Opening Statement of Republican Leader Greg Walden
Subcommittee on Health
"Safeguarding Pharmaceutical Supply Chains in a Global Economy"
October 30, 2019

As Prepared for Delivery

Chairwoman Eshoo, thank you for holding this hearing today. Making sure our government agencies have the tools necessary to ensure the safety and quality of the U.S. drug supply is a top priority for this Committee. Recent recalls issued for a class of drugs known as angiotensin II receptor blockers, or ARBs, which are generally used to treat high blood pressure, and media attention on the questionable conditions and practices at foreign manufacturing facilities, have led to public concern about the country's sourcing of finished drug products and active pharmaceutical ingredients (APIs) overseas.

Historically, medicines intended for use in the United States have been produced here. However, over the past several years, more drug manufacturing has moved offshore. Much of this shift can be attributed to low wages and less regulation in other countries, resulting in lower production costs to drug companies. With this shift overseas it has become more difficult for us to verify these products are made in compliance with U.S. standards.

This Committee has long held an interest in FDA oversight of the manufacturing of finished drug products and active pharmaceutical ingredients intended for the U.S. drug supply. In 2012 with the passage of the Food and Drug Administration Safety and Innovation Act, Congress provided FDA with new resources needed to inspect both domestic and foreign generic drug facilities. Data from the most recently issued GAO report in 2016 found that FDA had increased its foreign drug inspections and enhanced its ability to prioritize drug establishments for inspection. For example, GAO found that FDA foreign inspections increased from 333 in 2007 to 842 in 2015.

However, it has been reported that FDA surveillance inspections of foreign facilities have declined in the past two years, including in China where inspections fell by almost 11 percent. While inspections are not the only means for ensuring the drug supply is properly protected, it is an important piece of the puzzle and we must ensure that FDA has the appropriate oversight measures in place.

Because of our continued concern over the quality and safety of the U.S. drug supply, we have requested, in a bipartisan manner, answers from FDA about practices currently in place to adequately oversee foreign drug manufacturing. We have also requested an updated

report from GAO on FDA's drug inspection program. If there are gaps in the agency's ability to properly oversee these facilities, action must be taken to resolve those shortcomings and protect the public health.

The United States' reliance on overseas manufacturing not only raises quality concerns, but it also poses national security risks as well. Foreign manufacturing of medical products critical to the Strategic National Stockpile are subject to the same quality and safety concerns, but dependence on foreign countries for drugs used as medical countermeasures could also leave Americans vulnerable to chemical and biological threats, among others.

Further, reliance on foreign suppliers, particularly in those countries with which we have unstable relationships, poses an increased risk to Americans. If a country monopolizes the production of a drug and wishes to retaliate against the U.S., they could substantially increase drug prices or reduce supply in an attempt to cause shortages, limiting access to critical medications. And that is in the absence of a crisis. In a time of crisis, such possible actions could mean American lives.

My concerns are amplified by the fact that we will be considering Speaker Pelosi's partisan drug pricing plan on the floor in the coming

weeks. This legislation will further drive innovation and manufacturing overseas, leaving the American people at the mercy of foreign manufacturers – particularly those in China, who have shown a strong interest in creating their own biotech manufacturing base – for their life-saving and life-sustaining drugs.

I look forward to hearing from the witnesses today about the challenges that face us in the wake of the globalization of the pharmaceutical industry and the solutions we can put forth to protect the U.S. drug supply and our constituents.

Thank you, and I yield back.