

Opening Statement  
Chairman Frank Pallone, Jr.  
Energy and Commerce Committee  
Subcommittee on Health  
Hearing on “Safeguarding the Pharmaceutical Supply Chains in a Global Economy”  
October 30, 2019

American consumers rely heavily on prescription drug products that help them live longer and healthier lives. Over the last several months, this Subcommittee has taken action to lower drug costs to ensure that all Americans can access the prescription drugs they need. Making prescription drugs more affordable is a top priority of this Committee – after all, prescription drugs are essentially useless if people cannot afford them. Today, we are focusing on another important component of prescription drugs – maintaining the safety and quality of medications in our market.

The Food and Drug Administration (FDA) plays a central role in ensuring the safety of drugs on our market. The rigorous drug review process at FDA is recognized worldwide as the gold standard. While regulatory processes can always be improved, American patients should take comfort in the knowledge that drug products approved by the FDA are among the most rigorously reviewed in the world.

And FDA’s authority is not limited to those drugs manufactured here in the United States. It can inspect and review information related to both finished dose drug products and the active pharmaceutical ingredients, or A-P-I, that come from other countries.

Over the years, this Committee has acted to improve FDA’s authority to regulate what is a complex and increasingly global supply chain. We provided FDA with the ability to inspect facilities on a risk-based schedule. We gave FDA the ability to enter into agreements with other regulatory authorities to share inspection information for foreign facilities. And we required entities in the drug supply chain to maintain and track information related to drug products.

All of these authorities are particularly important given recent trends in pharmaceutical manufacturing. Many manufacturers are getting their pharmaceutical ingredients from manufacturers overseas, particularly from China and India. Some of the ingredients from abroad have caused serious quality concerns with certain drug products.

We need to make sure that FDA has the authority it needs to address these concerns and to remain vigilant over the marketplace. We also need to ensure that manufacturers are still incentivized to produce their pharmaceutical ingredients and products domestically.

Some manufacturers are implementing innovative manufacturing methods, like continuous manufacturing, to make their processes more efficient and to keep their facilities here in the United States.

Encouraging the use of continuous manufacturing methods has long been a priority of mine not only because these methods are the next frontier of manufacturing, but also because they are

quality production methods that help U.S. manufacturers compete in the global market. Earlier this week, I reintroduced legislation with Representative Guthrie to expand support for continuous manufacturing. This bipartisan legislation will foster the development of emerging technology by expanding opportunities for FDA to partner with universities across the country that are leading these efforts, including Rutgers University in my congressional district. It is the next step in my work on the continuous manufacturing grants program that was included in the 21st Century Cures Act.

I look forward to hearing from the witnesses today, including Dr. Woodcock, about the safety and sourcing of active pharmaceutical ingredients. It is critical that we ensure American patients have access to the highest quality medications in the world.

Thank you, and I yield back.