Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Ranking Member Frank Pallone, Jr.

Hearing on "Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains"

May 11, 2023

Today, we are examining the root causes of drug shortages, which negatively impact the health and well-being of so many Americans.

Drug shortages are not a new issue, but unfortunately they are currently at a five-year high. Shortages can last anywhere from a year to over a decade, with 15 critical drugs in shortage for over ten years. This past year alone, we've seen harmful disruptions in the availability of children's pain medication and medication to treat conditions like ADHD. These shortages can result in delayed care, ineffective treatment, increased hospitalizations, and even death.

We need to do more to prevent drug shortages, including building a robust and resilient drug supply chain. This is not only critical to the health and well-being of Americans but also to our national security and economy.

However, we cannot effectively tackle the challenges associated with drug shortages without more information about the current supply chain. Key gaps remain in our understanding of how drugs are manufactured and brought to market.

The Administration for Strategic Preparedness and Response has shared that there can be up to 20 key materials per pharmaceutical. However, our public health agencies currently do not know which materials are used in the production of each drug, and in what quantity.

We also do not know the quantity of active pharmaceutical ingredients used in drugs for the U.S. market that is manufactured overseas. While we know that 72 percent of active pharmaceutical ingredient manufacturers serving the U.S. market are overseas, we do not know the actual volume of the ingredients that they manufacture. That number is likely much higher than 72 percent.

FDA has some limited tools to examine the supply chain. Recently, as part of the CARES Act, Congress took bipartisan action to start addressing drug supply chain information gaps. The law included a requirement that manufacturers develop risk management plans and annually report to FDA on the amount of each drug they make available for commercial distribution.

This is a step in the right direction – providing us more information than we had before. And while it has been useful, it is not enough to fully address drug shortages caused by supply

chain issues. FDA has repeatedly told us that, with its limited tools, it is simply not capable of using its existing authorities to directly prevent or mitigate a shortage.

For example, FDA's current reporting requirements don't allow the agency to determine which suppliers of active pharmaceutical ingredients manufacturers rely on. This makes it difficult to predict how a disruption with one supplier would affect the manufacturer's ability to produce their drugs.

FDA's tools are even more limited when it comes to forecasting and anticipating changes in demand. We have seen how sudden spikes in demand for certain drugs can cause a shortage—most recently in the market for Adderrall and children's pain mediation. However, manufacturers are not required to report those demand surges to FDA, which means FDA may lack the information it needs to foresee a shortage. Without that information, FDA cannot take the necessary action to identify new manufacturers, expedite additional inspections, or review new products that can fill gaps.

Giving FDA these tools will allow the agency to understand why these shortages occur so that it can take action to predict and address them. I would like to hear from our witnesses how greater visibility into the supply chain will help alleviate challenges that drive disruptions in drug availability. And, most importantly, I look forward to discussing how more reliable access to important drugs would improve the lives of patients and their families.

I am pleased the Subcommittee is also hearing from experts about what we can do to increase pharmaceutical manufacturing efficiency for greater domestic production. I especially want to thank Professor Muzzio from Rutgers University in my Congressional district for being here today. Dr. Muzzio directs Rutgers' Center for Structured Organic Particulate Systems. He is a national leader in the development of continuous manufacturing methods and technologies, which will help us improve drug manufacturing efficiency and quality.

Dr. Muzzio was also instrumental in supporting passage of my legislation, the National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing Act, which President Biden signed into law last year. The law empowers FDA to partner with universities across the country to further develop continuous manufacturing technology, which will hopefully strengthen domestic pharmaceutical manufacturing and help prevent future drug supply chain shortages. Thank you for being here today, Dr. Muzzio.

I appreciate all of our witnesses' work and attention to this issue and look forward to the discussion today. And I yield back.