

**Chairman Peters Opening Statement As Prepared for Delivery**  
**Full Committee Hearing: Drug Shortage Health and National Security Risks: Underlying**  
**Causes and Needed Reforms**  
**March 22, 2023**

Today's hearing will examine ongoing and rising shortages of medications, which range from drugs used in hospitals to provide critical care and treat serious diseases like cancers, to prescription medications, and even common over-the-counter remedies to treat cold and flu symptoms.

After a winter with high cold, flu and RSV cases, many of us have gone to the store and seen bare shelves due to shortages of children's Tylenol and Motrin. Others have faced shortages of key prescription medications, including antibiotics.

Throughout the country, hospitals regularly experience shortages of a range of drugs needed for emergency care, surgeries, and other procedures. These often include sterile injectable drugs like IV saline solution and sodium bicarbonate needed to provide critical care, dialysis, and other life-saving treatments. Some of these products have been in shortage for over a decade. For example, lidocaine, used to manage pain, has remained in shortage since 2011.

Vancomycin, used to treat bacterial infections, has been in shortage since 2009. Even drugs needed to treat childhood and adult cancers, including some that have no alternative treatment, are regularly in shortage. While some shortages may only be an inconvenience, others can have devastating impacts on patient care.

These shortages, which reached a peak of 295 individual drugs in shortage, at the end of 2022, have left health care professionals grappling with limited resources to treat patients in need.

Drug shortages are not new. There are a number of factors that contribute to drug shortages, including economic drivers that lead to a lack of manufacturers willing to enter or remain in the market or invest in quality manufacturing systems, insufficient visibility into the entire supply chain for critical medications, and an overreliance on foreign and geographically concentrated sources for the materials needed to make these drugs.

Taken together, these underlying causes not only present serious concerns about providing adequate care to patients, they also represent serious national security risks.

In 2019, I released a report identifying many of these national security risks, and how they contributed to drug shortages and in some cases, price hikes.

My report found that nearly 80 percent of the manufacturing facilities that produce active pharmaceutical ingredients, or APIs, the key ingredients that give a drug its intended effect, are located outside of the U.S., and many of our APIs are sourced from China and India.

Just months after I released that report, as the COVID-19 pandemic spread around the globe, we saw firsthand how our overreliance on foreign producers for medical products, along with

failures to adequately prepare for a pandemic, quickly led to widespread shortages of desperately needed medications and medical supplies like personal protective equipment.

Today, I am releasing a new report that builds on those previous findings, and identifies additional recommendations to strengthen domestic manufacturing of critical drugs and limit the disruptions caused by shortages and supply chain issues.

My report finds that between 2021 and 2022, new drug shortages increased by nearly 30 percent, and that both the pharmaceutical industry and the federal government, including the Food and Drug Administration, lack the information needed to effectively detect and prevent shortages.

Most significantly, this updated report found that our continued overreliance on foreign suppliers for the key materials needed to make critical drugs, primarily those in China, remains an unacceptable national security risk.

For example, over 90 percent of generic injectable drugs used to treat serious injuries or illnesses in the U.S. rely on key materials from China and India, and nearly 90 percent of generic API manufacturing sites are located overseas.

My report makes several recommendations to help protect our health and national security, including to invest in advanced manufacturing capabilities to produce critical drugs here in the U.S., and require that the FDA and its interagency partners can get the information needed to better monitor supply chain vulnerabilities and anticipate possible shortages.

I am encouraged by recent legislative and executive actions to bolster our medical supply chain resiliency. Last Congress, I helped author a bipartisan provision to increase visibility into where critical medical supplies and drugs are produced, and this Congress, I am working on legislation that builds on many of the report recommendations to protect our health and national security. I look forward to working with my colleagues to advance these important measures.

Today's discussion with our panel of expert witnesses will provide even more detail about what Congress and our federal agencies should do to address both drug shortages and the national security risks they pose.