

Committee on Energy and Commerce

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

Hearing on “Legislative Proposals to Prevent and Respond to Generic Drug Shortages”

September 14, 2023

I am pleased that after months of refusing to work with Democrats to address the drug shortage crisis, the Republican majority has finally called a hearing to discuss legislative proposals to address this serious ongoing problem for patients.

Democrats put forward three of the bills noticed for discussion in the hearing today during consideration of the Pandemic and All-Hazards Preparedness Act (PAHPA). We wanted to immediately act because experts, including doctors providing care on the front line, told us drug shortages are an ongoing emergency for their patients and a threat to national security. They also told us that the Democratic bills could help address the crisis patients are facing by providing new authorities to the Food and Drug Administration.

Unfortunately, Republicans refused to work with us to include these policies in the PAHPA reauthorization, and instead pursued a Republican-only bill that slashed health preparedness funding and will have difficulty passing the House before PAHPA expires at the end of this month. After our nation was caught unprepared for the worst pandemic in a century, it is inexcusable that Republicans have failed to learn the lessons of COVID-19 and have refused to properly invest in public health preparedness. This failure is putting American lives at risk.

Then, just after gaveling out of session for the August recess, Republicans finally put forward their ideas to address drug shortages. Unfortunately, many of the proposals in the Republican discussion draft may actually lead to more drug shortages and increased profits for the pharmaceutical industry, while raising costs for consumers. I oppose many of the policies in the Republican discussion draft because I simply do not believe they will help end the drug shortage crisis – in fact, I think they will make it worse.

That’s not the approach Democrats want to take. Over the last month, we’ve been highlighting our efforts to expand the middle class, including by making drugs more affordable under the Inflation Reduction Act. For the first time, the Inflation Reduction Act allows Medicare to negotiate the prices of drugs for seniors, institutes a \$2,000 cap on out-of-pocket costs for drugs in Medicare Part D, and prevents huge price increases by requiring drug companies to pay a rebate back to the government if they raise drug prices faster than the rate of inflation.

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Every Republican voted against lowering drug prices, and now they are trying to eat away at the consumer protections Democrats created. The Republican discussion draft would allow some drug companies to raise prices on consumers faster than the rate of inflation without paying a penalty to Medicare or Medicaid. I am deeply concerned that this proposal could unintentionally provide an incentive for drug companies to keep drugs in shortage or near shortage for longer periods of time in order to raise drug prices on the American people. While it's true that market conditions affect manufacturing and supply issues – two major causes of the drug shortage crisis – the Republicans' proposal to simply allow drug companies to raise prices is not the answer to the problem.

In stark contrast to some of the misguided policies in the Republican discussion draft, the Democratic bills before us today are commonsense, and take significant steps toward better securing our supply chain.

We should know where our drugs and their critical ingredients are being made, so when a drug shortage or other supply interruption happens, FDA and manufacturers can react appropriately. Ranking Member Eshoo's legislation, the Drug Origin Transparency Act, would require drug companies to report the sources of active pharmaceutical ingredients to FDA, and include the source of API on a drug's label.

We should also be ensuring that FDA knows at the earliest possible time when a surge in demand for a drug is likely to cause a shortage. That's exactly what the bipartisan bill introduced by Representatives Jacobs and Mills will do. And we should make sure that we are not needlessly throwing away safe and effective drugs that could be used past their shelf-life date. Representative Slotkin's bill, the Ensuring Access to Lifesaving Drugs Act, will help address that by requiring manufacturers to report to FDA on the longest possible shelf life of their drugs.

I am interested in hearing more from our panel and am hopeful that we can find a bipartisan path forward on these drug shortage policies, as patients and providers are facing life-altering consequences if we don't do more to address this critical problem.

Thank you. I yield back.