

Chairman's Opening Remarks October 8th Hearing

"The U.S. Senate Special Committee on Aging will now come to order.

Last month, this committee held a <u>hearing</u> about the dangers older Americans face due to unsafe foreign generic drugs.

We exposed not only the threat posed by poor quality generic drugs that can hurt or even kill American seniors, but also how dependent the United States is on dangerous supply chains that threaten shortages keeping live-saving drugs from getting to those who need them.

The terrifying reality we face is that our nation is completely beholden to Communist China and India for the vast majority of our generic drugs and their ingredients.

Communist China is the world's largest producer of active prescription drug ingredients and India relies on Communist China for approximately 80% of the active drug ingredients it uses in drug manufacturing.

A study from one of our witnesses, Mr. Tony Sardella, found that 83% of the top 100 generic drugs consumed by U.S. citizens have no U.S.- based source of active drug ingredients and another 11% have only one domestic source of active drug ingredients.

We also learned in our last hearing that if Communist China or India shut off the flow of these essential drugs, the U.S. would only have months of prescription drug supply, forcing us to begin rationing drugs and turning away all but the most in need within a matter of weeks!

Let me say that again, if Communist China, our adversary, or India decide to shut off supplying generic prescription drugs to the United States, we would run out of prescription drugs in a matter of months and be forced to begin rationing drugs and turning away all but the most desperately in need within a matter of weeks!

I think everyone here remembers the supply shortages we faced during the COVID-19 pandemic of PPE supplies and even baby formula. Think about the catastrophic scenario we would face if millions of Americans didn't have the prescription drugs they need to survive.

The health of older Americans is too important to leave up to chance. Congress has to work with the Trump administration and act now to make sure that Americans have safe and high-quality drugs and to secure the prescription drug supply chain.

91% of prescriptions filled in the United States are for generic drugs. It is essential that the quality and safety of generic prescription drugs meets the same high standards of brand-named drugs.

A study showed that serious adverse events like hospitalization and even death were 54% more likely for foreign generic drugs compared to American-made generic drugs.

I am not exaggerating when I say that people are dying in America today because of bad medicine from underregulated markets in India and Communist China.

When I asked Peter Baker, a former FDA inspector, if he would allow himself or his family to take generic drugs made in India or Communist China, he said absolutely no, and told us that he believed that Americans were being killed every day from foreign-made generic drugs.

I want to say that again: a former FDA inspector who worked in China and India told this committee that he believes Americans are being killed every day from dangerous foreign made generic drugs.

Mr. Baker also told a heartbreaking story of having to go to multiple pharmacies with his elderly grandmother to find a safe generic drug for her prescription, only to be forced to accept an Indian-made drug that had paid a massive settlement to the U.S. Department of Justice for falsifying quality testing.

Peter knew the drug in his grandmother's prescription was potentially dangerous but had no other options.

No American should ever have to deal with what Peter talked about and be worried that a family member will be hurt or killed by the medicine that is supposed to heal or treat them.

It is unacceptable for that to be happening in our country and every American needs to get loud and demand change.

Everyone knows how I feel about Communist China, but I'm not the only one concerned about the dangers of foreign made generic drugs.

The BBC reported earlier this year that doctors in Communist China are worried about the quality of their generic drugs. One doctor said that antibiotics coming almost entirely from Communist China were causing allergies and elevated blood pressure.

Unsurprisingly, the Chinese Communist Party downplays these reports just like they've denied using slave labor. But this is a real problem, and we cannot rely on low-quality, ineffective generic drugs from Communist China.

In our last hearing our witnesses underscored quality issues that present real dangers to the health of patients. In 2007 and 2008, Heparin that sourced contaminated ingredients from Communist China killed up to 100 people in the United States.

These problems continue to happen nearly 20 years later. In 2023, contaminated eye drops from India killed one person and caused adverse events in at least 55 patients.

The federal government needs to ensure access to safe and high-quality drugs now. Following our hearing last month, Ranking Member Gillibrand and I sent a <u>letter</u> to the FDA asking what steps they are taking to stop dangerous drugs from coming into our country.

I also met with FDA Commissioner Makary, and he talked about his fight to fix the issues we have highlighted.

I applaud his attention to this dire issue and the Trump administration's work to increase the amount of unannounced foreign inspections, a crucial first step to holding foreign manufacturers accountable to the same standards we hold American manufacturers.

When it comes to solutions, I believe one of the most important things we can do is establish a federal buyer's market.

The federal government is the largest purchaser of drugs in the United States, accounting for 40% of outpatient prescription drugs purchased as of 2018.

On the Senate Armed Services Committee, I have pushed for the Department of War to leverage its buying power to prioritize purchasing drugs made in America using American ingredients. Senator Warren held a hearing last year on the same issue.

If no American option is available, then the federal government should prioritize drugs and ingredients from allies and trade act compliant countries.

The buying power of the federal government can move the needle and bring manufacturing for essential drugs back to the United States.

The national security risks of relying on Communist China for essential drugs and drug ingredients are unacceptable.

These same risks are unacceptable for seniors, who trust that they will have access to the drugs they need.

In 2024, the U.S. manufactured 37% of its consumed drugs. This number is down from 2002, when it was 83%. So in just over 20 years, we have ceded control of our medical supply chain to Communist China and India.

Even if we started by prioritizing certain drugs or types of drugs, like antibiotics, which Communist China supplies 90% of the ingredients for globally, we would be making our medical supply chains much safer, not just for seniors, but for all Americans.

I will continue fighting for the federal government to purchase American-manufactured drugs. We cannot rely on Communist China for something as important as the health of Americans.

Every American deserves to know where the drugs they are purchasing came from. That is why I support mapping our supply chains as well as country of origin labeling.

I've introduced the <u>Country of Origin Labeling Online Act</u> to require country of origin labeling for consumer products.

Consumers deserve to know where items they purchase are made, and for something as important as the medications you take, that information is absolutely crucial.

I will be introducing legislation on country of origin labeling for prescription drugs that would require drug labels include the country where each drug ingredient and the finished drug are manufactured, processed, or compounded.

We've already seen Communist China place export restrictions on rare earth elements as part of trade negotiations, and there's no reason why they won't do the same for medicines.

Agencies like the Department of War and Veterans Affairs stepping in to purchase American-made drugs could bring industry back and create a steady supply of important medications and ingredients for the American people.

Other steps like the Department of Commerce's Section 232 investigation could level the playing field for American manufacturers. Section 232 tariffs are for goods that

impact our national security, and I can't think of anything more critical to the health of our seniors than generic drugs. On Friday, I sent a <u>letter</u> to Secretary Lutnick and U.S. Trade Representative Greer encouraging them to immediately place Section 232 tariffs on generic drugs.

This is a national security and a public health issue for seniors and all Americans. I look forward to this discussion with our witnesses on how we can make sure Americans never have to worry about missing a dose of their medication or the quality of drugs in their medicine cabinet."