

## Statement from Peter J. Pitts President, Center for Medicine in the Public Interest

## U.S. House of Representatives Committee on Government Oversight Hearing on the United States Pharmaceutical Supply Chain April 9, 2025

My name is Peter Pitts. I am the President of the Center for Medicine in the Public Interest, a Visiting Professor at the University of Paris School of Medicine, and a former FDA Associate Commissioner where I was proud to serve on the agency's inaugural Counterfeit Drug Task Force.

Foreign nations are holding America's medicine cabinets for ransom. Right now, as we sit here, there is the very real risk of drug shortages being caused, on purpose, by foreign governments for political goals that put American patients at risk.

Why is this happening? What can we do about it? Who is in charge?

Our national supply chain for essential medicines, for both domestic use and for our soldiers in the field, is a global one. One key problem is that we have allowed countries, not always friendly to our own national interests, to have their fingers on the buttons that controls the flow of pharmaceuticals and medical devices (both finished products and Active Pharmaceutical Ingredients) to our shores.

According to the FDA, "We don't know whether Chinese facilities are actually producing APIs, how much they are producing, or where the APIs they are producing are being distributed worldwide, including in the United States. Similarly, we do not have information that would enable us to assess the resilience of the U.S. manufacturing base, should it be tested by China's withdrawal from supplying the U.S. market."

We are allowing patient safety to take second place to supply chain savings. And we are playing Russian Roulette with often unsavory Chinese partners and their political masters. Why have we allowed this to happen? That answer is simple – follow the money.

In nations such as the People's Republic of China, labor is cheap, quality standards are often low, and FDA oversight is both thin and limited. Thin because of the absurdly small number of in-country FDA inspectors and limited because of the restraints placed on those inspectors by Beijing to undertake and accomplish such basic tasks as surprise inspections.

When you are required to tell them you're coming, manufacturing logs get altered, factory floors get cleaned, expired supplies get moved, and access to many key areas get restricted. This is a recipe for disaster.

We have not learned from the lessons of Covid-19. During the pandemic, we suffered an acute shortage of contrast agent -- the substance used in medical imaging to enhance the visibility of organs, blood vessels, and tissues, making them appear clearer on X-rays, CT scans, and MRIs.

In 2022, a large contrast agent manufacturing facility outside of Shanghai shut down during a pandemic lockdown. Here at home, this resulted in radical decreases in angiograms, perfusion scans, and other tests crucial for stroke assessments, cancer diagnoses, and other urgent medical care. This one plant in China provides almost all the contrast agent used in the United States. And that was because of Covid-19. It's not hard to imagine similar supply chain crises for diabetes test strips or ADHD medications, or penicillin driven by geopolitical purposes.

It's not hard to imagine – because shortages of these products are already happening due to our lack of interest and oversight.

And that's not even mentioning the deaths that have occurred because of inappropriate quality oversight. In 2008, substandard heparin from China (an anticoagulant used to decrease blood clotting), killed 81 people, and left 785 severely injured -- in the United States. These are supply chain deaths.

What can we do about it? We need to strengthen our national supply chain for essential medical products by giving the FDA the authorities it needs to more closely monitor materials sourcing and manufacturing and to advance both on-shoring and friend-shoring manufacturing strategies.

We must extricate our medical supply chain from countries that could weaponize this dependence, by manufacturing on our own shores when practical and shifting our foreign partnerships from places like China to more friendly nations such as those of the Abraham Accords. That's called "Friend-Shoring."

In fact, there is a section in the pending Give Kids a Chance Act that instructs the FDA to open an Abraham Accords office for precisely this purpose. I think it's a good idea.

Any proper risk-benefit analysis of this friend-shoring initiative shows a highly positive outcome for both the nations of the Abraham Accords and the United States. For the members of the Abraham Accords, it represents an opportunity to grow their biopharmaceutical sectors and for the U.S. it means a strengthened supply chain forged with stronger fraternal links — all within a framework that prioritizes quality, patient safety, and cost-savings -- in that order.

As President Eisenhower said, "In the final choice a soldier's pack is not so heavy as a prisoner's chains."

Thank you.

## Additional Resources

Establishing an FDA office in the Middle East/North Africa: An Abraham Accords Initiative

Biopharma, Supply Chain & the Abraham Accords

The Danger of Shorting Drug Shortages

Beyond baby formula: advancing best practices in FDA's efforts to prevent shortages

House Hearing: China's Enforcement of Intellectual Property Rights and the dangers of the Movement of Counterfeited and Pirated Goods into the United States

The Spreading Cancer of Counterfeit Drugs