilities are usually inspected without notice. These conditions are concerning because there have been notable cases of systemic falsification and deception by firms determined to subvert FDA regulations. Putting FDA at this kind of a disadvantage against such misconduct is not acceptable, particularly when we are talking about drugs consumed by millions of Americans daily.

The FDA has known for decades about the need to globalize its foreign inspection program and operationalize it effectively. A strategy is needed to change the unbalanced dynamic where domestic facilities are usually inspected without notice, yet foreign facilities are given up to three months to prepare.

Despite the additional resources provided by user fees since 2013, it appears that FDA has had a deficit of inspectors for several years. For staff based in the

United States, FDA management should consider every tool available for creative hiring and incentives and consult with other federal agencies who effectively staff similarly situated personnel. FDA getting direct hire authority is a good start, but more must be done to increase hiring and—just as important—retain and promote inspectors who take on these responsibilities.

With additional staff, FDA should increase the number of inspections conducted by teams rather than a single inspector, and with translators independent of the firm being inspected. Surveillance inspections are data-dependent, yet the potential for negligent or corrupt business practices overseas is well-known. A trust-based inspection system must be closely evaluated to assess the true usefulness of data and information accepted at face value from foreign-based facilities.

With the majority of drug ingredients and drugs being imported into the U.S., we are vulnerable to drug shortages, compromises in quality, and reliance on foreign sources. The question for FDA should not be, "How do we find solutions?" Instead, the question should be, "How quickly can we put solutions into action to continue to make sure America's drug supply is safe?"

On another note, while I know that this is not the direct focus of today's hearing, I want to emphasize that lowering drug prices is one of the top things I hear back home and one of my top priorities as a member of this committee. I am disappointed that my colleagues on the other side of the aisle have chosen to pursue partisan legislation on the floor this week instead of bipartisan policies that have broad support. I look forward to working with my colleagues to advance bipartisan reform that will actually lower drug prices.

The FDA must maintain the public's confidence in America's drug supply by ensuring it has a smart, effective foreign drug inspection program strategy that is not just planned or discussed but is both operational and successful. I welcome the witnesses and look forward to the testimony.