## Opening Statement Chairwoman Anna G. Eshoo

## Subcommittee on Health Energy and Commerce Committee

Hearing on "Safeguarding Pharmaceutical Supply Chains in a Global Economy"
October 30, 2019

There is a hidden health care crisis in this country that will affect us all: the crippling inadequacy of the American drug supply.

Today, 90 percent of the medications that Americans take are generics. That's because they're cheap, and they're supposed to be just as safe and effective as expensive brand name drugs.

But the generic industry is broken, and it is putting millions of Americans' health at risk.

Our generic drug supply is broken in three devastating ways: shortages of lifesaving medications, subpar manufacturing contaminating our drugs, and an overreliance on foreign production of critical drugs and their ingredients.

The first crisis is the shortage of lifesaving medications. Right now, hospitals are rationing critical drugs. This month, children and their families woke up to the news that they may not be able to get the pediatric cancer drug Vincristine (VIN-cris-tine). Little children, who with Vincristine would be cured of their cancer, now can't get the drug they need. This shouldn't happen in the United States.

The second crisis is subpar manufacturing contaminating our drugs, contributing to shortages. Over the last year, we've seen recalls of common blood pressure medications because they contain carcinogens. One of the drugs affected, Losartan, is the ninth most commonly used drug in our country.

Our generic drug supply is so fragile that the FDA often must make the hard choice between enforcing quality at a plant and avoiding a shortage.

The third crisis is an overreliance on foreign production for critical medication which is a national security risk. China globally dominates the manufacturing of active pharmaceutical ingredients, and China has gained a chokehold over the global supply of penicillin. In fact, according to a witness on our second panel, Ms. Rosemary Gibson, there are no plants in the U.S. that manufacture penicillin. If tensions with China escalate, Beijing could use U.S. dependence for critical drugs as an economic weapon and exploit the health and safety of our armed forces and the American public. This is a threat to our nation's security.

China flaunts the FDA's rules. An analysis of FDA inspection reports published on Wednesday in STAT News found Chinese plants were cited for data integrity issues nearly twice as often as American plants. These data issues include falsifying drug tests or deleting findings that could indicate contaminated or poor-quality drugs.

Taken together, these overlapping crises of shortages, subpar manufacturing, and foreign reliance threaten the overwhelming majority of drugs taken by Americans every day.

This is a crisis, and today we will define it in depth – and most importantly, focus on solutions.

Much of what we will hear today will sound shocking. Not only because of the scary state we find our drug supply in, but also how little attention it has received.

I'm issuing a call to action to the FDA, to industry, and to my fellow members of Congress to take these problems seriously and work together to address them. If we fail to act, America will continue to be vulnerable to potential foreign adversaries and at the mercy of subpar plants or cutbacks on quality.

We cannot allow this to happen.