



## **Chairman's Opening Remarks**

### **September 17<sup>th</sup> Hearing**

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

*Nearly everyone will be prescribed a medication at some point, whether it be an antibiotic for an infection or a treatment for a chronic condition, people depend on access to safe and high-quality medications.*

*This is especially true for seniors. In 2021, a federal study found that 88.6% of older Americans surveyed reported having been prescribed at least one medication in the past 12 months.*

*91% of prescriptions filled are for generic drugs.*

*The problem is, the United States relies disproportionately on foreign made generic drugs from Communist China and India.*

*The U.S. currently depends on overseas manufacturers for about 75% of its essential drug supply.*

*Communist China is not our friend – they are the world's largest producer of Active Pharmaceutical Ingredients and India relies on Communist China for approximately 80% of the Active Pharmaceutical Ingredients they use.*

*A study from Washington University in St. Louis found that 83% of the top 100 generic drugs consumed by U.S. citizens have no U.S.-based source of Active Pharmaceutical Ingredients.*

*Not only is the U.S. overdependent on foreign drugs, but these foreign drugs are often lower quality and more dangerous than drugs manufactured in the United States.*

*Earlier this year, a study showed that serious adverse events like hospitalization and death were 54% more likely for foreign generic drugs compared to American-made drugs.*

*Bad drug quality doesn't just mean that a drug is less effective, it can kill!*

*In 2007 and 2008, the medication Heparin had contaminated ingredients from Communist China, killing nearly 100 people.*

*Deaths from unsafe medications like this contaminated Heparin devastated families. LeRoy Hubley lost his wife of 48 years, Bonnie, and his son, Randy, just weeks apart. Bonnie and Randy died due to contaminated Heparin that they needed for their dialysis treatment they were undergoing due to a genetic kidney disease.*

*People who relied on their medication and trusted that it was safe died. This was an absolute tragedy and must never happen again.*

*But almost 20 years later, we are still seeing many of the same problems and quality issues that existed back then.*

*There is still no routine testing done by the FDA and no incentives for quality.*

*In 2023, contaminated eye drops from India killed 4 people and caused adverse events in at least 55 patients.*

*Foreign drug manufacturing plants simply aren't subject to the same level of oversight as manufacturing plants here in the United States, and it doesn't make sense to any American.*

*Inspections of drug manufacturing facilities in the United States are unannounced. In Communist China and India, many inspections are preannounced up to weeks in advance, giving manufacturers time to present false conditions or conceal non-sterile and unsafe manufacturing practices.*

*While many quality issues present an immediate threat to the lives of seniors and their loved ones, supply chain vulnerability presents an existential threat to the country.*

*I know my remarks paint a very dark picture of the reality we face, but it gets much worse.*

*Think about this, if Communist China or India want to shut down the supply of prescription drugs to the United States, they can do so at any moment!*

*And currently, the United States does not have a backup plan!*

*Let me say that again, if Communist China or India decide to stop supplying the United States with prescription drugs, we will run out of prescription drugs very quickly and people will die!*

*Let that sink in. Millions of Americans will not have lifesaving drugs available to them. Americans will get sick and Americans will die!*

*We've seen China place export restrictions on rare earth elements before over trade negotiations, and there's no reason they can't do that for pharmaceuticals.*

*Additionally, during the COVID-19 pandemic, we saw India block the export of critical pharmaceutical ingredients.*

*Many of the disruptions were prompted by supply chain disruptions from Communist China – the birthplace of the COVID-19 pandemic.*

*We simply cannot rely on other countries, especially those who want to destroy us like Communist China, for something as vital as essential medicines.*

*Yet despite these dangers, we still depend almost entirely on Communist China and India for generic medications, and their grip on the market continues to grow.*

*As of 2021, Communist China and India accounted for 85% of active drug master file submissions – applications submitted to the FDA by companies that want to supply drug ingredients to another company. In 2000, they accounted for just 24%.*

*The Administration for Strategic Preparedness and Response, the federal agency that oversees the Strategic National Stockpile and ensures the nation has medical countermeasures ready for public health emergencies, lacks the data to understand the supply chain of the key starting materials or critical building blocks for pharmaceuticals.*

*Communist China has a stranglehold on antibiotics, with 90% of global antibiotics being of Chinese origin.*

*While Communist China and India have dominated the market, American manufacturing has just withered away.*

*A 2024 report from the API Innovation Center stated that in the past decade, the number of facilities located in the U.S. that produce active pharmaceutical ingredients has decreased by 61%.*

*In 2024, the U.S. manufactured 37% of its consumed pharmaceuticals. Just over 20 years ago in 2002, that figure was 83%.*

*Over 40% of generic drugs sold in the U.S. have just one FDA-approved manufacturer.*

*I'm a business guy, we'd never rely on just one supplier.*

*This means in the event of shortage, the FDA must scramble to find an alternative.*

*In 2023, the chemotherapy drug Cisplatin went into shortage due to the FDA placing import restrictions on the manufacturer that accounted for 50% of the market.*

*There was no FDA-approved alternative, which forced the FDA to turn a then unapproved Chinese pharmaceutical company to fill in the gap.*

*The supply chain is unacceptably vulnerable, and we can't just hope that shortages won't occur.*

*If we can't solve this problem, our public health and national security are in grave danger and people will die.*

*We will soon hold another hearing to discuss the solutions to these problems, but the American people deserve to know the dangers of bad-quality medications and vulnerable supply chains."*

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