

**Republican Leader Michael C. Burgess
Opening Statement
Health Subcommittee Hearing
Safeguarding Pharmaceutical Supply Chains in a Global Economy
October 30, 2019 at 10:00am**

As Prepared for Delivery

Thank you, Madame Chair. The Energy and Commerce Committee has a history of being engaged in the safety of the pharmaceutical supply chain, and I look forward to continuing our oversight work today. As research and development yields amazing scientific breakthroughs in the form of new treatments and cures for patients, there is an increased need for an efficient and secure pharmaceutical supply chain to ensure safe access to active pharmaceutical ingredients (API) coming from across the globe. Nearly 80% of active pharmaceutical ingredients come from other countries. The Food and Drug Administration examines API once they are imported or offered for import to the United States, subjecting them to the FDA's requirements.

Many of you may remember the United States faced a deadly contamination of the blood thinner, heparin, in 2008. Heparin contained an active pharmaceutical ingredient from China that was adulterated resulting in hundreds of adverse effects and the death of 81 American patients. At the time, more than one million multidose vials were sold each month in the United States.

The Food and Drug Administration conducted an investigation and was unable to pinpoint the exact source of the adulteration, however, it appeared to have been at a Chinese active pharmaceutical ingredient production site. Ultimately, the manufacturer of the Heparin, including the adulterated active pharmaceutical ingredient, recalled all Heparin. This amounted to roughly half of the Heparin supply in the U.S. As a result of this contamination, FDA asked manufacturers of products containing heparin to test the active pharmaceutical ingredients with two screening methods recommended by the FDA.

Despite efforts by the FDA, numerous letters sent by members of this Committee, and hearings on this mass Heparin contamination, we have still not identified the culprit or contamination source. This Committee remained engaged on this issue for years following this contamination and never learned the true cause of this contamination. This serves as an example of how seriously we must take the safety of the pharmaceutical supply chain.

The international supply chain for pharmaceuticals is complex. Merely investigating contamination after patients start dying fails to adequately protect Americans. An understanding of this global system is instrumental to ensure a safe pathway for important active pharmaceutical ingredients used in drugs taken every single day. This continues to be an issue as pharmaceutical manufacturing grows increasingly global and manufacturing shifts away from the United States.

As a physician, I know the importance of being able to prescribe the exact drug or treatment that your patient needs. A safe and efficient international supply chain is essential to avoid drug shortages and therefore, ensuring that physicians can focus on what their patient needs, rather than whether the drug is even available.

In June of this year, I wrote a letter along with Chairman Pallone, Republican Leader Walden, Ms. DeGette, and Mr. Guthrie, to FDA about a series of recalls involving drugs manufactured overseas that contained trace amounts of known carcinogens. While it is important to ensure safety by recalling these drugs, it shows that the threat of contamination is still alive and well.

The Food and Drug Administration Safety and Innovation Act, which was signed into law in 2013, codified the Food and Drug Administration's authority to inspect drugs and active pharmaceutical ingredients manufactured outside the United States.

Since then the FDA has issued guidance and final rules on agency procedure concerning adulterated drugs, domestic and foreign registration and inspection and destruction of imported drugs refused admission to the U.S. This was an important step in the direction of ensuring a safe pharmaceutical supply chain and I look forward to learning more about this today. Thank you Madame Chair, I yield back.