Committee on Energy and Commerce
Opening Statement as Prepared for Delivery
of
Subcommittee on Health Ranking Member Anna Eshoo

Hearing on "Check Up: Examining FDA Regulation of Drugs, Biologics, and Devices"

May 22, 2024

Good morning, colleagues. Today we welcome leaders from the Food and Drug Administration (FDA) to discuss the work of the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Devices and Radiological Health. Drs. Cavazzoni Marks, and Shuren, it's good to see you.

FDA oversees the safety of more than $3.6 trillion worth of products, including more than 6,500 medical devices, 1,600 FDA-approved animal drug products, and 20,000 FDA-approved prescription drugs. The FDA also regulates 78 percent of our nation's food supply.

Overall, FDA-regulated products account for 21 cents of every dollar spent by U.S. consumers. The FDA's mission to protect the public's health leaves no room for error. Yet the FDA has a herculean task: oversee a huge segment of products Americans rely on with almost the same amount of money a single county in Maryland funds its schools with.

The FDA's budget was $6.7 billion in Fiscal Year 2023, with over half of the funding provided by the federal government. The remaining funding was provided by the industries the FDA oversees in the form of user fees. Per capita, FDA's budget amounts to $10.78 per American.

Congress has not set the FDA up for success. Drug shortages are a key example. Drug shortages have for decades threatened adequate delivery of quality patient care and severely limited Americans' access to lifesaving drugs. Drug shortages are caused by long-term structural factors, including our over-reliance on foreign sources for essential medicines and active pharmaceutical ingredients (APIs).

Last September, our Subcommittee held a legislative hearing on drug shortages after months of horror stories shared by physicians and patients about shortages of lifesaving treatments for treating cancer.

Included in the hearing was my Drug Origin Transparency Act to provide the FDA with the information they have repeatedly said they need to identify where drugs and APIs are made to prevent shortages. Almost a year later, we haven't advanced legislation to address drug shortages. The stories I hear from patients and physicians, especially those treating children, haven't stopped coming in.

An April 2024 Survey by the American Society of Health-System Pharmacists found shortages of critical drugs reached another record-high this year, with more than 323 drugs in

shortage. Democratic Members of this Subcommittee have put forward well-thought-out policies to require manufacturers to inform the FDA if there is a sustained increase in demand for a drug or ingredient and allow the FDA to recall products from the market to prevent harm to consumers.

We can't keep doing what isn't working and expect a different result. It's in our nation's best interest to ensure the FDA can comprehensively address drug shortages and other issues that touch the lives of millions of Americans. I hope our Subcommittee takes on this critical issue in earnest without further delay.

We can start by meeting President Biden's request for $7.2 billion in funding for the FDA in Fiscal Year 2025, which is a $495 million increase over the previous year. Additional funding means faster reviews and approvals of drugs and more frequent inspections of foreign manufacturing facilities, two topics our Subcommittee and industry agree are needed.

I look forward to hearing from our distinguished witnesses today on how Congress can best support the FDA's work.

Thank you and I yield back.