Committee on Energy and Commerce

Opening Statement as Prepared for Delivery of Subcommittee on Health Ranking Member Anna Eshoo

Hearing on "Legislative Proposals to Prevent and Respond to Generic Drug Shortages"

September 14, 2023

Today is an important day. After months of pleading by the Democratic members of this Subcommittee, we are finally having a legislative hearing on drug shortages in our country. I've been frustrated by our Subcommittee's inaction through the spring and summer as I heard from so many physicians in my Congressional District and read about cancer patients, especially children, left behind due to shortages in lifesaving treatments.

A quick scan of the headlines demonstrates the magnitude of the shortages:

• *The New York Times* in June: "How the Shortage of a \$15 Cancer Drug Is Upending Treatment"

• *The Wall Street Journal* in June: "They Got Cancer. Then Their Drugs Were Rationed."

• *STAT* in July: "Cancer drug shortages deliver 'gut punch' to patients unsure if their survival odds will be undercut."

The Food and Drug Administration reports that more than 130 drugs are currently in shortage. A July survey by the American Society of Pharmacy Professionals found that over half of the respondents said shortages of chemotherapy drugs were "critically impactful."

Long-term structural factors cause drug shortages, including high concentration among manufacturers, swings in consumer demand, complex manufacturing processes, and mismatched pricing. Today we will discuss five proposals that attempt to address the crisis:

First, my *Drug Origin Transparency Act* addresses manufacturer concentration by providing the FDA with the information they have repeatedly said they need to identify where critical drugs and Active Pharmaceutical Ingredients are made to prevent shortages.

Second, the bipartisan *Drug Shortage Prevention Act* by Rep. Sara Jacobs of California requires manufacturers to inform the FDA if there is a sustained increase in demand for a drug or ingredient.

Next, the *Ensuring Access to Lifesaving Drugs Act* by Rep. Elissa Slotkin of Michigan and the *Patient Access to Urgent-Use Pharmacy Compounding Act* by Rep. Morgan Griffith of Virginia attempt to mitigate shortages by allowing drugs to be safely used after their expiration date or through pharmacy compounding.

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Finally, we are considering Chairwoman Rodgers' long-awaited proposal, the *Stop Drug Shortages Act*. This Subcommittee delayed action on the drug shortage crisis during the spring and summer with the promise of legislation that comprehensively addresses the issue, but I believe that this proposal mostly studies the problem with more reports.

Where the proposal has actionable policy, I think it's a grab-bag of talking points. It weakens the 340B program and chips away at the Inflation Reduction Act by excluding certain manufacturers from the inflation rebate. The proposed inflation rebate policy misunderstands the market failure that causes drug shortages. Many of the chemotherapy shortages were caused by manufacturers choosing to drop their prices in an unsustainable attempt to gain market share.

I look forward to working with my colleagues to ensure any final package to address drug shortages contains policies like my *Pediatric Cancer Drug Supply Act of 2023*, which I will introduce in the coming days. This bill establishes a program at the Department of Health and Human Services to create a long-term contract for the manufacturing of essential pediatric cancer drugs to ensure there is a consistent six-month supply available.

I look forward to finding a bipartisan way to craft a proposal that thoroughly addresses the threat drug shortages pose to our nation and its patients.