Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Subcommittee on Oversight and Investigations Ranking Member Kathy Castor

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

May 11, 2023

Thank you, Mr. Chairman, for calling this critical hearing on the causes of drug shortages, which are becoming more prevalent due to a warped marketplace. As witness Laura Bray states in her testimony: "no patient should have to hear the words, 'we don't have the medicine to treat you'".

Drug shortages in America is at a five-year high. In 2022, we experienced a 30 percent jump in the number of drugs in shortage. FDA has documented 136 drugs on its shortage list, and health care providers suspect the actual number may be far higher. These shortages can last years, and some critical drugs have been in shortage for over a decade.

The impacts of these shortages on our neighbors on people receiving cancer care, children, and their caregivers are incredibly upsetting, because when drugs are in short supply, lifesaving care can be delayed or cancelled. Patients may be placed on medication that is less effective or more expensive.

The cascading impacts of not receiving appropriate medicine can impair a person's ability to live a full life, attend school, and work. Plus, it can lead to increased costs of care, and more serious health complications like adverse drug reactions, increased hospitalizations, and even death.

Children and their providers can be hit particularly hard by drug shortages. Children's hospitals often frantically respond to these shortages by scrambling for necessary and appropriate drugs. They have to devote additional staff, time, and resources to finding appropriate replacement drugs and determine the correct dose of that replacement drug that is safe for kids. It takes children's hospitals 50% longer to address shortages than other hospitals because of the time needed to compound replacement products into pediatric dosage forms. And it is costly - one drug in shortage alone can cost a children's hospital north of $50,000 dollars in labor and substitute products.

We need to get ahead of shortages before they happen, so that our neighbors and providers are not blindsided and left scrambling to find workarounds. This past winter's triple epidemic of flu, RSV, and COVID-19 were exceedingly difficult because shortages of basic medicine like Tylenol and ibuprofen ultimately got so severe that retailers began imposing purchase limits at the counter, sending parents searching multiple locations for medication to take care of their families.

FDA took the action it could within its limited authority to ensure that more products were available for consumers, but the current haphazard approach of addressing crises episode-by-episode is not working to give American families the certainty and quality of care they need and deserve.

So together we need to require greater transparency from manufacturers about where they source raw materials for drugs. We know that 72 percent of manufacturers supplying the U.S. market with active pharmaceutical ingredient, or API, are overseas—mostly in India and China, and the percentage of APIs manufactured in those countries by volume may be far higher.

I sit on the Select Committee on Strategic Competition between the United States and the Chinese Communist Party, and API manufacturing is another example of how overreliance on raw materials from China creates real life risks to the well-being of Americans. Greater transparency will help us better understand where we need to shore up domestic production and invest in new technologies.

But the need to address shortages doesn't end with manufacturers. We also need to make sure that anti-consumer behavior by intermediaries, like pharmacy benefit managers and group purchasing organizations, does not create affordability barriers for patients that magnify the effects of drug shortages for families in need.

We have a model for bipartisan action on this. When faced with a semiconductor shortage, Congress acted to adopt the CHIPS and Science Act and invest in Americans and supply chains. This will require a coordinated approach across government, manufacturers, providers, and payers to increase domestic production, shore up supply chain vulnerabilities, and revitalize scientific research that strengthens our economy and our health care system.

FDA has done critical work predicting and responding to shortages, but its ability to secure steady and reliable drug supply is limited by its current authorities and funding. If armed with more timely data on manufacturing sources and anticipated surges in demand, FDA will be better able to take corrective action and mitigate harm to patients long past the end of the public health emergency.

I hope that our witnesses today can help us better understand the reasons why shortages occur and persist, and how better and smarter tools for federal agencies would improve insight into the supply chain to better guide strategies to strengthen it. By better understanding the various root causes of these shortages, Congress and our public health institutions can enact policies and procedures to address them.

I look forward to hearing from our witnesses today and I yield back.