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BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS

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C O N T E N T S

BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS

Wednesday, October 8, 2025

U.S. SENATE
SPECIAL COMMITTEE ON AGING
Washington, DC.

The Committee met, pursuant to notice, at 3:27 p.m., Room 216, Hart Senate Office Building, Hon. Rick Scott, Chairman of the Committee, presiding.

Present: Senator Scott, Tuberville, Johnson, Moody, Gillibrand, Warren, and Kim.

OPENING STATEMENT OF SENATOR RICK SCOTT, CHAIRMAN

The CHAIRMAN. The U.S. Senate Special Committee on Aging will now come to order. Last month, this Committee held a hearing 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 life-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 percent of the active drug ingredients it uses in drug manufacturing.

A study from one of our witnesses, Mr. Tony Sardella, found that 83 percent of the top 100 generic drugs consumed by U.S. citizens have no U.S.-based source of active drug ingredients. Another 11 percent 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 turn away all but then the most in need within a matter of weeks. Let me say that again. If Communist China, our adversary, or India decided to shut off supply and 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; PPE supplies and even baby for-

mula. 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 to chance. Congress has to work with the Trump Administration, and now, to make sure that Americans have safe and high-quality drugs, and secure the prescription drug supply chain. Ninety-one percent of prescriptions filled in the United States are for generic drugs. It's essential that the quality and safety of generic prescription drugs meet the same high standards of brand name drugs.

A study showed that serious adverse events like hospitalization, even death, were 54 percent more likely for foreign generic drugs compared to American-made generic drugs. I'm not exaggerating when I say that people are dying in America today because of bad medicine from under-regulated 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 not. He 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 paid a massive settlement to the U.S. Department of Justice for falsifying quality testing. Peter knew that 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's unacceptable for that to be happening in our country. Every American needs to get loud and demand change.

Everyone knows that how I feel about Communist China, but I'm not the only one concerned about the dangers of foreign, major generic drugs. The BBC reported earlier, earlier this year that doctors in Communist China are worried about the quality of their generic drugs. One doctor said that antibiotics coming out 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 four people, and caused ad-

verse events in at least 55 patients. The Federal Government needs to ensure access to safe and high-quality drugs today.

Following our hearing last month, Ranking Member Gillibrand and I sent a letter to the FDA asking what steps they're 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 the 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 to establish a federal buyer's market. The Federal Government is the largest purchaser of drugs in the United States, accounting for 40 percent 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 this 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 risk of relying on Communist China for essential drugs and drug ingredients are unacceptable. The same risk risks are unacceptable for seniors who trust they will have access to the drugs they need. In 2024, the U.S. manufactured 37 percent of its consumed drugs. This number is down from 2002 when it was 83 percent. In just 20 years, we have seeded control of our medical supply chain to Communist China and India.

Even if we start prioritizing certain drugs or types of drugs like antibiotics which come as China's supplies, 90 percent of the ingredients for globally, we'd 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 their purchasing came from. That is why I support mapping our supply chains as well as our country-of-origin labeling.

I've introduced the Country of Origin Labeling Online Act 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 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 drugs are manufactured, processed, or compounded.

We've already seen Communist China place export restrictions on rare earth elements as part of trade negotiation, 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 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 crucial to health of our seniors than generic drugs. On Friday, I sent a letter 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. I'd like to turn it over to Ranking Member Gillibrand for her opening statement.

OPENING STATEMENT OF SENATOR KIRSTEN E. GILLIBRAND, RANKING MEMBER

Senator GILLIBRAND. Thank you, Chairman Scott, for today's hearing. Thank you to all our witnesses for being here today. We really appreciate you. I'm looking forward to continuing our robust discussion on ways to improve and secure our domestic generic drug supply, which includes ensuring that pharmaceuticals entering the United States are of the highest quality and standard.

During our previous hearing, we heard about some of the problems that consistently plague the generic drug industry and some proposals to begin to help to address the issues. Today, we will dig deeper into some bipartisan solutions that this Committee and other committees of jurisdiction can work on together to ensure Americans can access high-quality drugs that they need when they need them.

Currently, too many active pharmaceutical ingredients and key starting materials are made outside the United States. Given recent instability in geopolitics and international trade policy, this reliance increases the risk that Americans may not have access to life-saving drugs in times of crisis, threatening our national security.

However, we must approach strengthening and reforming this extremely complex supply chain thoughtfully and thoroughly. Generic drug manufacturers cannot simply flip a switch and move all components of production to the U.S. or other allied nations. To ensure Americans have a reliable supply of safe and affordable drugs, Congress will need to work to make more targeted investments in biotechnology, research, and infrastructure, to create long-term support and stability for this critical industry in our Nation.

We must examine the underlying economic dynamics in the current marketplace and adjust incentives to fix the ″race to the bottom″ in generic drug pricing, which can create drug quality issues, drive manufacturing outside of the U.S., or cause companies to stop production of certain drugs altogether.

Additionally, we must strengthen the ability of federal agencies to ensure strict oversight of foreign manufacturing facilities, to strengthen the supply chain and enable patients to access the qual-

ity medicines they need. As we look to address these issues, we must make sure drugs remain affordable for our constituents, particularly our seniors, many of whom are on fixed incomes.

Americans are already struggling with high costs across the board, and I'm committed to working with Chairman Scott and my colleagues across the aisle to find solutions that serve our constituents by strengthening the generic supply chain, promoting quality domestic production, and protecting our national security.

I look forward to this robust discussion, as well as the future potential bipartisan legislation on the issue.

The CHAIRMAN. Thank you, Ranking Member Gillibrand. Now, I'd like to welcome our witnesses who are here to talk about their work to bring drug manufacturing of essential drugs back to the United States, and making sure the American people have access to the drugs they need.

First, I'd like to recognize Tony Sardella. Mr. Sardella is the founder and chair of the API Innovation Center, a non-profit that establishes public-private partnerships to secure a drug supply chain. He is a distinguished fellow for health innovation at the Olin Business School at Washington University in St. Louis. Thank you for the critical work you do and for being here today. Please begin your testimony.

STATEMENT OF TONY SARDELLA, FOUNDER & CHAIR, API INNOVATION CENTER, DISTINGUISHED FELLOW OF HEALTH INNOVATION, WASHINGTON UNIVERSITY IN ST. LOUIS OLIN BUSINESS SCHOOL, CHESTERFIELD, MISSOURI

Mr. SARDELLA. Thank you. Good afternoon, Chairman Scott, Ranking Member Gillibrand, and members of the Committee. As chairman indicated, I'm the founder and chairperson of the API Innovation Center, dedicated to building health security of our generic drug supply chain. I'm honored to be here this afternoon and share how our work at the API Innovation Center is addressing the severe challenge of a vulnerable U.S. generic pharmaceutical supply chain.

There are three key things that I want to share with you today. The first, is the U.S. generic drug supply chain is over-reliant on foreign manufacturers, and specifically placing our seniors and veterans at severe risk. Second, the API Innovation Center's private-public partnership model is showing promise in addressing this complex issue and the economic roots that drove the dependency. Third, policy instruments can foster increased U.S. private sector investment and production to address our vulnerabilities.

Our over reliance on foreign sources to meet our Nation's needs are quite stark. As Chairman Scott mentioned, research we've done found 83 percent of the top 100 generic medicines prescribed to Americans have no U.S. source. I'd like to share some new research we just conducted on behalf of the Committee.

Our mapping of generic supply chain reveals that for 10 of the most frequently prescribed medications for our elderly and veterans, 95 percent of those medicines have no U.S. API source. Even more stark, 84 have no finished drug production and they're dependent primarily on China.

This continues with the research we provided before that mapped our generic supply chain from drug all the way to key starter mate-

rials, and showed that for 40 critical medicines that we identified for our Nation to have its own secure supply, that the key starter materials were exclusively 100 percent dependent on China. For half of them, half of those critical medicines and nation require.

The API Innovation Center focuses on addressing this national security. It emphasizes modernizing existing idle domestic manufacturing that we uncovered through our research with manufacturers and doing so to ensure our resiliency and stable supply chain.

The model has three key components. First, investment of public funds that APEC has received from the State of Missouri, as well as from the bio map as per federal program. That capital modernizes the production methods to produce these medicines.

We not just bring back production, but we're producing it in modern, advanced, more efficient manners and also using new technologies, many of which have been developed here in the United States by equipment manufacturers. We take the investment in the new modern techniques and we contract existing idle FDA facilities that exist already to produce these modern methods of production.

Third, we partner with long-term agreements with end healthcare systems, national retail pharmacies, as well as drug production companies to be able to ensure predictable demand and supply for the entire network.

The approach is delivering promising results. Over 70 U.S.-based manufacturers are collaborating and entering into agreements with APIIC to build an end-to-end domestic supply chain capable of sourcing, developing, producing, and distributing cost-competitive, U.S.-made medicines, with a near-term focus on 25 priority medicines that we've itemized, and a long-term goal of 300 medicines made here in the United States.

The partnership enables the U.S.-based API and drug manufacturers to gain certainty of their demand and economic viability to produce in the U.S. It gives healthcare systems and national retail pharmacies certainty of supply and stability of cost, and our citizens and seniors gain a drug supply resiliency and we as a nation gain national security.

While innovative partnerships are essential, policy plays a decisive role. There's a need, a critical need to clarify and harmonize the definition of made in America. For pharmaceuticals, current procurement rules allow drugs assembled in America, but comprised of foreign APIs to be labeled as USA-made. Second, the Federal Government's purchasing power can be leveraged. Last, sustained public-private investment to modernize idle facilities. The vulnerabilities are significant but solutions visible.

Thank you for the opportunity to share our research and perspective.

The CHAIRMAN. Thank you, Mr. Sardella. Now, I'd like to introduce Tony Paquin, the co-founder, president, and CEO of iRemedy, a company from my home State of Florida, working to provide buyers with American made medical products. Mr. Paquin's company worked tirelessly to supply the Federal Government with medical supplies during COVID, and he brings a wealth of expertise into the medical supply chain.

Mr. Paquin, thank you for being here today. Please begin your testimony.

STATEMENT OF TONY PAQUIN,
PRESIDENT AND CHIEF EXECUTIVE OFFICER
IREMEDY HEALTHCARE, INC., STUART, FLORIDA

Mr. PAQUIN. Chairman Scott, Ranking Member Gillibrand, and members of the Committee. Thank you for the opportunity to testify.

For over 25 years, I've worked in the healthcare technology, logistics, and distribution. At iRemedy Healthcare, we manage an artificial intelligence procurement platform that supports manufacturers worldwide. My experience includes building software, scaling networks, partnering with hospitals, manufacturers, and government agencies, all of which has given me a clear view of how our supply chain actually functions on the ground.

That vantage point has revealed two urgent truths. First, that far too much of our production of essential medicines has been ceded to China and India, leaving our Nation dangerously exposed to weak oversight, counterfeit risks, and most importantly, price manipulation. Second, then an unintended consequence of that globalization is the concentration of our supply chain into a small group of intermediaries that restricts the flow of drugs into American hospitals, locking providers into contracts, and stifling supply chain and market innovation. Combined, these two truths are deadly.

I grew up in Flint, Michigan, and have seen firsthand the prosperity of an active manufacturing economy as well as the devastation when industries are hollowed out. Today, I'm here to say bluntly, we must end our dependences on foreign adversaries, and restore control of our medical supply chain to the United States.

During Operation Warp Speed, my company was a key supplier of needles and syringes. We delivered more than one billion items for the country's needs. What I witnessed during that period was alarming. At one point the Chinese Communist Party seized 40 percent of our China-based inventory awaiting shipment. We routinely dealt with bad actors attempting to bribe dock workers and factory managers peddling fake FDA 510(k) certifications.

As you know, the vast majority of prescription medicines are generic, yet those drugs overwhelmingly come from high-risk overseas suppliers. When supply lines are disrupted, we quickly see shortages of life sustaining medicines for conditions like diabetes, heart disease, and cancer oversight is essential for immediate relief.

We must enforce unannounced FDA inspections overseas as we do here in the U.S. We must require a clear country of origin labeling, and independently validate imported shipments for quality.

These are Band-Aid fixes that do bring transparency and deter quality failures, but they won't fix the problem. The only real cure is to reshore the supply chain, and I'm here to report that we can do so. First, APIs nearly all come from overseas, especially China. We must invest in new technologies and fast track permits for factories. We must treat this as the national security issue that it is and prevent bureaucratic delays.

Second, generic drug manufacturing. Here's the truth. The technology already exists in this country to make generics profitably without raising costs for consumers. What we lack is fair competition. Generics are often a commodity, and foreign governments have learned how to weaponize commodity pricing against us. Until we level that playing field, American manufacturers will never have a chance to compete.

Let me give you a real-world example. Oxford Pharmaceutical is an Alabama-based generic drug manufacturer with the capability to produce life-giving medicines domestically. They're a high-quality modern U.S.-owned example of American manufacturing excellence. They make drugs here in America efficiently, safely, and at scale.

What stands in their way is a market that has been deliberately tilted against domestic producers. Even when companies like Oxford can produce at competitive costs, they're forced to compete against artificially subsidized Chinese and Indian importers that are all too often unfairly awarded U.S. Government contracts. Shockingly, this happened to Oxford just a few months ago.

That system has to end. We must protect American producers with targeted licensing and trade enforcement. We must use artificial intelligence to overhaul the drug marketplace, and reform federal procurement so that U.S.-made drugs are the default, not the exception. If given fair access, domestic manufacturers can compete and win. If not, we remain captive to adversaries abroad.

President Trump has shown leadership with executive orders to prioritize American made medicines, but we need an all-government response involving regulation, legislation, and procurement. We must act now. First, apply the immediate Band-Aid fixes; unannounced FDA inspections overseas, clear country of origin, labeling and randomized testing on imported drugs.

These bias transparency, and time, then cure the disease reshore API production with new technology manufacture domestics generics domestically with fair trade protections free from foreign price manipulation, and use the full weight of government purchasing power to put resilience above cheap imports.

Members of the Committee, this is not just economics. This is sovereignty. This is national security. It is needed to protect our seniors, our soldiers, and our families when the next crisis strikes.

Thank you, Mr. Chairman, for your leadership, and to the Committee for this opportunity.

The CHAIRMAN. Thank you, Mr. Paquin. Next, I'd like to introduce Andrew Rechenberg, with the Coalition for Prosperous America, a nonprofit organization that represents American manufacturers and producers across a number of industries and sectors, to support domestic industry and protect our national security. Mr. Rechenberg has experience with the Department of War, as well as the Department of Commerce, and is an expert in trade industrial policy.

Mr. Rechenberg, thank you for being here today. You may begin your testimony.

STATEMENT OF ANDREW RECHENBERG, ECONOMIST, COALITION FOR A PROSPEROUS AMERICA, WASHINGTON, DC

Mr. RECHENBERG. Chairman, Ranking Member, and members of the Committee, thank you for the opportunity to testify here today. My name is Andrew Rechenberg, and I'm an economist with the Coalition for Prosperous America, leading analysis on pharmaceutical supply chains and domestic manufacturing.

America's medicine supply chain is in a crisis. Two decades of offshoring have caused domestic pharmaceutical production to fall from 84 percent of the U.S. market in 2002 to just 37 percent today, leaving 80 percent of active pharmaceutical ingredients with no U.S. source whatsoever. India and China have captured the market by undercutting American producers, not through efficiency, but through state subsidies, poor labor standards, and safety shortcuts.

This dependence has consequences. As U.S. production collapsed, drug shortages tripled from 88 in 2002 to more than 300 in 2024, driving 300 to 500 percent price hikes that erased any supposed cost savings. This is because 40 percent of our essential drugs rely on only a single manufacturer.

When I was in Pharmaceuticals in India and was shut down in 2023 for falsified data and safety failures, U.S. hospitals had to ration chemotherapy because one factory made half of our cisplatin supply. These failures show what happens when we chase the cheapest offshore medicine instead of safe American production. That is not resilience. It is a national security breach at the heart of America's healthcare system.

It can be fixed. At CPA, we've developed a five-pillar strategy to rebuild pharmaceutical independence. Pillar 1, the tariff rate quota system restores control. The TRQ allows a limited volume of imports from trusted countries at zero tariff rates. Imports above that quota volume or from high-risk nations face steep tariffs. Quota volumes are based on the gap between total U.S. demand and current U.S. production, then adjusted each year as capacity grows.

Trusted in-quota countries would be limited to those with equivalent FDA-recognized safety standards. This TRQ system rebuilds capacity steadily without disrupting short-term supply.

Strengthening domestic production directly is just as vital. Pillar 2, the PILLS Act, provides production and investment tax credits for U.S. made generics, active pharmaceutical ingredients and biosimilars, plus a domestic content bonus for U.S. sourcing. This creates the conditions for sustained growth in U.S. pharmaceutical manufacturing.

Rebuilding does take time. Pillar 3, FDA reform, ensures the safety of current imports. Ninety percent of foreign FDA inspections are pre-announced, and many plants go five years or more without review. When inspections do occur, they often reveal falsified tests and unsafe conditions, reflected in studies showing that generics made in India have a 54 percent higher rate of severe adverse events.

Yet, for imports, the FDA still relies on company paperwork instead of independent testing. We can address all of this by requiring independent batch testing for imported drugs in U.S. labs, reg-

ular unannounced foreign FDA inspections, and strict penalties for offenders, including import bans.

Next, Pillar 4, federal purchasing realignment treats medicine procurement as a matter of national security. It ensures that federal programs prioritize reliable U.S.-made medicines. This aligns directly with the pharmaceutical supply chain, Defense and Enhancement Act to strengthen domestic resilience and minimize reliance on risky and adversarial nations.

Finally, we must look to the frontier of medicine. Pillar 5, biotechnology leadership. The U.S. must invest heavily in NIH and biotech startup innovation, and raise clinical trial standards that protect U.S. patients and ensure drug quality. These steps will ensure the next generation of cures is discovered and made here at home.

These five pillars are how we end shortages, ensure safety, and restore America's capacity to make the medicines our people depend on. America's medicine system is fragile by design, but it does not have to stay that way. Congress can act now to rebuild what was lost, and ensure that never again will our patients, our hospitals or our troops depend on foreign supply for life itself. Thank you.

The CHAIRMAN. Thank you, Mr. Rechenberg. Now, I'll turn it over to Ranking Member Gillibrand to introduce our next witness.

Senator GILLIBRAND. Thank you, Chairman Scott. I want to move to introduce our next witness, Dr. Marta Wosińska. Dr. Wosińska is a senior fellow at the Brookings Institution Center on Health Policy, with expertise in prescription drugs and pharmaceutical supply chains. Dr. Wosínska previously served in the Federal Trade Commission, in the Office of Inspector General at the U.S. Department of Health and Human Services, and the U.S. Food and Drug Administration Center for Drug Evaluation and Research. She's also served as economic advisor to the U.S. Senate Finance Committee. You may begin.

STATEMENT OF DR. MARTA E. WOSIŃSKA, PH.D., SENIOR FELLOW, CENTER ON HEALTH POLICY, THE BROOKINGS INSTITUTION, WASHINGTON, DC

Dr. WOSIŃSKA. Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee, thank you for the opportunity to testify at this important hearing. My name is Marta Wosińska, and I'm a senior fellow at the Brookings Institution. Today, I speak in my personal capacity, reflecting nearly 15 years of studying drug supply chain issues from within the government and outside, and with no financial stake in the outcome.

Over all these years, I have observed what policy solutions catch the interest of lawmakers. I have seen that many of the solutions that resonate sound good, but they don't address the problem that lawmakers claim they want to solve.

Today, as we talk about solutions, I urge you to ask the following questions; What specific problem is the solution meant to address? What else is needed for this solution to succeed? How do we handle the unintended consequences? Is this the most effective and efficient cost effective and efficient path? Only when you ask these questions, you will be best prepared to design policies that not only

do the job well for patients, but also assured that taxpayer dollars are used wisely.

For instance, if persistent drug shortages in hospitals are the top priority, durable solutions require shifting hospital incentives so that reliability, not just low cost is valued. Transparency to hospitals around supply chain reliability will be important, and you will want to keep far away from tariffs unless you fix various payment systems.

If the concern centers on China, then the focus should be on antibiotics and, —for pretty much any other drug— the focus should shift upstream away from pharmaceutical production steps and toward chemicals that are not regulated by FDA. You will also want to think about how to leverage India in de-risking from China.

If the objective is to increase domestic drug manufacturing, which by the way, is a solution to supply concerns, not the problem, then any new facility counts as progress, regardless of whether it addresses areas of critical need or shortage risk. If domestic manufacturing is the goal, then you may not pay as much attention to whether policies designed to promote onshoring like tariffs could destabilize supply.

What if we're concerned that weak FDA oversight abroad creates opportunities for defective drugs making their way to American patients? Onshoring could help because we will be building newer, more automated facilities, and FDA would have an easier access to these facilities.

Let's be realistic. Onshoring will require government support to undo the economic forces that moved production offshore. In fact, a lot of government support. With constrained budgets, this means policymakers should prioritize. I would urge you to consider that essential medicines and choke holds with China are much more pressing onshoring targets than Indian-made statins or blood pressure medications.

Fortunately, we do have other options for addressing product defect risks in commonly used medications. FDA can create greater quality assurance by increasing unannounced inspections, and Congress can support FDA by providing more resources, but we would need to do more because many industry observers and compliance professionals tell me that the current inspection-based model for oversight is not enough.

This is where I urge the Committee to consider the proposal I published this morning, which would require every importer to designate a qualified person based in the U.S. with personal responsibility for verifying that each batch meets quality standards. Mandatory product testing would be part of that process. This system is already working for drugs in Europe and has precedent in U.S. drug regulations and other U.S. sectors like finance, where CFOs must personally certify financial disclosures.

To conclude, let me reiterate that lasting policy must focus on clearly defining the problem, aligning incentives, so the right behaviors follow, and adapting proven practical solutions from other settings facing similar challenges. When reforms are grounded in clear objectives and match to the challenge, they will best protect patients and ensure prudent use of public resources.

Thank you again for inviting me to participate. I look forward to your questions, and to this Committee's leadership in advancing meaningful reforms that will enhance both the quality and reliability of America's drug supply.

The CHAIRMAN. Thank you, Dr. Wosińska. Now, we'll turn it over to questions we'll start with coach Tuberville.

Senator TUBERVILLE. Thank you, Mr. Chairman, and thanks for the panel being here today. I'm going to ask the obvious question, Mr. Rechenberg. If we closed our borders, do we have the ability, and the assets, and the chemicals that we could mine to make every drug that we need in this country?

Mr. RECHENBERG. No, not currently. That's why in the TRQ plan that I'm proposing, we do work with trusted countries with regulatory standards equivalent to our own. The FDA already recognizes this through mutual recognition agreements with the European Union, the United Kingdom, and Switzerland as well. We do have enough capacity when working with trusted equivalent regulatory nations like that, but currently on our own, no, we do not. That's why we need to rebuild this capacity.

Senator TUBERVILLE. Would we have to use China at all?

Mr. RECHENBERG. No, we would not.

Senator TUBERVILLE. Okay. Good. Mr. Paquin, when you talk about how companies like Oxford Pharmaceuticals should be used as an example of how it is possible to own shore drug manufacturing in a competitive environment?

Mr. PAQUIN. That's correct, Senator. They are a very well run, significantly sized, highly automated production facility in Birmingham, Alabama. They really can produce pretty competitively. I think sometimes, we sort of misunderstand a little bit of the cost factor of these drugs.

Amlodipine, for example, costs about two cents a dose to manufacture, but it is reimbursed by Medicare Part D at 10 cents. Actually, the manufacturing cost is a very small part of the total cost that ends up going to the consumer or to the payer. The manufacturers like Oxford Pharmaceutical here in the United States can operate pretty competitively if they're not at target of unfair competitive practices coming out of India.

Senator TUBERVILLE. What changes do you think we need to make to have Oxford and other companies to be on a level playing field? What do we need to do?

Mr. PAQUIN. Well, I think there's really two main things we can do, but there's two immediate actions that we could be looking at. I think Andrew and the Coalition for Prosperous America made a good recommendation about, you know, quotas based on the marketplace, and not allowing a country like India to overwhelm our supply, thereby driving down the value of those drugs.

Second, the VA and the U.S. Government should really prioritize domestic manufacturing over foreign manufacturing, and that is something that can be done without any major additional cost to the government and is not happening currently.

Senator TUBERVILLE. You mentioned in your testimony that Oxford has modern FDA-approved facilities, but still loses contracts to virtual importers tied to China and India. Can you explain what that says about the way our current system works?

Mr. PAQUIN. Well, first off, I would say it doesn't work very well in terms of recognizing the national security implications and just the good sense of supporting a domestic manufacturer. Those contracts that they recently lost were probably a lowest price, technically acceptable type of contract.

I think what's happening there is the VA is really not applying the right way to think of technically acceptable. All generic drugs, I would argue, are not equivalent. A generic drug manufactured in Birmingham, Alabama, is probably going to be much higher quality and reliable than a drug made somewhere in India where we don't have good access to surveillance of that manufacturer.

I think that—and then also, when we look at technically acceptable, we should consider resilience issues, investing in our domestic manufacturing capability should be one of the considerations when somebody like the VA is putting a contract out for bid.

Senator TUBERVILLE. Thank you. Mr. Rechenberg as we saw during COVID, United States is way too relying on China, we mentioned that, and India. How can a well-designed tariff rate quota system be used to strengthen domestic production and mitigate shocks or supply shortages in the U.S. market?

Mr. RECHENBERG. Yes. The main cause of the supply shortages in the market right now is disruptions to these very few sole manufacturers in China and India. We're very much reliant on the single source vulnerabilities, but if we give the market space for U.S. producers through a tariff rate quota system, it very much encourages companies to reinvest in the U.S. and bring production because there's this guaranteed market space that domestic producers can capture.

Over time, it will bring back and diversify our supply base, which will lead to less shortages over time as we have more backup options and more U.S. domestic supply.

Senator TUBERVILLE. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Ranking Member Gillibrand.

Senator GILLIBRAND. Senator Kim.

Senator KIM. Thank you. Dr. Wosińska, I wanted to just start with you. I was intrigued by what you raised in terms of that idea about the EU-qualified persons. I guess I just wanted to start by just asking, does the framework like that model already exist in other sectors in the United States? I felt like you said something about on the finance side and others, but I just wanted to get a little bit more clarity from you just how novel of an idea this is.

Dr. WOSIŃSKA. It's actually not a novel idea. I mean, for one, it has been used in Europe for decades, but in the United States, in terms of FDA and something that FDA is already familiar with during when FSMA passed, so the Food Security Modernization Act, there are a couple of programs for drug importers.

I discuss in the paper that I published earlier today where the importer is an extra layer of verification that the product that is being imported into the United States, they have to do a certain set of checks, and in a sense, verify. There's a person who is responsible for verifying and signing off that everything meets the standards that are expected.

We have that, we have it in the Sarbanes-Oxley Act. It's the same general concept that somebody takes on personal responsi-

bility for what is being put forward. It also exists in an of other professions where there is actually this kind of accountability that's added.

Senator KIM. Given your knowledge about, you know, our markets and our structures here in terms of this industry, how challenging would it be to be able to implement this? How significant of a change would this create?

Dr. WOSIŃSKA. You would have to modify legislation. You would have to—the HELP Committee would need to make changes to the Food Drug and Cosmetic Act. That would be necessary.

In terms of how big of a shift it would be, it would depend how it would be designed. I don't think we have enough time to kind of go into the details about what are the levers, but for example, the qualified person framework in Europe applies to every manufacturer, including domestic European manufacturers.

Here, the idea is to, in a sense, complement what FDA is already doing, complement the areas where they are struggling much more, which is with countries that don't have comparable regulatory systems, and so, you could narrow it down in that particular way.

You know, there's a question, do you do it? There's mandatory testing that Europe does, and the product actually have to make it into Europe first before it gets tested. It sits there in warehouses. Would that be necessary? It adds to cost, but then it also adds a certain level of assurance.

One thing I would like to mention is that there are different ways of trying to solve this and level the playing field. If you were to ask me, I would prefer to level the playing field in a way where we actually have this kind of quality assurance, because overnight, we're not going to be able to switch away from our reliance, especially on India.

India in 2024 produced 61 percent of solid oral dose products that we sell in the United States, and the full market is 187 billion pills, and India makes 60-61 percent of them. We're talking about 180 different facilities. We're talking about API facilities of probably over 200, well over 200. The size of this is massive, and I think we need to prioritize. One way for us to deal with that is to save onshoring for priorities and figure out some other ways to deal with manufacturing quality.

Senator KIM. Well, I think the idea is that we can have multiple tools that don't have to run sequentially——

Dr. WOSIŃSKA. That's right.

Senator KIM [continuing]. but simultaneously. Mr. Rechenberg, you raised the issue about independent batch testing and things that are somewhat similar to what we just heard. I don't know how familiar you are with this qualified person model. What's your sort of initial reaction to that, and what else can we be thinking about in terms of independent batch testing?

Mr. RECHENBERG. Yes, I think that this is also a critical point for anything that we're currently importing needs to be verified for quality. Because a lot of the time, in the U.S. currently, we're getting drugs that are imported, and we only find out after the fact that they have these bad tests, and then they're recalled, and U.S. patients have already taken them.

If we adopt a more European-style model where we have this independent batch testing that in order to have these drugs released into the U.S. market, they have to be tested and verified that they are quality drugs, that they work for what they say they're going to work for. Then this will greatly reduce the risk. This is an essential first step.

Senator KIM. You think it's worth exploring these different ideas that are out there?

Mr. RECHENBERG. Absolutely.

Senator KIM. Okay. Well, thank you so much, and with that, I'll yield back.

The CHAIRMAN. Senator Johnson.

Senator JOHNSON.

Thank you, Mr. Chairman. You know, having supplied the medical device industry for close to 30 years, I mean, this is just quality control 101 we're talking about here. It's actually shocking it's not in place. Chairman knows I'm big into data, so I want to understand the raw material supply chain here. We talk about precursor chemicals. Approximately, how many precursor chemicals do you need? What's the universe of that? I'll ask you, Mr. Paquin, or whoever knows it.

Mr. SARDELLA. I could say within one dimension. We looked at 40 critical medicines. They were based on seven foundational chemistries, so seven to make the 40 started with raw chemistry, seven raw chemicals, they got converted into key starter materials. Those got converted to active pharmaceutical ingredients and then drug. The ratio is not of magnitudes of order that's insurmountable. It's achievable.

Senator JOHNSON. How many total drugs are we—how many total drugs? Anybody have a number?

Mr. SARDELLA. It is 3,200 approved drugs for use in the United States.

Senator JOHNSON. Over 3,000?

Mr. SARDELLA. Correct.

Senator JOHNSON. How many active pharmaceutical ingredients comprise those 3,000 drugs?

Mr. SARDELLA. We don't have specific data on it, but I would say in the hundreds, not thousands, by any means.

Dr. WOSIŃSKA. For API it would be the same number. Because a drug is the API. It would be the same number, but the question is how many intermediates, or reagents, or solvents, or key starting materials, that will be less.

Senator JOHNSON. Again, I'm just—so are there 100 precursor chemicals, or is that overstating the case?

Mr. SARDELLA. Probably, a little higher than 100 as raw chemicals. I mean, within magnitude of order.

Senator JOHNSON. Almost all those are produced in China.

Mr. SARDELLA. A predominant number of those are produced in China. Our chemical manufacturing base moved to China many decades ago, and they control that.

Senator JOHNSON. If you're getting a brand name drug, are those precursor chemicals for the brand name drugs produced here in America?

Mr. SARDELLA. No. They would be likely also produced elsewhere. Keeping in mind that most of our new branded drugs are biologicals, and we're talking about drugs that are called small molecules. They're chemically derived.

Senator JOHNSON. We are highly deficient in the base raw material, right, the precursor chemicals. Most in China, even with brand name drugs, that's a precursor chemical coming in from China. Is it easier to quality control than the active pharmaceutical ingredients?

Mr. SARDELLA. The key starter materials from a control standpoint still have issues in regards to their quality. If you want to say, like, impurities still exist in those key chemicals——

Senator JOHNSON. Because we're taking those precursors chemicals now for brand drug, are they also getting the API then primarily?

Mr. SARDELLA. That is correct.

Senator JOHNSON. Then, they're just stamping the pill. Dr. Wosińska, you're shaking your head.

Dr. WOSIŃSKA. API is largely for branded drugs, is largely made in the United States and Europe.

Senator JOHNSON. Okay, say that over again?

Dr. WOSIŃSKA. For branded drugs, API is overwhelmingly made in the United States and Europe, but using——

Senator JOHNSON. Not in China, but using precursor chemicals primarily from China.

Dr. WOSIŃSKA. Only if they are small molecules. Back to the point that Tony made, if you have biologics, the ones—and a lot of the branded drugs are biologics, those are made with an entirely different process. That's not chemical. You actually grow them in cells.

Senator JOHNSON. Okay. Then that's done here in the U.S.?

Dr. WOSIŃSKA. That would be done in U.S. and in Europe.

Senator JOHNSON. The precursor chemicals, that's a frightening process, requires permitting. Why was that off shored? Because of permitting process? Or is there any kind of—I wouldn't think in big man, you know, large refining process, you're going to have much cost advantage due to offshore. Is it a primary problem of permitting?

Mr. SARDELLA. No, the genesis of that offshoring had multitude of factors. One was regulatory oversight in the United States for those facilities versus foreign, the cost of labor in foreign countries versus the United States.

Senator JOHNSON. Refining, you got a lot of equipment, and there's not many people hanging around a refinery plant.

Mr. SARDELLA. Well, and the third part was this a desire not to have those facilities here or near populations in the United States

Senator JOHNSON. Because it's a dirty manufacturing process.

Mr. SARDELLA. Just large emissions, large facilities.

Senator JOHNSON. Correct. We're going to first have to overcome that. There're basic and precursor chemicals, and we have to have that honest discussion.

By the way, Dr. Wosińska, you know, we are staying on the same hymnal here. You know, solve a problem. You had to first properly define it. That's why I'm—again, I've only got five minutes. I'm ba-

sically out of time here. We need to properly define this problem. We need to understand the raw material supply chain. We need to understand volumes. We need to understand how many—what we're talking about. Before we leap to a solution that's mistargeted, but let's get all this data down. Again, this, Mr. Chairman, I really appreciate this hearing. This is extremely important. We need to fully understand this. We need more data.

Mr. SARDELLA. If I could add to it, one of the things I'd mentioned was the fact that we're not just reshoring, we're using advanced technology. The ability to convert those large facilities into equipment that fits on this table is a critical added value. Bringing it to United States with advanced technologies, advanced equipment that allow us to make those facilities smaller, cleaner, and more efficient.

Senator JOHNSON. But let me, final point. Doing a QC check on even imported drugs, this is not rocket science. Now people can cheat on it, it needs regulatory oversight. This should not be hard. It's shocking that it's not already in place. It shows the failure of our federal health agencies. Truthfully, it's the utter failure that this is happening today.

The CHAIRMAN. Well, the fact that we don't have, we don't have a supply chain, we don't have a map, right? There was no—we haven't thought about having a map. We've allowed ourselves to be so dependent, it doesn't make any sense.

Senator JOHNSON. We've known about these drug shortages for a long time and we've done nothing about it. Thank you, Mr. Chairman.

The CHAIRMAN. Ranking Member.

Senator GILLIBRAND. Thank you, Mr. Chairman. I welcome this Committee's eager efforts on this issue, because I think we can make a difference on a bipartisan basis on this.

Dr. WOSIŃSKA. Let's talk a little bit more about China, specifically. You mentioned your concerns about antibiotics, and that should be prioritized. Tell us what else you think should be prioritized. What specific medicines do you believe are most vulnerable to dependency? Lay the out the risk for us.

Dr. WOSIŃSKA. Thank you for this question. I think every one of us here at this table would agree that antibiotics are by far the most vulnerable. If you actually look at India and what the Indian government is concerned about, they are also themselves very nervous about their own reliance on China, especially around antibiotics.

A lot of the subsidies that they are doing is to actually de-risk their own supply chains, actually on our behalf to a large extent, so, this is great because they're invest, they're making these investments without the American consumers having to pay, for taxpayers to pay for this, but there's this concern about antibiotics. That's by far the most concerning. I think it's much more difficult back to the mapping exactly which drugs have the largest exposure to China other than that.

I would say is, that we don't have to figure that antibiotics need support and we need to move on other things. We do need to do more homework and understand it. I will say that in terms of mapping, I am a little wary about mapping it for everything. I would

much rather start with: here are the essential medicines, and here, let's figure out where they come from, because those are the ones that we know we will be able to secure

I would probably start prioritizing drugs first in terms of their importance, and then really in detail mapping, because it's not just figuring out where the KSM comes from. The key starting material is only one of the chemicals that you use. You need reagents and you need solvents. Those are largely made in China.

You need to know all the pieces. If you try to do this for 3,000 drugs, we're going to be stuck in analysis paralysis for a really long time. I would say yes, absolutely mapping, but let's prioritize where we map first.

Senator GILLIBRAND. Does anyone want to add to that answer from their perspective?

Mr. SARDELLA. I do. On the mapping, one of the things we've found is we have worked to map several hundred, is that there's purposeful obfuscation of where the supply comes from and so on.

Senator GILLIBRAND. By whom?

Mr. SARDELLA. By companies in China, who in other areas where they don't——

Senator GILLIBRAND. They pretend they're from the United States.

Mr. SARDELLA. Correct. They are many different versions of a company. You can't quite track back to is it produced in a China facility? It could be a multitude of reasons. It could be that maybe the facility has some sort of FDA warning. It could be just based on business and ownership structure that they don't want it to be known who owns which company. It's very difficult.

We've found that although we're working through it, there are data sets that allow you to identify where those sources of are coming from, from beginning to end.

Senator GILLIBRAND. Tony or Andrew, do you have anything you want to add to the China problem?

Mr. PAQUIN. Yes, I would just add that I think it underscores our inability, ultimately, to have oversight into China, and to really understand what the problem and the sourcing is. I agree that we should focus on essential medicines. That's a definable problem. We can zero in on that. I think the strategy is to then move that into domestic manufacturing as quick as possible. Then we have control of the supply chain.

Mr. SARDELLA. If I could add to that. We've also taken a lens on not only essentials because some of these are very, very low-cost medicines, but also what do the healthcare systems need? What do national retailers need? What does the government need? What makes economic sense to produce here in the United States with advanced technology? When we put those lists together, we did come together with a prioritized list where it makes economic sense. There's demand for those medicines, there's a need for them and they can be a sustainable investment by the us.

Senator GILLIBRAND. Have you submitted that list to us?

Mr. SARDELLA. We've submitted it in collaboration with ASPR, and be happy to submit those as well.

Senator GILLIBRAND. Please submit it to the Committee.

Mr. SARDELLA. I'll be happy to.

Senator GILLIBRAND. Andrew?

Mr. RECHENBERG. Yes. The final part that I would add is that this does have to be a drug-by-drug approach, especially for a program like the TRQ. I agree that the antibiotics are one of the most critical and one of the most urgent to start on. These are going to have different solutions because they have different supply chains.

Additionally, I would say that India is not necessarily a de-risking from China. India has plenty of its own problems, whether it's safety issues, FDA flags that have been in Indian facilities. As on top of that, India had the same problems during COVID. They cut-off some of their supply to the United States, not because of any adversarial, geopolitical reasons, but they have their own population they're trying to supply. The more we can bring back to the U.S., the safer our supply chain will be.

Senator GILLIBRAND. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Moody.

Senator MOODY. Thank you, Chairman Scott. Thank you to our witnesses for being here today, especially a great Floridian. Always appreciate seeing a fellow Floridian.

You know, I think during the COVID years, a lot of things came to light that maybe Americans weren't paying attention to, even those in the industry. Dependencies for our drug supply chains on these four nations, I think, really started hitting home for a lot of people.

I don't think most Americans know that more than 50 percent of the manufacturers supplying our market, it's coming from overseas. I don't think they know that. I don't think that they know that, one of you mentioned, 80 percent of active pharmaceutical ingredients are manufactured overseas, or that China and India combined, make up 85 percent of active API filings. I don't think Americans understand that.

Just for having this hearing, I think, Chairman Scott, does Americans a service in shining a light on this specifically when you look at the fact that drug and API manufacturers in China and India receive the most FDA warning letters for violations, which can mean carcinogens and medicines destroying, or falsifying data and non-sterile manufacturing. Everybody's shaking their head, correct.

I mean, how long has this been prevalent, that we've been seeing these types of violations? Has that increased as our dependencies on these foreign nations has increased?

Mr. PAQUIN. I think this is a, you know, unintended consequence of the globalization activity over the last 20 years. Senator, and I think you make a very good point. COVID really created the awareness because it broke the global supply chain, and then we all experienced what you're referring to. I think that the average person in America is not really aware of this problem.

I do believe that there is a growing awareness that we didn't have maybe five or ten years ago. You know, when we talk about the various actions to take place, and obviously, I keep going back to the idea of bringing supply back to domesticating here, the United States. The idea of country of origin labeling on a medication would probably do a lot toward what you're describing, and that is making the average consumer, and by that, I mean not just

patients, but also the doctors, and pharmacists, and healthcare professionals aware of this risk, and that'll probably serve us well as we try and correct the problem.

Mr. SARDELLA. I wanted to add, when we commenced the initiative informed the API Innovation Center, it's only been three years in existence. The first study we did was a perception gap study, and that study looked at the perception of our reliance, of shortages, versus real data around the shortages.

What was striking at that time was the two most important stakeholders in our country underestimated the risk scientists and government. I really commend these hearings to expose that both from a government and a scientific community. By nation, we greatly underestimated the risk of shortages and overreliance compared to other nations like China, India, and Europe.

That perception gap is starting to close thanks to these types of sessions and the interest. We're working effortly to continue with our publications to close those gaps.

Senator MOODY. I have to imagine that if consumers had the information and the choice, knowing where about the increase in violations, I mean at this point is are consumers ever informed that where the main ingredients and the drugs that they're taking are manufactured?

Mr. SARDELLA. Very unlikely. There's no transparency. This is a very interesting concept. This is an industry like any other supply chain. Any other supply chain, you can look and understand where the product comes from, what the ingredients are, and where it's sourced. Not our pharmaceuticals.

Any other product that you procure has clarity where you can compare quality of that product. You cannot compare the quality of the pharmaceuticals as a result. One in every four prescriptions in the United States is from a facility that has an FDA violation. A quarter of the prescriptions have a violation. I don't want to create alarm. Some of them are simple procedural violations, but nonetheless, it means a quarter are being prescribed that have some sort of violation on the FDA. It is not known.

What's also striking is while we overestimate the cost when we work with manufacturers, we're talking like less than a penny to have a U.S. existing manufacturer manufacture that medicine here in the United States with the highest quality of manufacturing standards.

Senator MOODY. I'm out of time, but I hope you will explore, Mr. Chairman, as you do your questioning, the national security implications for a failure in that supply chain. Thank you.

The CHAIRMAN. Thank you, Senator. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman, and thank you Ranking Member for holding this hearing today. We're talking about a broken supply chain, and I was looking at the numbers on this.

The U.S. imports seven times the amount of drugs that we were importing in the year 2000. That's how much this has gone up, and you-all are discussing how our reliance on foreign-made pharmaceuticals exposes Americans to drug shortages, to safety risks, and exposes seniors more than anyone.

For years I've been working with my colleagues to try to advance reforms, establishing stronger transparency rules, closing loopholes in the Buy American requirements. I just want to say we've gotten a lot of pushback from people who make a lot of money by keeping all of this opaque, and maximizing their profits, and minimizing safety for the American people.

Today, I want to hit on something that you all have mentioned, and that is how we get more drugs manufactured domestically. How do we move our supply chain here to the United States. Mr. Rechenberg, you're an expert on drug supply chains. You know that other countries are subsidizing the manufacturer of prescription drugs. How does that affect our ability to make these drugs here in the United States?

Mr. RECHENBERG. Yes, and this is one of the main problems; that these foreign companies are being subsidized by their own governments. They're able to severely underprice U.S. producers and drive them out of the market.

We really need a comprehensive approach here, starting with something like a tariff rate quota system to create a space in the market for U.S. producers. We need to supplement that with direct production incentives for companies, whether through an act like the PILLS Act or through federal procurement. Federal procurement can be a huge part of this, and incentivizing and prioritizing American-made medicine.

Senator WARREN. Let's talk a little bit about buying here in the United States. The Federal Government could make it easier and less risky for manufacturers to make their products in the U.S. if we would just leverage the power of our federal contracts.

That means the government makes a deal with the manufacturer, and says, we guarantee we will buy a certain volume of drugs over the next several years. That makes it better for you. Make the investments, you get out there, you produce the drugs.

Now, the DOD actually has contracts for essential medicines, because for obvious reasons, it is important to make sure that our service members have the drugs they need as a national security issue. I have been pushing DOD to make those contracts, domestic production advances.

Mr. Sardella, you lead the API Innovation Center, and you've actually looked in to how many critical drugs rely on ingredients manufactured exclusively in China, I think you were talking about this earlier. Would it help national security to expand federal contracting programs at DOD and other agencies and focus them on domestic drug manufacturing?

Mr. SARDELLA. Absolutely. It would be a significant lever to bring back a strong U.S. industrial base for manufacturing. I commend all the incredible work you've done in this area. Then second, one of the elements that would be also very effective is shifting the contracting vehicle from what is an IDIQ, indefinite demand, indefinite quantity, in business.

Indefinite demand and indefinite quantity does not reduce the risk. There's no certainty you could lose a contract or volume turning that into a certainty of demand and volume and even cost or price so that a manufacturer can make an investment. We have a small business in Missouri where we've placed two medicines for

manufacturing for a healthcare system. We've provided them our technology that we developed. They are now making investments to expand their facility because they have certainty that the healthcare system is giving them a long-term agreement. If the newest government did the same, we expect the same.

Senator WARREN. You and I are in the same place on this; that more robust federal contracting can create the kind of sustained demand that manufacturers need so that we can eliminate these supply chain vulnerabilities and protect our national security.

For me, that is reason enough to implement them. Some critics have warned that, oh, if you shift to American-made drugs, it will be too expensive. On the other hand, we're paying a price, A for vulnerability, and B, if our seniors end up taking drugs that are ineffective and so they are sicker, they stay sick, or if our hospitals are getting price gouged during shortages.

Mr. Rechenberg, do you think that shifting to more domestic manufacturing of pharmaceuticals would over the long run cost more money or save more money?

Mr. RECHENBERG. It would save far more money. We've seen, as I mentioned in my opening statement, 300 to 500 percent price hikes during a shortage. That's one way we would save money, but also, we're paying a lot more every time the medicine's not there, and the PE have to be in the hospital longer, or you have to have substandard medicine or the hospitals have to pay extra staff to take care of people. Over the long run, you save much more money than you would otherwise because you stop these shortages and you guarantee safer, more effective medicine.

Senator WARREN. Thank you. You know, Americans shouldn't have to worry about the quality of their prescriptions, whether they're safe to be able to take, whether they're effective, what will happen if the supply chain breaks. For me, that's reason enough to manufacture right here in the United States and using federal contracts to lower those production costs.

I think there are a lot more benefits for doing this. That is why I have a bill, the Pharmaceutical Supply Chain Defense Enhancement Act that would do just that. I hope we can get some bipartisan support and get that moving. Thank you very much. Again, thank you Mr. Chairman for holding this hearing today.

The CHAIRMAN. Thanks. Senator Warren, we served on a subcommittee together, Subcommittee on Armed Services. We had she had a hearing and the individual from DOD tried to explain that he couldn't buy American because there's regulation that required him to buy foreign, and then, we found out that there was no regulation.

Senator GILLIBRAND. I think there's a regulation that says to buy the cheapest. There's always a cheap thing, and that's the problem that we talked about.

The CHAIRMAN: He couldn't explain.

Senator GILLIBRAND. He probably didn't know.

Mr. SARDELLA. We have analyzed those costs for specific molecules among our industrial base, and we verify that they can be produced by U.S. manufacturers an equivalent price. What's preventing that is certainty that they will have a long-term agreement to supply it so that they can make the investment.

Then, second, we submitted data for the Congressional Budget Office based on this bill that showed one must and think of it as one temporal point in time where an adversarial country or a foreign manufacturer purposely to drive out, all U.S. manufacturers put the price way below the cost.

If you look at it on a five-year average, as Andrew said, you would save significant dollars because once they drive every U.S. manufacturer out, they increase the price, massive volatility. It has to be looked at from a budgeting office on a five-year average basis. That's not even, to bring in what Andrew said, it costs over tens of millions of dollars per shortage of drug within a healthcare system. They're incurring significant costs of those shortages as well.

The CHAIRMAN. You know, and I just get followup——

Senator WARREN. I was just going to say, I get really frustrated on this, that people treat risk as if it's free. We are paying a price for risk, for the fact that yes, we got it right down to the tightest nickel on how to purchase this stuff. It's a very fragile system for way, just pay for another way. That's a cost.

The CHAIRMAN. We'll go back to what Senator Warren was bringing up. If we had—if we took the DOD and we took the VA, right, if we just took those two and they—I'll just take their drug buying, would that be enough volume to move volume?

Mr. SARDELLA. You would transform the U.S. generic supply chain, and you would also cause a force function for private markets to then also now procure from U.S. manufacturers, because of the reasons we just said, you don't want a quarter of your pharmaceuticals in an FDA violation site. You want to have certainty in local response time resiliency. You would fundamentally transform our generic supply chain.

The CHAIRMAN. What percent of the generic drugs that the—if the DOD and VA did just their generics, what percent of the volume that come into the country, would that be you? Just like, is that of 100 percent of generics sold? What percentage does DOD of that 100 percent and VA together.

Mr. SARDELLA. Oh, I don't have specifically those numbers, but it from a standpoint of moving the market and creating an industrial base, 200, 300 medicines into generic would cause a significant resiliency base and a U.S. manufacturing base.

The CHAIRMAN. All right. Then Mr. Sardella, so you've worked with companies that have opened up plants——

Mr. SARDELLA. Expanded.

The CHAIRMAN [continuing]. so have they been able to make the price almost equivalent to what's being bought from overseas?

Mr. SARDELLA. Correct. With new technology. We're not just saying make it the same way. We're through the private investment in public from State of Missouri and ASPR, they're making it in modernized methods. I give the example, it's like they currently make them in batches, the size of this room. Now, they make them in equipment that's the size of this table.

The CHAIRMAN. Do you have what the return on investment is? Do you know if—so if you were going to invest, how much would it take to open up a plant and how, what would be the how long would it take to get your money back? Do you have any idea yet?

Mr. SARDELLA. On some of the drugs, because we're focused on expansion because there's 30 billion doses of idle capacity in the United States, 30 billion just sitting there. We're focused on taking those idle facilities that are already FDA-approved. What it means is they can get the drug commercialized in less than five years and they get a return on investment in three years.

The CHAIRMAN. Three years. Okay. We actually don't have to invest money—I'm a business guy. If you gave me a three-year return, I'll do that every day. Right?

Mr. SARDELLA. Absolutely.

The CHAIRMAN. I mean, so, okay, so number one, we can get the cost down and number two, we can get the investor gets a return.

Mr. SARDELLA. Correct. The return's so strong that our partners are going and getting their own loans to be able to expand facilities.

The CHAIRMAN. What we got to do is go back to what Senator Warren said; we got to commit volume.

Mr. SARDELLA. Correct.

The CHAIRMAN. If just DOD and VA did it, and that's it.

Mr. SARDELLA. It'd be transformational.

Dr. WOSIŃSKA. Can I just add? It's in maybe 10 percent of total volume. I mean, it absolutely would bring some domestic manufacturing to the U.S., it would help secure supplies for VA, but it's too small of a fraction to really create change in the rest of the market. It's not to do it, I absolutely encourage you to do it. This is a perfect thing to that, you know, very sensible thing to do. We need to think beyond that because we need to sort of change the dynamics in the rest of the markets in the 90 or so percent, in the markets, to change how those markets operate and what they value.

The CHAIRMAN. Just a caution, I ran a hospital company, and I was two percent of the entire healthcare dollar. I focused on, you know, I could move all the volume in the whole country, I could force everybody to change based on buying, based on quality. Everybody had to change. I would just even—because nobody would, there's no—I was the biggest committed buyer in the VA. I think you're—what you said makes sense, but reality is most people are not committed buyers. That's why if we have really committed buyers, then I think it'd have a bigger impact.

Dr. WOSIŃSKA. I'm sorry that Senator Warren left because Senate Finance actually has a proposal on that that was put forward last year, that exactly does this; the idea for the most vulnerable supply chains, which are a lot of the generic sterile injectables is to create committed contracts, and then have add-on payments for choosing reliable manufacturers. Absolutely, the same concept. It really would be great to see movement on that side.

The CHAIRMAN. Have any of you done business with the DOD or VA?

Mr. PAQUIN. Yes, we've done business with the DOD and the VA.

The CHAIRMAN. Did they care about quality?

Mr. PAQUIN. No. You know, I was going to bring that up. I commented earlier about technically acceptable, and I think that's a mis defined term in this circumstance. They're not considering resilience. For example, they're not considering the benefits of supply chain, and they're viewing that drug overseas as equivalent to the

drug domestically made. I think that's the big mistake. I would say that what we could use would be a DOD set aside requirement for American made for example. I completely agree that the VA could lead the charge.

I think you'll find that private hospitals or the commercial hospital business that you're familiar with would actually follow that lead. I think they're ready to recognize the need for resiliency and stability in the supply chain. You need that big buyer to step up and start the process. I think that's the VA and the DOD.

Mr. SARDELLA. I can confirm what Tony is saying, because we are aggregating demand with healthcare systems and retail pharmacies knowing that this is a national priority for our Nation. They are willing, as he said, and that would give a further indication to aggregate demand across their systems to procure U.S.-based supply for the benefit of the system.

The CHAIRMAN. For each of you, if you had a choice, there's two different, same drug, and you had one little bottle that said, ″Made in the United States,″ okay. The other bottle said, ″Made in China.″ How many of you would buy same price? Look, they both look really nice. Same little, pretty bottle. How many of you would buy China?

Mr. SARDELLA. I might want to disclose that my original background is as a toxicologist in this context, I would absolutely buy the U.S. medicine.

The CHAIRMAN. Anybody buy China? No? What if it added on there that whether American or Chinese, that it's under an FDA violation, however small. There's some website that you can go to see what it was. Would that have an impact on you?

Mr. PAQUIN. Yes. Clearly, we would avoid buying anything that had an FDA violation. You know, when you think about something so sensitive as a drug, right, we're not buying a toy or a vitamin. We're buying something that affects our health in a very personal way. We'd buy quality.

The CHAIRMAN. The thing about the buyers in this country, Federal Government, hospitals, nursing homes, GPOs, doctors, pharmaceutical chains, have you known any of them that required—they did it based on quality?

Mr. PAQUIN. No, I regularly do business with all those entities, and they don't really require—they may want to, but there isn't a method for them to assess that quality as we've been describing. There's really no independent way to measure a report.

The CHAIRMAN. Good, but Tony, they could say, ″I'm not doing it. If you haven't had an FDA inspection within three years, I won't do it.″

Mr. PAQUIN. They could do it for sure.

Dr. WOSIŃSKA. Can I add something?

The CHAIRMAN. Sure.

Dr. WOSIŃSKA. I have studied generic sterile injectable shortages really for 15 years. Transparency often comes up that we don't know which manufacturer is reliable, but at the end of the day, it's the lack of incentives, and the fact that hospitals and GPOs do not fully internalize the harm that comes with it. The numbers that Andrew commented on——

The CHAIRMAN. Can you go through—when you say the harm, how would you define the harm?

Dr. WOSIŃSKA. Yes. The amount of money that hospitals—and there was a study, $360 million from additional costs resulting from shortages. It seems like a large number. This comes out——

The CHAIRMAN. Just because of costs.

Dr. WOSIŃSKA. Right. They have to have additional staff and whatnot that comes out to $60,000 per year. That's nothing for a hospital. That $60,000 is nothing for a hospital. If you look at how much for a day——

The CHAIRMAN. That's for a day, by the way,

Dr. WOSIŃSKA. This is for a year, right?

The CHAIRMAN. I know.

Dr. WOSIŃSKA. If that's the level of the cost, you know, hospitals are very strongly incentivized to buy the cheapest. In a sense, it makes sense. These drugs are therapeutically equivalent. You're paying for quality, right?

The CHAIRMAN. We're not paying for quality.

Dr. WOSIŃSKA. We are not paying for quality. We're not paying for quality. I will say that I have to disagree with Andrew here. I don't think there's free lunch. If we want to have reliability, if we want to have resilience, if we have to want to have quality, we will have to pay for it. I think it's a—you know, we have to ask ourselves how much are we willing to pay for it? But there are ways to do it, but you have to change incentives.

I think, you know, Civica Rx, I don't know if you're familiar with that organization, right? They do a lot of homework around where the drugs are made. They have stockpiles, they have long-term contracts. Hospitals are not signing up for these contracts. They're really wary about this because, oh, my goodness, they might actually end up paying more, right? We have to change the fundamental incentives, and shift sort of how hospitals are thinking about it.

The CHAIRMAN. Well, the problem—I used to be in the business, I just say nobody came to my hospital because I served Pepsi over Coke. Nobody came because I did this, you know, I had this drug or that drug, or I bought my drugs in the United States, or I bought my drugs someplace else.

Dr. WOSIŃSKA. There isn't accountability for hospitals either. If they have a shortage, they point as the manufacturer, right? It ultimately ends up with the patient, unfortunately.

The CHAIRMAN. Andrew, when you say that it pays for it, have you been able to do a study of what the additional costs, additional hospitalization, blah blah blah, any of those things? Have you done that?

Mr. RECHENBERG. Yes. We're currently working on a study to get an exact number here. From all the research that we've done so far, looking at the productivity costs, the shortage costs, and as well as just the worst patient outcomes, whether it's delayed care, rationed care, or getting substandard treatment, the cost vastly outweighs.

We're currently in the process of making a study to get an exact number on this, but it is clear already that the long-term cost is

much, much more savings than it would be by paying the marginally more rates in the beginning.

Then on top of that, I'll add for this buyer's side, for the hospital, because we don't have this mandatory country of origin labeling, the hospitals themselves often don't know what the supply chain risks are

The CHAIRMAN. Even if they wanted to do the right thing.

Mr. RECHENBERG. Exactly. Especially when it comes back to the API. They have so little visibility into the quality side, they have to go for the price, and that inevitably pushes things more offshore.

Dr. WOSIŃSKA. I can tell you that where it really does pay off is for the patient. There was one study that looked at one particular shortage, one shortage of a drug, and the fact that more patients ended up dying of septic shock because the alternative was not available. When you looked at the cost of life, and you calculated the number of patients that died, that single shortage cost over $13 billion.

Senator GILLIBRAND. The hospital doesn't pay that cost.

Dr. WOSIŃSKA. Exactly. The hospital does not pay that cost. There's a big gap between the——

The CHAIRMAN. It's worse.

Senator GILLIBRAND. You pay the hospital.

The CHAIRMAN. That's right. The worst is that we don't pay for results like we should pay. We should pay different. Like, if somebody doesn't do your car, fix your car, right, you don't pay, but every healthcare provider thinks, well, you still have to pay. Why?

Senator GILLIBRAND. The problem is, you're talking about dynamic scoring, which is not how the hospitals balance their budgets. When you do your analysis, you say it's only costing them $60,000 a year because they're not obligated to factor in all the costs and harm caused to the patient, or to society, or to any other stakeholder outside of their bottom line. That's the problem. Like, the costs are spread to us. The profits are given to the provider.

When they're doing their cost-based analysis, they're saying, ″Well, we are going to go with the cheaper drug.″ The DOD is the same. Every purchaser in the system today has multiple factors, but cost is almost always the factor. I believe——

The CHAIRMAN. It's the decision today, not the long-term cost.

Senator GILLIBRAND. Correct. No one does dynamic scoring. No one actually wants to bear the full brunt of the cost. I think part of this Committee's job is to really do all the pieces that you've all suggested; country of origin labeling, making sure we know the quality upfront, have an incentive as you say, to do the quality testing, make sure that the cost, as you've decided, Andrew is documented to the world, to the patient, to the United States.

Then to the other piece of national security that's not even you calculable. You can't calculate what will happen if we're at war. The risk if we're at war with China and you can't get antibiotics into this country and how many millions of people die, the cost of that is trillions of dollars. It's incomprehensible.

The truth is, this is a reason why no one's done this work before because the cost is incalculable. I'm really excited about the work this Committee's doing, and I think it's important.

The CHAIRMAN. It seems like if you go through the process to make movement, the easiest thing is because they report to us, DOD and VA, right, if they started buying based on buying American, that would move the needle, right? That would move it the fastest. The other is why doesn't—we talk about these violations, FDA, or the FDA knowing that we only have one supplier. Why aren't they doing something?

Mr. SARDELLA. In regards to diversifying?

The CHAIRMAN. Yes, I mean, why wouldn't they? I mean if they're responsible for us staying safe, right?

Mr. SARDELLA. Well, their mandate is to ensure that manufacturers comply with CGMP manufacturing practices, and that before they even produce those medicines, that they've been vetted through analysis of them. Going beyond as to managing the supply chain itself and saying how many, that would be outside their bounds in regards to what they would work on. I would also ask——

Dr. WOSIŃSKA. Yes——

Mr. SARDELLA. I would also say that—sorry Marta. Just one line. I would also say that that strategy also does something very different as well. It's a strategy of redirecting as opposed to countering, right, as opposed to countering and trying to counter India and counter China, which will be very resourceful, right? Being able to start with redirecting manufacturer through procurement U.S.-based requirements, U.S.-based prioritization.

Which by the way, we're the only nation that does not prioritize their domestic manufacturing source over foreign. The ability to do that is a far more higher probability of success because you're redirecting, you're not countering, which is difficult.

The CHAIRMAN. Did you want to say something? Okay. Just off the top of our head, we can think about the VA, DOD, we should have some sort of map. Even if we start, like you said, you can't start big, you should even if we start small and then we should have higher expectations for all of our buyers.

Senator GILLIBRAND. Demand transparency, I definitely think that can require transparency.

The CHAIRMAN. Sorry, go ahead.

Senator GILLIBRAND. We should require transparency. We should require labeling. We should require information. Then, that also can move a market because you can shame people into not—like if they're not caring where their drugs are coming from, and they're not caring about the outcome to their patients, you can shame them into better participation.

Then, if the DOD and the VA can be the standard bearer or the hallmark of success, and show that long-term their costs aren't going skyrocketing high, they can then make the case you should do these long-term investments, get the quality drugs you need.

Then pushing Governors and pushing Presidents to invest domestically, because the other point you all raised up is that most of our adversaries and most of our competitors, they do domestic investment. I mean every company in China is wholly owned by China. Like, they will do all the baseline investments.

We can create an investment fund that actually invests in domestic production to incentivize it. Even if we don't want to create

a pot of money, we certainly can create massive tax incentives. There's many ways to create carrots.

The CHAIRMAN. Well, and what if Tony said it's right, there's a three-year payback. I mean you don't have to invest a dime.

Mr. SARDELLA. Especially, if you're using existing facilities, and that's the key.

The CHAIRMAN. At least short-term, we have plenty of capacity.

Mr. SARDELLA. We have over 30 billion doses of capacity.

Senator GILLIBRAND. Also, you can use the Defense Production Act to require us to use that capacity.

Mr. SARDELLA. That is correct.

Senator GILLIBRAND. Once we map capacity, if you've already done that, we can publish that to say we will then ask the DOD, and the VA, and the President to ask each of these manufacturers to use all their capacity to begin to ramp up domestic production of the top 10 required generic drugs for our safety and survival.

Mr. SARDELLA. You have facilities that are highly experienced at producing these medicines. They should be leveraged first and foremost because they're experts in these areas, like the companies that Tony brought up. Before even starting up new facilities, we will need, ideally—hopefully, we'll be able to open new facilities. Leveraging the incredible experience we already have in this industrial manufacturing base that is elite and being able to provide them new technologies, that's where the investment, I believe, is the greatest place.

It's about investing and allowing for sustainable independence by these manufacturers. We don't want the government to continue to have to invest in them, modernize their facility, leverage their expertise. Let them invest themselves now that there's a market and allow them to be sustainable long-term economically to produce these medicines.

You've created the demand. Demand investment in modernization so they can compete so long-term we don't have to revisit this and have to continue to fund it. The industries themselves can do it.

The CHAIRMAN. Great. Okay, go ahead.

Dr. WOSIŃSKA. Can I comment on transparency? I think it's really, really critical. The way I think about transparency is who needs what information and what are they going to do with it? I think it's really, really critical to ask that question because some transparency for the sake of transparency is not going to get you anywhere. Transparency can actually sometimes backfire.

I am a very big proponent about the government having transparency. This is how you decide what to prioritize, where to invest. This is why it's important for FDA to know that manufacturers might have a problem and this buys them time. For example, hospitals really want an early warning system of shortages. You know what that means? That means that they basically have a sign to a stockpile really early, and then FDA actually has much less time to try to fix the problem.

Where I get really nervous is transparency to consumers. I'll tell you why. I actually have a story very similar to Peter Baker's story, and it actually involves my mother, if I would be allowed to share this story. I've never shared it publicly.

My mother was diagnosed with cancer in early 2020, and she needed to get radiation, and chemotherapy, and it was going to be oral chemotherapy. It was a 60-day supply of a pill, and it was going to be an old generic, and knowing what I know, I got very nervous. I started to—I basically thought; if my mom doesn't respond well to this therapy, I will never forgive myself because what if that product was not made to specification?

I actually have access to a lot of information, and I looked at who the manufacturer is for this NDC, and I looked, you know, where it might be manufactured and what are the alternatives. It was really difficult for me, and I have access to really top information. You would think that I would be the first person to say, ″We need to fix it.″

You know, what I learned from this experience is the complete opposite because of what happened next. I went to one pharmacy, and I said, ″Can you dispense me this NDC?″ They said, ″No, we don't do special orders.″ I went to another pharmacy, I got the same answer. Pharmacies are reimbursed in exactly the same way. It's a low business margin.

You have one option when you go to a pharmacy. Unless we were to fix how pharmacies are reimbursed and how pharmacies stock, the patient only has one choice; to pick it up or not pick it up. This is not like going to a store where you have five shirts and you get to choose one. They don't have a choice.

By giving this information to consumers where there's absolutely no {financial) incentive for a pharmacy to do anything about it and respond, that is a recipe for a lot of non-adherence. Yes, I would prefer to choose the non-Chinese drug over a Chinese drug, but in a pharmacy, I'm not going to have that option. It's really, really, really important that we either fix the pharmacy reimbursement policy or look for solutions elsewhere.

The CHAIRMAN. Let me give you my response. I really believe in transparency, and I'll give you a story. I've run a bunch of companies, and you know what every employee wants, they want every hospital in the network. That means you get no discounts, right? The reality is if I had two plans, and everybody's included in a plan that's cheaper with just one hospital, include a smaller network.

Some people would pick one because they know it, but some people would pick a bit more expensive. I actually really believe that people, they'll look at it and look, is it going to be perfect? No. People buy bad, ugly sweaters sometimes, but I believe over time it'll force whoever the pharmacy is.

If I walked in, and I had one, and it said if I would just—I'd start bugging them. We see it now. We see it with people buying America. You know, you can even get on Amazon, which still doesn't disclose all country of origin, but you go to Amazon now and they have sections. I can tell you, I've talked to people that make it America, they put the label on made the America, their revenues go up.

I believe it's—I agree with you, it's not going to be easy. It's not going to be perfect. The information never is perfect, if we do it all, it will force people to change. They will change. I've seen it in too many businesses. Do you want to add anything?

Senator GILLIBRAND. No, you can close us out.

The CHAIRMAN. I want to thank everybody for being here today and participating. I look forward to continue working with members across the aisle, down the dais. If any Senator has additional questions for the witnesses or statements to be added, the hearing record will be open until next Wednesday at 5:00 p.m.

I want to thank each of you for being here, and if you have any suggestions for either one of us going forward, we are going to get this fixed. Thank you.

[Whereupon, at 5:01 p.m., the hearing was adjourned.]

APPENDIX

Prepared Witness Statements

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

PREPARED WITNESS STATEMENTS

Tony Sardella

United States Senate Special Committee on Aging

Prescription for Trouble:

Drug Safety, Supply Chains, and the Risk to Aging Americans

Submitted for the Record: October 3, 2025

Anthony Sardella

CEO & Chairman, API Innovation Center (APIIC)
Distinguished Fellow of Health Innovation, Washington University in St. Louis Olin Business School

Good morning, Chairman Scott, Ranking Member Gillibrand, and Members of the Committee:

My name is Tony Sardella, and I serve as the founder and chairman of the API Innovation Center, a non-profit, public benefit corporation in St. Louis; API refers to active pharmaceutical ingredient, the component of medicine that makes it effective. I am also a distinguished fellow of health innovation at the Olin Business School at Washington University in St. Louis Olin Business School focused on research related to the business of health.

I am honored to be here this afternoon to share information about the work we are doing at the API Innovation Center, and how the work could be transformational in helping solve a major challenge facing our country—a vulnerable generic pharmaceutical supply chain that threatens our health security.

There are three key messages I wish to share with you today.

First, the U.S. generic drug supply chain is over-reliant on foreign sources to meet our nations' needs, placing our seniors, veterans and American citizens at risk. This over-reliance, driven by the economics of drug manufacturing, has created a fragile supply chain that leaves us vulnerable to disruption.

Second, the API Innovation Center is testing a private-public partnership model that shows promise in addressing the economic root causes that fostered this dependency. By leveraging existing idle U.S. Food and Drug Administration (FDA)-approved manufacturing capacity, APIIC is expediting U.S.-based production and supply.

Third, there are several areas of policy that can drive increased U.S. based production and investments to address our overreliance and vulnerabilities to geopolitical risks and enhance U.S. health security, where health security refers to both our national security and ensuring patient access to important medicines.

U.S. Generic Drug Supply Overreliance

Our overreliance on foreign manufacturers presents a national health security risk by leaving us highly dependent on foreign adversaries for our medicine supply, creating geopolitical vulnerabilities.

In 2019, the FDA testified that only 28 percent of the API manufacturing facilities serving the U.S. market are domestic, leaving 72 percent located overseas.[1]

My 2021 research at Washington University in St. Louis' Olin Business School— which was referenced during the last hearing on the pharmaceutical supply chain— highlighted the severity of our dependency. **83 of the top 100** generic drugs lack a U.S.-based source for their active pharmaceutical

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[1] U.S. Food and Drug Administration Testimony (October 2019) - Safeguarding Pharmaceutical Supply Chains in a Global Economy: https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019.

ingredients (APIs), the critical component of a drug that provides its therapeutic effect, with 91% of all prescriptions in the U.S. being generic medicines.[2]

This year, we conducted a study focused on 40 critical medicines, that we deem the "Vital 40," that are clinically essential, frequently in shortage and have a high impact for public health and national security. Where data was available, our findings determined nearly half of the key starter materials (47%) for the vital are *only* sourced from China representing a single point of failure in our nations supply chain. This level of concentration creates a significant vulnerability in our national medicine supply chain.

Recently, we assessed generic medicines through the lens of those prescribed specifically to the elderly and veterans. Our analysis of the top 10 medicines most relied upon by veterans and seniors highlights a significant dependence:

- 95% of APIs are manufactured overseas.
- 84% of drug products are made abroad.
- Our dependency is concentrated in India and China which provide nearly half of our drug products and almost two-thirds of APIs.

Three of the top ten medicines for veterans and seniors are currently in shortage which include two heart failure drugs (metoprolol, losartan) and albuterol used in inhalers for asthma.

Our analysis further focused on urgent and emergent medicines that are necessary for immediate treatment in unforeseen medical situations. These medications are part of the U.S. Department of Veteran Affairs (VA) Urgent-Emergent Formulary, which allows veterans to access medications quickly at community-based pharmacies participating in the VA's Community Care Network.

The result for veterans reveals a similar severe foreign dependence and vulnerability:

- 94% of APIs are manufactured overseas.
- 83% of drug products are made abroad.

While many supply chains are global in nature and source from foreign manufacturers, there is a significant distinction relative to generic medicines. Many of the global supply chains provide low-cost products for items that drive convenience. However, access to critical medicines is an issue of survivability.

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[2] U.S. Food and Drug Administration - Office of Generic Drugs 2022 Annual Report: https://www.fda.gov/media/165435/download?attachment.

The implications of this overdependence and a fragile geo-concentration of foreign suppliers include:

- Placing veterans' access to life-saving therapies at risk whenever global supply chains are disrupted.

- Making our supply vulnerable to geopolitical events such as when foreign suppliers are restricted from exporting product, as the Government of India did during COVID to ensure supply for their citizens.

- Creating price volatility with sharp and repeated price swings in cost, affordability crises and delayed access to treatment.

Examples of price volatility based on soon to be released APIIC research, include:

- **Atorvastatin:** *instability* — Prices reversed 44 times, with a spike in Q1-Q2 2022 after Dr. Reddy's Laboratories (India) recalled multiple lots for out-of-spec impurities and degradation. In Q1–Q2 2023, Accord Healthcare Inc. (sourcing from Intas Pharmaceuticals Limited, India) recalled atorvastatin and other products following an FDA Form 483 citing serious quality deficiencies. These disruptions removed significant supply and drove +40% price surges. The U.S. relies on 48 drug product suppliers for atorvastatin, but only three are domestic; of 36 API suppliers, just one is U.S.-based. The vast majority of atorvastatin supply is therefore exposed to foreign shocks.

- **Losartan:** *stress* — An approximately 60 percent price increase over months was triggered when the NMBA nitrosamine impurity was found in Hetero Labs' (India) API in 2019, sparking cascading recalls across U.S. distributors including Camber, Torrent, Teva, and Avet. With sourcing alternatives limited, Avet and Torrent discontinued losartan tablets in 2021, driving prices higher. Compounding the crisis, a nationwide "power crunch" in China shut down key chemical parks that supply ARB intermediates, leaving the U.S. market exposed and driving another sharp price spike and a shortage of all losartan from 2019-2022, with losartan and hydrochlorothiazide tablet combination still in shortage to this day. The U.S. has 37 drug product suppliers for losartan (only three are domestic) and 39 API suppliers (only four are domestic), showing again how vulnerable the market is to disruptions abroad.

- **Omeprazole:** *fluctuations* — Prices climbed steadily through 2023 as Red Sea shipping disruptions from attacks on commercial vessels extended transit times, while API costs rose in China under stricter energy and environmental rules. U.S. firms over-purchased to secure supply, but by mid-2024 this led to oversupply and weak demand, triggering a price crash, with the price halving over three months. As inventories ran down, the need to restock ahead of the Chinese Lunar New Year factory shutdowns and continued logistic bottlenecks caused prices to rebound in late 2024 with prices rising back up approximately 50 percent in December 2024. The U.S. has 27 drug product suppliers for omeprazole (five are domestic) and 37 API suppliers, none of which are U.S.-based. For omeprazole, the U.S. is entirely dependent on foreign API sources.

These cases underscore how the U.S. medicine supply is highly vulnerable to external shocks- whether it is quality-related recalls in India, disruptions from attacks on commercial vessels in the Red Sea, or China's fluctuating production capacity of key starting materials (KSMs) and Intermediates. Our nation's access to essential drugs is effectively at the mercy of foreign events beyond our control. **By investing in strong U.S. pharmaceutical manufacturing capacity, we can build a supply chain that is stable, safe, and resilient—ensuring that veterans, seniors and all patients have reliable access to the medicines they depend on.**

Further, public-private partnerships present a viable path forward.

The API Innovation Center Approach

The API Innovation Center represents a novel private-public partnership approach that is showing promise to address the two critical priorities cited by Administration for Strategic Preparedness and Response (ASPR)'s Essential Medicines Supply Chain & Manufacturing Resilience Assessment:[3]

1. Greater collaboration across key players in the supply chain to de-risk production.

2. Investment in manufacturing technology to make domestic production competitive and cost-effective.

In addition, APIIC addresses an underlying root cause. Economic instability of U.S. generic manufacturing industry is a significant cause of our fragility and overreliance on foreign suppliers for our medicine.

In research published in April 2023,[4] which analyzed the economic stability of the top 20 Global Gx manufacturers supplying the U.S., I found:

- Continued generic price pressures are contributing to unsustainable industry economics and compromise supply.
    - Since 2016 there has been 50 percent price erosion, an average high-volume 30-count bottle of medicine is now less than $1.50, the equivalent of 5 cents per tablet, further accelerated by the market consolidation of the number of drug wholesalers and group purchasing organizations.

    - Manufacturers are vying for the business of fewer, more powerful buyers. With no distinguishing product differentiation, cost reduction trends continue year after year, in what has been referred to as the 'race to the bottom,' squeezing generic manufacturer's margins further, and further degrading the economic viability of the manufacturing supply base.

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[3] U.S. Department of Health and Human Services – Public Health Supply Chain and Industrial Base One-Year Report (February 2022): https://aspr.hhs.gov/MCM/IBx/2022Report/Documents/Public-Health-Supply-Chain-and-Industrial-Base%20One-Year-Report-Feb2022.pdf.

[4] US Generic Pharmaceutical Industry Economic Instability: https://apicenter.org/wp-content/uploads/2023/07/US-Generic-Pharmaceutical-Industry-Economic-Instability.pdf.

- Decreased earnings to fund capital expenditures creating bankruptcies, asset exits and consolidation and further reduced supply, with median return on capital of the top 24 generics manufacturers being five percent in 2022.

- A low return on invested capital decreased close out rates of FDA warning letters from 24 percent in 2018 to 4 percent in 2022. Without investment in modernizing facilities or upgrading manufacturing technology, it is more difficult for manufacturers to address FDA compliance concerns when raised. Often, manufacturers conclude that it is more economical to cease manufacturing in their U.S. sites than to make the necessary upgrades.

Moreover, foreign manufacturers — supported by direct government subsidies and strategic industrial policy — can engage in aggressive pricing practices that effectively drive U.S. producers out of the market.

Recently, India's Production Linked Incentives program offers up to 20 percent financial incentives through 2027.[5] Additionally, China has poured significant investments into biotechnology parks, infrastructure and R&D, giving their manufacturers structural cost advantages that U.S. firms have not matched.[6]

Ultimately, the analysis showed the root cause of the drug supply chain fragility is not logistics, but economics.

The mission of the API Innovation Center is to drive national health security and economic growth through U.S.-based production of medicines so that every citizen, health care system and pharmacy retailer has access to critical medications by addressing the economic factors that drove offshoring.

To address supply chain vulnerability, APIIC has established a novel approach called the Invest-Contract-Partner Model, or ICP Model™, that includes:

- First, **investing** public–private secured funding to modernize the production of generic medicines. The investment develops new synthetic chemical pathways and deploys the new pathways within advanced manufacturing technology at scale. The State of Missouri has appropriated more than $24 million for API development, and ASPR has awarded APIIC $14 million under the Defense Production Act Title III and its BioMaP-Consortium to develop six new routes of synthesis for APIs.

- Second, entering **contracts** with existing U.S.-based, FDA-approved facilities with idle capacity to produce APIs using the modernized pathways and new advanced manufacturing equipment, as demonstrated by APIIC. Their expertise and experience in drug production enables domestic API production to be brought online more quickly and efficiently than if a

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[5] Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of Bulk Drugs (Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs): https://pharmaceuticals.gov.in/schemes/production-linked-incentive-pli-scheme-promotion-domestic-manufacturing-critical-key.

[6] How Innovative Is China in Biotechnology?: https://itif.org/publications/2024/07/30/how-innovative-is-china-in-biotechnology/#_edn93.

new facility was to be constructed.

- Third, entering **partnerships** with both drug product manufacturers and major purchasers of drug products, such as health care systems and national pharmacy retailers who are willing to enter into long term agreements to ensure certainty of supply and cost for domestically produced medicines.

The collaboration across the supply chain enables an end-to-end solution to source, develop, manufacture and purchase cost-competitive U.S.-produced critical drugs. The partnerships address key supply chain issues and demonstrate the following key benefits:

- U.S.-based manufacturers gain certainty of demand, revenue and price for their investments, making the investment worthwhile and the returns clear for capital allocation and lending.
- Health systems and pharmacy retailers gain certainty and stability of supply and cost within a shortened timeframe of 5-7 years versus 10-12 years with construction of new facilities.
- A reduction in supply chain risk from geographic concentration and reliance on China and India, enabling a more resilient U.S. drug supply, and reducing costs from shortages.
- API manufacturers gain modernized and innovative methods and equipment such as equipment produced by Corning to produce APIs competitively in the United States.

Currently, we have six medicines in process at the API Innovation Center with a goal to bring manufacturing of 25 medicines to the U.S. by 2030 and over 300 in the next 10 years. We have in our system over 65 U.S.-based manufacturers of key starter chemicals, APIs and drug products that are prepared to initiate production leveraging new advanced manufacturing methods.

Case Study: Metoprolol

One of the examples of the ICP Model™ in action is our work to reshore metoprolol, a widely prescribed hypertension and heart disease medication and a medicine I mentioned earlier as relied upon by our veterans and seniors.

After receiving support from ASPR, coupled with funds received through the State of Missouri, APIIC allocated funds to develop a new, continuous flow route of synthesis at our labs at the University of Missouri–St. Louis. The process will then transition to a highly experienced manufacturer with available capacity, Mallinckrodt Pharmaceuticals, to scale up large scale production for our nation.

The modernization of the process enabled production steps that would take 24/hrs per step one minute per set allowing for dramatically improving output, speed, consistency, and quality — all without the cost of building new facilities.

Case Study: Lomustine

A second case involves reshoring a low-volume, high-need medicines, lomustine, a chemotherapy used to treat glioblastoma—an aggressive brain cancer that has recently taken the life of former Rep. Mia Love, and previously the life of Senator John McCain and Beau Biden, son of former President Joe Biden. In 2018, the lone company producing lomustine had increase the cost of drug by >1500% from $5 to $768 per capsule, since 2013.[7] This includes removing the product from Medicare coverage in 2021.[8] Today, the cost of lomustine is approximately $1,390 per 100mg capsule.[9]

Through our national consortium and support by the State of Missouri, APIIC funded the development of an innovative production method that allows our nation's entire yearly requirement for lomustine to be produced in two weeks. Together, with investment by a Missouri manufacturer with available capacity, we constructed a dedicated cancer drug suite to produce not only lomustine, but future cancer medicines as well.

Policy Considerations to Drive U.S.-Based Production and Investments

Lastly, and importantly, there are a range of policies approaches that could help address the economic challenges and obstacles facing U.S.-based manufacturers, while also encouraging greater investment in domestic production. As a non-profit, our mission is centered on national health security and the well-being of the American public, and as the government advances efforts to reshore, APIIC offers several considerations and would welcome the opportunity to discuss these pathways further in support of this shared goal.

Areas of opportunity including addressing current made-in-America language for medicines which reflect "assembled in America" and not "made-in-America."

Harmonizing conflicting definitions across the Trade Agreements Act, the *Acetris* ruling [10] and federal procurement language, is necessary to establish a clear, consistent definition of "substantial transformation" for pharmaceuticals to drive health security. The 2020 *Acetris* court decision created a loophole that allows products made with foreign APIs to be labeled as U.S.-made under federal procurement rules, undermining domestic sourcing initiatives.

The second opportunity includes placement of U.S.-sourced API/drug product onto Tier One drug formulary (state and federal level) to leverage federal purchasing power to create predictable demand.

Federal procurement is one of the most powerful market signals available to encourage private investment. By committing to long-term, volume-based contracts for medicines with domestically sourced APIs and KSMs, the federal government can de-risk the capital expenditures required to

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[7] The lomustine crisis - awareness and impact of the 1500% price hike: https://pmc.ncbi.nlm.nih.gov/articles/PMC6303421/#CIT0013.
[8] Expensive brain-cancer drug no longer an option under Medicare: https://www.cbsnews.com/news/brain-cancer-drug-gleostine-no-longer-an-option-under-medicare/.
[9] GoodRx – Gleostine (lomustine): https://www.goodrx.com/gleostine/what-is?dosage=100mg&form=capsule&label_override=Gleostine&quantity=1&sort_type=popularity.
[10] 18-2399: ACETRIS HEALTH, LLC v. US [OPINION]: https://www.cafc.uscourts.gov/2-10-2020-18-2399-acetris-health-llc-v-us-opinion-18-2399-opinion-2-10-2020_1529718/.

reshore production. These contracts should go beyond short-term price competition and instead prioritize resiliency, reliability and national security outcomes.

Leveraging the buying power of the federal government is critical, as it accounts for more than 30 percent of overall U.S. healthcare spending.[11] According to National Health Expenditure data from the Centers for Medicare & Medicaid Services, U.S. prescription drug expenditures totaled $449.7 billion in 2023[12]—an area where federal purchasing decisions, though a smaller share of overall healthcare spending (approximately $4.9 trillion in 2023), can still influence broader private market practices. For consideration, other nations, including Germany, Brazil, India and China have established sourcing policies that encourage domestic production. In the U.S., a similar approach could be explored around policies that promote domestic production, reward stronger compliance records, or otherwise align federal purchasing with long-term supply chain resilience.

Improving provider reimbursements for U.S.-made generic products and realigning preferred drug lists/formularies for Medicaid and Medicare can drive incentive for U.S.-based manufacturing.

Thirdly, investments in private-public partnerships enable the transition and adoption of advanced manufacturing technologies enabling economically competitive and sustainable U.S. production.

Ongoing investment in public–private partnerships to enable sustainable, long-term solutions that leverage advanced manufacturing technologies is critical to modernizing and expanding the capacity we already have and promises to be a more efficient and cost-effective way to scale production. This is becoming increasingly important than as foreign governments are making significant investments in their own pharmaceutical infrastructure. To remain competitive and ensure the resilience of our supply chain, the U.S. must match—and ideally outpace—these investments.

By utilizing existing U.S. FDA-approved facilities, we can dramatically improve efficiency and reduce costs in an expedited and sustainable manner. These investments can also stimulate regional economies, create new high-quality jobs and strengthen the long-term competitiveness of U.S. manufacturers. By mobilizing underutilized U.S. manufacturing capacity, accelerating adoption of advanced manufacturing and aligning federal policy with procurement, the Congress and the Administration can deliver a durable solution that protects seniors, veterans and all Americans.

Thank you for the opportunity to share our research and details of our work at the API Innovation Center as well for the committee's leadership on this critical national priority.

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[11] Centers for Medicare and Medicaid Services – National Health Expenditure Data (Fact Sheet): https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.
[12] Ibid.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

PREPARED WITNESS STATEMENTS

Tony Paquin

UNITED STATES SENATE
SPECIAL COMMITTEE ON AGING
Hearing on
"Bad Medicine: Closing Loopholes that Kill American Patients"

Written Testimony of
Tony Paquin
Chief Executive Officer
The iRemedy Healthcare Companies, Inc.

Submitted to:
Senator Rick Scott, Chairman
Senator Kirsten Gillibrand, Ranking Member
United States Senate Special Committee on Aging
Date: October 8, 2025

I. Introduction

Chairman Scott, Ranking Member Gillibrand, and Members of the Committee — thank you for the opportunity to testify before you today.

My name is Tony Paquin, and I serve as the Chief Executive Officer of The iRemedy Healthcare Companies, Inc., an American medical supply and technology firm headquartered in Florida. I appreciate the Committee's leadership in holding this hearing — "Bad Medicine: Closing Loopholes That Kill American Patients."

For more than thirty years, I have built and led companies in the healthcare logistics and technology industries. I have worked inside the global supply chains that deliver critical medicines, medical devices, and protective equipment to our hospitals, pharmacies, and military facilities. And I am here to tell you what I have seen: our dependence on foreign adversaries for essential medicines is not only dangerous —it is deadly.

What is happening in our pharmaceutical supply chain is not an abstraction. It is a matter of life and death for American patients, and a matter of national survival for our country. I have witnessed firsthand how Communist China, and its network of state-controlled suppliers manipulate, restrict, and exploit the flow of medical goods to the United States. This is not a hypothetical future threat — it is happening right now.

The problem cannot be solved by better oversight alone. We can inspect more factories, add new labels, and tighten regulations, but those measures can never fully protect Americans because they operate outside our jurisdiction. The only true solution is to rebuild the capacity to manufacture medicines here at home, under American law, with American workers, and with American accountability.

iRemedy is proud to be a member of Securing America's Medicine and Supply (SAMS), a national coalition committed to strengthening U.S. pharmaceutical and medical supply resilience. Through SAMS, we work alongside other industry and policy leaders to advance transparency, accountability, and efficiency in the healthcare supply chain — principles that are central to the issues before this Committee.

II. Background

I was born and raised in Flint, Michigan — a city that once embodied the strength and promise of American manufacturing. My father worked in the auto industry, and the hum of factories was the soundtrack of my childhood. But I also witnessed what happened

when that strength was allowed to erode. I saw factories close, families collapse, and an entire community lose its purpose when we began sending our industrial heart overseas.

That experience shaped everything I have done since. I became an entrepreneur not just to build companies, but to help rebuild American capability. I've spent three decades creating technology platforms that improve efficiency, transparency, and resilience in healthcare supply chains — because I believe innovation, not outsourcing, is the key to keeping Americans safe.

During the pandemic, iRemedy had the honor of working with the Operation Warp Speed team to source and distribute more than one billion critical medical supplies. In that effort, I saw how fragile our dependence on foreign suppliers truly is. Shipments were blocked, prices were manipulated, and even our own government had to compete against Chinese state-backed brokers to secure essential goods. It was, in every sense, a war — fought not with weapons, but through control of supply chains.

That experience reinforced what I had long believed: oversight and inspection can never substitute for sovereignty. When vital medicines are made in foreign jurisdictions, we surrender control over quality, availability, and safety. And when those jurisdictions are governed by adversaries, we surrender our leverage and our moral authority.

Modern technology can now connect manufacturers directly with hospitals and federal agencies, managing the complex regulatory and logistical requirements of drug distribution while reducing cost and risk. I've helped implement these systems firsthand. These platforms manage the complex regulatory and logistical requirements of the drug supply industry without creating costly and bureaucratic middle layers.

Our company focuses on direct distribution, regulatory compliance, and domestic sourcing to reduce foreign dependence.
Through iRemedy and as a former board member of Securing America's Medicine and Supply (SAMS), I've worked to strengthen U.S. healthcare resilience.

This approach reflects my core belief: we can modernize America's pharmaceutical supply chain without surrendering control to foreign powers. iRemedy demonstrates that the private sector has both the capability and the will to lead this transformation — if our national policy supports and prioritizes it.

I'm not here today as an elected official or as an academic. I'm here as someone who has lived inside the system that this Committee is trying to fix, and who knows, from experience, that this country has the talent, technology, and determination to restore our

independence.

That is why I fully support this Committee's mission — and Chairman Scott's leadership — in confronting the dangerous loopholes that allow bad medicine to enter our country. In the following sections, I will outline specific reforms to rebuild our domestic pharmaceutical base and ensure that no American patient ever again suffers because of foreign dependence.

III. America's Medical Supply Chain Vulnerabilities

Dependence on China and India

The United States has become dangerously dependent on foreign adversaries for the building blocks of its medicine supply. Nearly 90% of the world's antibiotic key ingredients come from China. India now supplies close to half of the generic drugs consumed in the United States but relies on China for up to 80% of the active pharmaceutical ingredients (APIs) used to make them. This creates a tightly linked chain of dependency where American patients are effectively at the mercy of two foreign nations.

This situation has developed gradually but with devastating consequences. In 2000, China and India accounted for only 24% of drug master file submissions to the FDA. By 2021, they accounted for 85%. The last U.S. penicillin plant closed in 2004 after being driven out of business by below-cost Chinese imports. Today, 83% of the top 100 generic drugs prescribed in the U.S. have no domestic source of API.

This is not a sustainable model. It leaves our nation's health system vulnerable to price manipulation, export restrictions, or political leverage. Dependence on adversarial nations for life-saving medicines is not diversification—it is concentration of risk at the highest level.

COVID-19 Shortages and Export Bans

The COVID-19 pandemic exposed just how fragile America's supply chain has become. As global demand surged, the Chinese Communist Party seized shipments of medical supplies bound for the United States and other nations. At the same time, India imposed export bans on essential drugs such as acetaminophen and antibiotics, prioritizing its own domestic population. These measures left U.S. hospitals and pharmacies scrambling for alternatives in the middle of a public health emergency.

The effect of these actions was immediate and severe. Hospitals were forced to ration critical products. Patients faced delays and uncertainty in accessing medications that were previously taken for granted. At the same time, counterfeit and substandard products entered the market, further endangering public health. These disruptions were not hypothetical risks—they were real and measurable consequences of our lack of domestic capacity.

The lesson is clear: in times of crisis, nations turn inward and protect their own citizens first. For the United States, which imports the overwhelming majority of its generic medicines and APIs, this means that the next global emergency will once again leave us vulnerable to shortages, black-market activity, and preventable loss of life. Without secure domestic manufacturing, America remains exposed.

Real-World Examples of Contamination and Death

Beyond shortages, reliance on poorly regulated foreign factories has repeatedly resulted in unsafe medicines reaching American patients. In 2007–2008, contaminated Chinese-made heparin caused nearly 100 deaths in the United States. In 2018, blood pressure medications produced overseas were recalled after carcinogenic impurities were discovered in their active ingredients. As recently as 2023, contaminated eye drops manufactured in India killed four Americans and left dozens more blinded or permanently injured.

These tragedies are symptoms of systemic weaknesses in oversight. In the United States, FDA inspections of manufacturing plants are robust and unannounced, ensuring accountability and compliance. By contrast, inspections of facilities in China and India are frequently announced weeks in advance, giving manufacturers time to stage conditions, conceal unsafe practices, or manipulate records. This disparity allows unsafe products to pass inspection and reach American consumers.

Quality failures are not isolated mistakes—they are the predictable outcome of an environment where cost-cutting is prioritized over safety, and where U.S. regulators lack the authority or access to enforce standards. Every contaminated shipment is a reminder that our dependence on overseas manufacturers places American lives at unnecessary risk. The cost is measured not only in dollars, but in preventable illness and death.

A System Without a Backup Plan

The most alarming aspect of this vulnerability is that the United States has no reliable backup plan if foreign supply lines collapse. Our healthcare system operates on “just-in-

time" inventory practices designed to minimize costs but incapable of withstanding prolonged disruption. The Strategic National Stockpile, while essential, was not built to sustain the nation through extended shortages of common medicines.

The stakes are stark. If China restricts exports, the U.S. could run out of antibiotics in a matter of weeks. If India halts shipments of generics, cancer patients could lose access to chemotherapy drugs. Even U.S.-based pharmaceutical companies would be unable to continue production, since the vast majority of their APIs are sourced from abroad. In such a scenario, the consequences for seniors, children, and patients with chronic illnesses would be catastrophic.

This is not an abstract concern. It is a national security risk hiding in plain sight. Just as dependence on foreign oil once posed a strategic vulnerability, dependence on foreign medicines now places our citizens and armed forces at risk. Without decisive action to build resilient domestic manufacturing and diversify supply sources, America remains only one geopolitical crisis away from a health emergency of historic proportions.

Geopolitical analysts often note the paradox in Europe's current posture toward Russia. While many European nations are supporting Ukraine in its defense against Russian aggression, they continue to purchase Russian energy resources. Russian drones and fighter jets routinely threaten NATO airspace, even as energy revenues from those same nations flow back to Moscow. This contradiction underscores a fundamental truth: dependence on an adversary for essential goods inevitably constrains national security decisions.

In the United States, we face a similar and equally dangerous vulnerability in our medical supply chain. Our reliance on China for critical medicines and components mirrors Europe's dependence on Russian energy—it limits our ability to respond decisively in times of crisis. We cannot claim to protect the health and security of the American people while remaining dependent on foreign adversaries for the very medicines that sustain life.

IV. Policy Gaps and Regulatory Loopholes

Transparency & Procurement Reform

The most urgent and actionable reform Congress can make is to waive penalties that hospitals and health systems face when they purchase American made medicines outside their exclusive supply contracts. This single change would have an outsized effect on resilience. Today, virtually every hospital in America buys through a group purchasing organization (GPO) or a major distributor under "sole-source" or "preferred-vendor"

contracts. Those agreements are structured around rebate formulas and volume guarantees that penalize off-contract purchases. A hospital that tries to buy directly from a U.S. manufacturer—often to secure a critical drug that's in shortage—can lose its rebates or face severe financial penalties that erase already-thin margins. The result is a perverse incentive: even when a domestic supplier has safe, FDA-approved stock available, hospitals are effectively punished for choosing it.

Waiving those penalties—specifically for purchases made from U.S. or allied-nation manufacturers—would immediately hep level the playing field for American manufacturers and diversify the supply chain without costing taxpayers a dime. It would not require new infrastructure, only new rules of engagement. Hospitals would regain the freedom to make ethical and safety-driven procurement decisions instead of being bound by anti-competitive contracts. For federal purchasers such as VA and DoD hospitals, the waiver could be codified through procurement guidance, for private health systems, Congress can condition GPO safe-harbor protections under the Anti-Kickback Statute on allowing these exceptions. The message is simple: when Americans' access to medicine is at stake, legacy contracts should not override national security or patient safety.

The second reform is to eliminate non-disclosure agreements (NDAs) that hide the true origins, pricing, and quality history of pharmaceuticals. These NDAs shield distributors and GPOs from scrutiny, preventing hospitals and regulators from knowing where drugs come from, who made them, and under what conditions. Without visibility, policymakers cannot even map the vulnerabilities they seek to fix. Transparency is not punitive—it is the prerequisite for accountability and an essential attribute of any competitive marketplace.

Third, procurement must reward sourcing diversity. The government's current "lowest-price wins" model has driven the market to its weakest point. When price alone determines winners, subsidized foreign producers inevitably dominate, hollowing out U.S. capacity. Adjusting scoring criteria to favor multi-source supply chains and U.S. or allied production would change that overnight. A slightly higher bid from a domestic manufacturer should beat a cheaper, single-source import if it strengthens national resilience.

The government procurement systems often fail to enforce existing buy American requirements. Technology systems are outdated and generally fail to approach procurement activities with state-of-the-art artificial intelligence that could be used to add resiliency and security conditions to purchasing processes.

Together, these reforms form a coherent strategy: *free hospitals to buy American, expose where our medicines really come from, and realign incentives toward diversity and reliability.* Operation Warp Speed proved that when procurement rules are flexible, transparent, and mission-driven, America can mobilize industry at record speed and scale. We should not wait for another pandemic to rediscover that lesson.

Oversight Failures

The second major policy gap lies in the failure of FDA oversight abroad and the lack of randomized quality testing on imported products. The FDA has neither the tools nor the authority to ensure that the medicines reaching American patients meet the same standards we demand at home. Inspections of U.S. drug plants are unannounced, rigorous, and data driven. But in China and India—where roughly 80% of active pharmaceutical ingredients (APIs) originate—inspections are pre-announced, infrequent, and often negotiated in advance with local officials. This loophole has become a gateway for falsified data, concealed contamination, and chronic quality failures.

We have seen the consequences. Contaminated heparin from China killed nearly 100 Americans in 2007–2008. In 2023, eye-drops produced in India blinded or killed dozens of patients. FDA import alerts routinely cite carcinogenic impurities, falsified batch records, and non-sterile conditions. Yet the same foreign plants continue to supply our hospitals. Roughly one-third of all FDA import alerts target Chinese facilities, and another 16% target Indian producers. The pattern is unmistakable: the countries that dominate our supply are also those most often cited for violations.

To close this gap, Congress should mandate unannounced foreign inspections, require third-party verification in trusted allied nations, and compel public disclosure of inspection results. When FDA resources or diplomatic constraints make direct oversight impossible, accredited U.S. or allied third-party auditors can fill the gap—just as they already do in aerospace and food safety. Public transparency would add another layer of deterrence: if a plant repeatedly fails inspection, providers and procurement officers should know that and have that quality data before buying.

Inspection data should be linked to procurement eligibility. A manufacturer with serious or unresolved citations should not be eligible for federal contracts until compliance is verified. In other regulated sectors, safety records determine market access; the pharmaceutical industry should be no different. Until we align FDA oversight with enforcement, the United States will remain dependent on a supply chain it cannot see and cannot trust.

Finally, we must establish a randomized and intelligence-driven drug testing program for all imported pharmaceutical products. This system should employ both statistical randomization and targeted enforcement based on prior violations, high-risk categories, or patterns of noncompliance from specific producers or nations. Testing should be robust, scientifically rigorous, and—critically—transparent. Results must be publicly reported in real time to all stakeholders across the supply chain, including hospitals, pharmacies, and consumers. Just as the USDA monitors food imports and the FAA inspects aircraft components, the FDA must oversee medicines with equal vigilance. An intelligent, randomized testing regime would deter bad actors, expose systemic fraud, and rebuild public confidence in the integrity of the nation's medicine supply.

Financing & Market Access

Even when American companies have the capability and technology to produce essential medicines, they are often locked out of the market by financial risk and procurement bias. Building or modernizing a pharmaceutical plant in the United States can take two to three years and hundreds of millions of dollars in capital investment. No private firm can justify that expense without predictable demand or fair market access. Meanwhile, foreign competitors—backed by state subsidies, tax holidays, and guaranteed export pipelines—can undercut U.S. producers long before the first domestic batch ever leaves the line. China has perfected the corporate-nation-state paradigm as there is very little disconnect between corporate control and CCP control. We witnessed this firsthand in OWS as we constantly negotiated with factory executives who were then in constant consultation with Party officials. The CCP really acts more like the Chinese Communist Corporation vs the Chinese Communist Party.

To correct this imbalance, federal financing and market access guarantees must be treated as national security investments. The same tools that built America's energy independence and semiconductor resurgence can be applied here: advance purchase commitments, multi-year IDIQ contracts, and federal loan guarantees that de-risk domestic production. These mechanisms do not create new spending; they redirect existing procurement toward resilient, U.S.-based capacity. A manufacturer that knows the government will buy its output for five years can secure private financing, hire American workers, generate tax revenue and scale production of critical drugs such as antibiotics and sterile injectables that are now chronically in shortage.

Tax incentives are the second pillar. A tiered credit structure for U.S.-made APIs and finished drugs—comparable to the renewable energy model—would reward both repatriation and expansion of key capabilities. Investments in automation and continuous

manufacturing should qualify for accelerated depreciation and R&D credits, lowering long-term costs while advancing quality and traceability.

Finally, market access must be explicit. Federal purchasing criteria should prioritize domestic and "friend-shored" manufacturers, not as protectionism, but as a matter of national security. If the Pentagon can require U.S.-made steel for ships, the Department of Health and Human Services should be able to require U.S.-made antibiotics for hospitals. Although there are existing laws in place to "require" American manufactured products in certain cases, those rules are frequently circumvented or ignored.

Procurement policies and technology need to be upgraded to force compliance. Financing and access go hand in hand: predictable demand fuels investment, and investment creates the capacity that keeps medicine affordable and secure. Without these structural supports, even the most advanced American manufacturers will remain on the sidelines while foreign subsidized rivals dominate the field.

Inventory Models for Crisis Readiness

The COVID-19 pandemic exposed a painful truth: America does not have a real-time, data-driven view of its medical inventory. The Strategic National Stockpile (SNS) still largely relies on a static warehouse model that cannot track where critical products actually are in the private sector, how long they have been on shelves, or when shortages are imminent. During Operation Warp Speed, we experienced this firsthand. Supplies moved through opaque, paper-based systems that made it impossible to see, in real time, which states were short, which distributors were hoarding, or which factories could ramp production. That information gap—not a lack of manufacturing capability—was what delayed lifesaving deliveries.

To fix this, the federal government should adopt modern Vendor Managed Inventory (VMI) and digital visibility systems that integrate directly with hospitals, distributors, and manufacturers. Under a VMI model, suppliers hold and rotate inventory on behalf of the government or health systems, ensuring freshness and continuity while avoiding the massive cost of idle stockpiles. When paired with secure digital tracking, the government can monitor stock levels down to the lot number and expiration date without owning every pallet.

This modernization is not theoretical. Platforms such as iRemedy's MetaCommerceRx already demonstrate how AI-enabled procurement and compliance tools can give federal and state agencies full line-of-sight into origin, quality, and movement of essential medical goods. By linking supplier feeds, shipment telemetry, and QA data, these

systems can forecast shortages before they happen and automatically reroute orders within compliant guardrails.

A digitally modernized SNS built on these principles would transform readiness from reactive to predictive. The system could flag when a single foreign source controls 80% of an antibiotic drug, automatically source alternatives from allied manufacturers, and document compliance for auditors in real time.

The SNS was founded on the concept of the government buying and holding large inventory of essential drugs and supplies. That is now an outdated model. The "Stockpile" of essential drugs and supplies should be viewed as a public – private partnership-based system that tracks domestic and allied manufacturing capacity, supply chain current inventory balances, raw material tracking, and end user demand predictive analytics.

V. Feasibility and Competitiveness of Domestic Manufacturing

Debunking the Cost Myth

For decades, policymakers have accepted a false premise—that producing pharmaceuticals in America would make drugs unaffordable. The data prove otherwise. Manufacturing cost represents only a sliver of a medicine's final price. For example, amlodipine costs roughly two cents to make domestically while Medicare Part D pays about ten cents per dose; buspirone costs three cents to produce but retails near eighteen; spironolactone, four cents to make, and sells for nineteen to twenty-five cents. In every case, production is less than 10% of the price patients and taxpayers pay.

Even if U.S. production costs doubled, the effect on the consumer price would be negligible. What drives cost inflation are inefficient distribution layers, opaque contracts, and intermediaries that add margin without value. The problem is not labor—it is layers. Reshoring manufacturing would not make drugs expensive; it would make them dependable, transparent, and secure.

In truth, domestic production can enhance competitiveness. Modern continuous-flow processes, digital quality systems, and smaller modular plants have reduced fixed overhead and increased yield efficiency. When combined with fair-trade enforcement and procurement reform, American factories can meet or beat import pricing. What the U.S. lacks is not affordability—it is policy alignment.

When we talk about "cost," we must also weigh the cost of failure: shortages, recalls, and contaminated imports that kill patients and force hospitals to scramble. The Heparin tragedy, carcinogenic impurities, and pandemic-era seizures of supplies show that the "cheap" option is anything but. Re-establishing production at home is both economically rational and morally imperative.

Friend-Shoring from Allies

While restoring domestic capacity is paramount, resilience also depends on trusted partnerships. "Friend-shoring" means anchoring supply chains in nations that share U.S. standards, transparency, and values. Today, India and China dominate active-ingredient production, but that concentration magnifies risk. Strategic collaboration with U.S. allies—such as Germany, the UK, Canada, and Japan—can create a distributed, secure network for critical inputs and finished drugs.

This approach aligns with bipartisan policy and existing trade frameworks. By pairing American finished-dose manufacturing with ally-sourced raw materials and APIs, we mitigate single-country exposure without re-creating every chemical supply line from scratch. Allied inputs already meet FDA and OECD standards and operate under rule-of-law systems that uphold intellectual property and labor rights.

Friend-shoring also amplifies economic and geopolitical benefits. It encourages cross-investment and technology exchange among democratic partners while reducing leverage for adversaries like the Chinese Communist Party. For example, Oxford Pharmaceuticals, a Birmingham, AL based manufacturer, sources some of its APIs from Germany—a trusted ally—demonstrating how quality and security can coexist with competitive costs.

A federal friend-shoring strategy should include (1) mutual recognition of GMP inspections to speed approvals; (2) targeted loan guarantees for allied plants producing critical inputs; and (3) coordinated stockpile agreements so surge capacity in one nation can support others during crisis. By treating pharmaceutical security like energy security under NATO-style principles, the United States can ensure continuity of care even when disruptions occur abroad.

We should not confuse friend-shoring with outsourcing. It is a strategic division of labor among allies, not a race to the bottom on price. Done right, it builds redundancy into our lifeline without compromising sovereignty.

Technology and Automation Advantage

The future of U.S. manufacturing rests on technology. Automation and artificial intelligence have erased many of the labor-cost gaps that once drove offshoring. Smart factories now integrate continuous monitoring, robotic handling, and predictive analytics to produce at higher throughput with fewer defects and lower energy use. These advances make domestic plants leaner and safer than their foreign counterparts.

Modern procurement platforms demonstrate how digital infrastructure can transform the supply chain itself. AI-enabled procurement systems can provide real-time inventory visibility, automated compliance verification, and data integration across manufacturers, distributors, and health systems. These capabilities reduce administrative costs, eliminate manual errors, and shorten time-to-market for new U.S. manufacturers. Technology is not a luxury add-on—it is the force multiplier that makes domestic production competitive.

Automation also strengthens quality assurance. Sensors and machine-vision systems detect variances beyond human capability, ensuring each dose meets specification. When integrated with AI-driven maintenance scheduling and digital batch records, these systems nearly eliminate downtime and non-compliance. The result is greater consistency at lower total cost of ownership.

Federal policy should accelerate this transition through tax incentives for automation equipment, fast-track FDA review of digitally controlled plants, and procurement preferences for validated "smart manufacturers." America once led the world in industrial innovation; we can do so again by marrying advanced manufacturing with AI-enabled procurement and distribution. Technology is how we bridge the cost gap, strengthen transparency, and build a supply chain worthy of our patients and our nation.

VI. Case Studies of Domestic Reshoring

Oxford Pharmaceuticals

Oxford Pharmaceuticals in Birmingham, Alabama, is proof that domestic generic production works when policy allows it to compete fairly. The company operates a state-of-the-art, FDA-compliant facility employing American workers and sourcing its APIs from Germany—trusted allies, not adversaries. Its site is fully vertically integrated, maintaining end-to-end control of quality and production records. Oxford embodies the resilient model envisioned in the President's Management Agenda: transparent sourcing, American jobs, and reliable supply.

Yet recently, Oxford lost a federal contract for Buspirone to a "virtual manufacturer" with foreign backing. That award went to an importer linked to Indian and Chinese production, despite Oxford's verified U.S. capacity and spotless FDA record. This illustrates how Lowest-Price-Technically-Acceptable (LPTA) procurement rules and opaque supply chains reward offshore operators masquerading as domestic firms. The result: taxpayer dollars subsidize foreign plants while American facilities idle.

Oxford shows that the barriers are not technical but structural. Its facility already meets cGMP and Buy American requirements; its costs are competitive once level standards apply. What is missing is enforcement of country-of-origin verification and procurement weighting for security and resilience. If federal buyers valued supply-chain integrity as much as unit price, Oxford and similar companies would thrive.

The Buspirone case should be a wake-up call: our laws favor domestic production in theory but fail in execution. By reforming federal contracting to close loopholes for "virtual manufacturers," Congress can immediately shift billions in procurement toward U.S. facilities. Oxford stands ready to expand output and replicate its model nationwide once the playing field is level.

UK-Owned Medical Device Manufacturer

Another success story comes from a UK-owned medical device manufacturer that is establishing a 15,000 sq. ft. facility that will operate on American soil, integrated directly into one of the nation's largest logistics networks. This partnership illustrates how foreign investment from allied sources can accelerate U.S. manufacturing without sacrificing control or compliance.

The facility leverages AI-driven technology and advanced logistics to cut costs and deliver products faster than imported alternatives. Once fully scaled, it is expected to supply millions of medical devices annually while saving U.S. hospitals approximately 30% in cost compared to current imported suppliers. Beyond the product itself, this model creates American jobs in logistics, quality control, and data management.

It demonstrates that friend-shoring and domestic production are complementary strategies. An ally's capital and technical expertise merged with U.S. infrastructure and governance yields a resilient supply chain free from the risks of adversarial dependency. By replicating this model across other product lines—syringes, catheters, diagnostic kits—the U.S. can build a network of "digital factories" linked through AI platforms. Each site would operate with real-time visibility, federal traceability, and market access

built in. This is what a modern industrial policy looks like in practice: ally capital plus American capacity for shared security.

iRemedy recently announced the creation of a "Made in America" products portfolio which it then offers to government agencies and hospitals to make 'Buy American' easy, efficient, and verifiable.

Results: Speed, Compliance, Resilience

The combined results of these reshoring efforts are tangible. Domestic and ally-anchored plants deliver faster, with greater regulatory certainty and lower total risk to patients and procurement agencies. At Oxford, delivery times are measured in days rather than weeks because there are no global logistics requirements. At the new medical device facility, production-to-delivery time is cut by more than half thanks to co-location within the 3PL provider. Speed is not just efficiency—it is readiness for the next crisis.

Compliance is another measure of success. Domestic plants operate under unannounced FDA inspections and stringent OSHA rules, a level of oversight rarely seen in China or India facilities. The result is a documented reduction in adverse events and recalls.

American-made medicines are safer because they are made under American rules. Finally, resilience. When COVID struck, overseas export bans and factory shutdowns crippled supply. Had domestic factories been at scale, many of those shortages could have been avoided. By building redundancy within U.S. borders and among allied partners, we create a strategic stockpile that is not just warehoused but alive—constantly producing, rotating, and ready.

Quantitatively, these models cut logistics lead times by 50% and reduce carbon footprints through shorter transport. They also keep procurement dollars in the domestic economy, creating a multiplier effect of jobs and tax revenue. Qualitatively, they restore public confidence that "Made in America" means safe, available medicine.

The lesson is clear: cost savings from offshoring are illusory once risk and failure are priced in. Domestic and allied manufacturing delivers measurable value in reliability, oversight, and national security.

VII. Technology as a Force Multiplier

Rebuilding America's pharmaceutical independence will require not only new factories, but also new intelligence in how our supply chains operate. Even the most well-

intentioned policy reforms cannot succeed if the systems that manage purchasing, compliance, and inventory remain blind, fragmented, or paper-based. Technology is the bridge between reform and readiness — the force multiplier that transforms policy into measurable protection for American patients.

For example, iRemedy's MetaCommerceRx platform is an AI-powered procurement and supply-chain infrastructure purpose-built for the healthcare sector. It was designed to close the very loopholes this Committee is examining: the lack of visibility into where our medicines come from, who makes them, and how they move through the distribution chain.

During Operation Warp Speed, we learned that digital visibility could save lives. When the federal government has real-time line-of-sight into production, quality, and inventory, we can prevent shortages before they occur. That's the model we should make permanent.

Technology of this kind does more than streamline operations — it enforces accountability. By embedding verification into every transaction, the systems can eliminate the opacity that currently allows unsafe or counterfeit products to slip through complex distribution layers. Artificial-intelligence modules could flag anomalies in pricing, sourcing, or shipment patterns that may indicate non-compliance or supply-chain manipulation. Every transaction is traceable; every product can be verified. That is how we prevent "bad medicine" before it reaches the bedside.

Technology is not a luxury add-on — it is the multiplier that makes domestic production viable. Advanced analytics and automation reduce administrative cost, shorten fulfillment time, and enable smaller manufacturers to compete with subsidized foreign suppliers. They also give policymakers and hospital leaders the visibility needed to make informed, ethical purchasing decisions. A modernized, AI-enabled supply-chain architecture can serve as the foundation for a digitally networked Strategic National Stockpile — one that is predictive, transparent, and permanently linked to domestic and allied manufacturing capacity.

In short, digital modernization is how we operationalize the reforms this Committee is pursuing. By leveraging artificial intelligence platforms, the United States can replace opacity with visibility, dependency with accountability, and reaction with prevention. Technology turns policy into readiness — and readiness is what saves lives.

VIII. Legislative and Policy Recommendations

Ban Anti-Free Market Contracting Practices

For decades, a small number of powerful intermediaries—group purchasing organizations (GPOs) and wholesale distributors—have quietly reshaped the American drug market into one of the least competitive marketplaces in our economy. These firms evolved as a natural response to the enormously complex supply requirements of a modern healthcare provider. However, the current distribution model has now created its own market risks.

Three national GPOs now control roughly 90% of hospital purchasing; three pharmacy benefit managers process about 80% of all prescriptions. The result is a closed system that rewards volume rebates and "administrative fees" rather than quality, resiliency, or transparency. The structure looks like a free market on paper, but it functions like a cartel in practice.

Hospitals are effectively penalized for buying American. When a health-system pharmacy or hospital purchases a U.S.-made product outside its GPO contract—even to avoid a shortage or support a domestic producer—it can face termination penalties or loss of rebate eligibility. This single dynamic, more than any other, keeps American manufacturers from breaking back into their own market. It also forces hospitals to source from the cheapest offshore bidders, even when those suppliers are repeatedly cited for quality violations by the FDA. A hospital that tries to act responsibly—to diversify sourcing or purchase from a domestic facility—is punished for doing so. That is not capitalism; it is coercion disguised as contract law.

These contracts are hidden from public view by nondisclosure agreements so broad that even the prices paid for essential medicines are treated as trade secrets. Manufacturers are routinely required to sign NDAs with distributors and GPOs that forbid them from disclosing pricing or origin data, even to federal buyers. The consequence is a total lack of visibility across the system: hospitals cannot see where their medicines come from, the government cannot verify compliance with Buy American rules, and patients cannot know whether their drugs were produced under safe conditions. Opacity benefits only those intermediaries who profit from it.

Congress should prohibit any commercial contract clause or NDA that restricts transparency or penalizes out-of-contract domestic purchasing for essential medicines. Just as the Stark Law and Anti-Kickback Statute protect medical decision-making from conflicts of interest, we need statutory language that protects procurement decisions from monopolistic coercion. Hospitals and federal agencies must be free to buy safe,

American-made medicines without fear of financial retribution. Administrative "fees" and bundled rebate structures that tie pricing to exclusivity should be banned or treated as anticompetitive behavior under the FTC Act.

True resilience will not come from more regulation or subsidies alone—it will come from restoring open, transparent competition. Every U.S. manufacturer that meets quality and compliance standards should have equal access to hospital and federal markets. Every hospital should be able to choose products based on safety, reliability, and national interest—not on rebate penalties buried in a 200-page contract. And every American patient should have confidence that the medicine in their hand was chosen for its quality, not for a back-room discount.

In short, Congress must end the contracting practices that punish transparency and reward dependence. By banning restrictive NDAs, eliminating exclusivity penalties, and requiring open disclosure of sourcing and pricing, lawmakers can re-establish the free-market conditions that once made American medicine the envy of the world. Only then can our hospitals buy freely, our manufacturers compete fairly, and our patients trust the system again.

Federal Procurement Reforms

If the federal government expects private industry to prioritize domestic manufacturing, it must lead by example. The current procurement system—particularly within the VA, DLA, and HHS—still treats pharmaceuticals as commodities purchased on a *Lowest Price Technically Acceptable* (LPTA) basis. In practice, this framework rewards the cheapest nominal bid regardless of origin, security, or sustainability. Contracts are routinely awarded to "virtual manufacturers" that simply broker offshore production, bypassing true U.S. producers who invest in compliance, workforce, and infrastructure. Federal procurement must evolve from "cheapest available" to "safest, most resilient."

Price alone cannot remain the sole determinant of value when national security and patient safety are at stake. I recommend that Congress and the administration amend the Federal Acquisition Regulation (FAR) to require multi-factor evaluation criteria for essential medicines—weighting domestic sourcing, API traceability, and supply-chain resiliency alongside cost.

No contract for critical drugs should be awarded without verified data proving where each ingredient and finished dosage form is manufactured.
To achieve this, agencies should deploy real-time verification tools that confirm manufacturing origin and compliance at the time of award, not months later in

audits. Platforms like existing AI-based verification tools, already proven in federal-scale logistics during Operation Warp Speed, can provide this visibility: automatic country-of-origin capture, API-to-lot tracking, and full audit trails integrated with agency systems.

Finally, Congress should establish a "Trusted Supplier Registry"—a vetted pool of U.S.-based and allied-nation manufacturers meeting stringent quality, cybersecurity, and transparency standards. Federal buyers would be required to source from this registry for all essential medicines, ensuring that taxpayer dollars strengthen our domestic base rather than subsidize adversarial supply chains.

If we modernize procurement in this way—combining technology, verification, and national-interest weighting—we can turn federal purchasing from a vulnerability into a force multiplier for American production.

Incentives for U.S. Producers

Even with fair access to markets, American manufacturers cannot compete on an even playing field when foreign governments are subsidizing production, waiving taxes, and manipulating pricing through state-owned enterprises. China's "Made in China 2025" policy, for example, pairs tax holidays and export rebates with lax environmental and labor enforcement, driving down costs by artificial means. India's API sector, which supplies half of America's generics, receives similar state support while relying on Chinese inputs for roughly 80% of its raw materials.

The U.S., by contrast, offers almost no structural support for its domestic producers of essential medicines. We are asking them to fight an economic war with no ammunition. Congress must change that.

We should treat essential medicines as critical infrastructure—no less vital than semiconductors or defense systems.

- Targeted tax credits and accelerated depreciation for U.S. API and drug manufacturing investments.
- Long-term guaranteed purchase agreements for domestically produced essential medicines, modeled on the Defense Production Act and pandemic-era "advance market commitments".
- Federal loan guarantees and fast-track permitting for facilities producing critical drugs and ingredients; and

- Public–private vendor-managed inventory (VMI) programs integrated with a digital Strategic National Stockpile, allowing manufacturers to maintain steady production while ensuring readiness for emergencies.

These incentives are not corporate giveaways—they are investments in national security and public health. Every new factory built here replaces a dependency abroad; every job created in Birmingham, St. Louis, or Rochester replaces one outsourced to Shenzhen or Hyderabad. The return on investment is reliability, resilience, and a stronger industrial base.

We already have proof of concept. Companies like Oxford Pharmaceuticals in Alabama are producing critical medicines and medical supplies domestically, demonstrating that reshoring is not theoretical—it is achievable today. With the right incentives, dozens more firms could follow their lead, restoring America's medical independence one product at a time.

Trade Enforcement

Even as we strengthen domestic production and modernize procurement, those efforts will be undermined if we continue allowing adversarial nations to manipulate markets without consequence. The current global trade environment for pharmaceuticals is neither free nor fair. China and India have built entire export industries on subsidized energy, tax-free industrial zones, and government-financed credit lines—while American manufacturers operate under the full weight of environmental, labor, and safety compliance costs. The result is an artificially distorted marketplace that punishes U.S. quality and rewards offshore exploitation.

Trade enforcement must therefore become a pillar of America's medical security strategy. We should expand Buy American Act and Trade Agreements Act (TAA) compliance from a paperwork exercise into an auditable, real-time requirement. Federal buyers should be prohibited from purchasing essential medicines that contain active pharmaceutical ingredients from noncompliant or high-risk nations. Country-of-origin data must be verified at the National Drug Code (NDC) and lot level, not self-reported through intermediaries. Customs and FDA inspection authorities should be integrated into this verification process so that shipments failing origin or quality validation are barred from entry.

In addition, the United States must use existing Section 301 and 201 trade authorities to impose countervailing duties on pharmaceuticals and APIs from countries that use state subsidies, export rebates, or currency manipulation to gain unfair advantage. The

Commerce Department and USTR already have clear evidence that these practices exist; it is enforcement, not knowledge, that has been lacking. Where foreign-made drugs are found to have violated FDA safety standards, those products should trigger automatic import bans and debarment from federal contracting.

Finally, enforcement must be coordinated through a whole-of-government approach under OMB's "Made in America" President's Management Agenda, aligning trade, procurement, and regulatory policy around a single goal: protecting the integrity of the U.S. medicine supply. Without this integration, we risk continuing to finance our own dependency through taxpayer-funded contracts.

Fair trade does not mean tolerating abuse. It means applying the same rules to all participants. Until that happens, American manufacturers will remain outmatched—not because they can't compete, but because they are competing against countries, not companies.

IX. Human and Economic Stakes

Seniors, Soldiers, and Families

Every American family — every senior, every soldier, every child — relies on the same fragile global pipeline of medicines. When that chain breaks, it is not an abstract market failure; it is a human catastrophe. In 2024 the American Society of Health-System Pharmacists recorded the highest number of active drug shortages in U.S. history — 323 essential medicines, many of them sterile injectables used daily in hospitals. These are the antibiotics that keep infections from turning fatal, the heart medicines that stabilize veterans with chronic conditions, and the chemotherapy drugs that sustain cancer patients.

Roughly 91% of all U.S. prescriptions are generics. Yet 83 of the top 100 generic drugs have no domestic source of APIs. That means the most vulnerable populations — our seniors on Medicare and Medicaid — depend almost entirely on imports from China and India, where manufacturing oversight is weak, quality control is inconsistent, and political leverage is high. A 2025 peer-reviewed study found that Indian-made generics carried a 54% higher rate of serious adverse events — including hospitalization and death — than U.S.-made drugs. This is not a supply-chain statistic; it is a death toll hiding in plain sight.

The elderly are the first to suffer when shortages hit. Hospitals substitute second-choice medicines or ration what they have, forcing pharmacists and clinicians into impossible

triage decisions. At the same time, front-line soldiers depend on the same supply network for antibiotics, pain control, and field treatments. If an adversary restricts exports of APIs or finished doses — as China and India each have done during past crises — those who serve on the battlefield will feel it first. Our national defense is only as strong as the health of the men and women who serve.

During Operation Warp Speed, I saw these fragilities up close. When the Chinese Communist Party seized nearly 40% of our in-China inventory of needles and syringes, American healthcare workers were left waiting while foreign bureaucrats decided whether our patients could receive their vaccines. That same dependency extends today to the drugs that keep dialysis patients alive and diabetics stable. The contaminated Heparin tragedy of 2007–2008 — nearly 100 American lives lost to a tainted Chinese ingredient —was a warning we have still not heeded.

Every senior filling a prescription, every parent of a child with asthma, every soldier receiving field care is in the same position: dependent on foreign suppliers that do not share our standards or our values. Protecting American health now demands more than rhetoric—it requires a structural commitment to domestic manufacturing, oversight, and transparency. No citizen should have to wonder whether the medicine that saves their life was produced under conditions their own government cannot inspect.

Jobs and Innovation

The same factories that make our medicines also make our middle class. For every pharmaceutical manufacturing job offshored, three to five ancillary positions — packaging, quality control, logistics, and tooling — disappear with it. Two decades ago, America produced 83% of its pharmaceuticals domestically; today that figure has fallen below 40%. Entire industrial communities that once anchored our economy — from Flint to Birmingham — have been hollowed out. Rebuilding drug manufacturing is not a nostalgic appeal to the past; it is a strategy to restore innovation, technical education, and economic resilience.

When I was growing up in Flint, 15,000 people earned a living at a single GM plant. Those families built cars, but more importantly, they also built stability, pride and prosperity. Today, Oxford Pharmaceuticals in Alabama and other domestic producers show that same American industrial DNA still exists. Oxford's state-of-the-art facility demonstrates that we can produce high-quality generic drugs competitively, with U.S. workers earning fair wages and adhering to strict FDA standards. Each modern pharma plant supports hundreds of direct jobs and thousands more through the supplier network

that feeds it — from engineers and data analysts to glass, metal, and chemical manufacturers.

Reshoring does more than create jobs; it re-establishes the feedback loop between manufacturing and innovation. When production moves overseas, research and development follow. That is exactly what we have seen in biotech: China has surpassed the U.S. in clinical trial volume and biotech patent filings. If we continue to treat drug manufacturing as a commodity business rather than a strategic asset, we will forfeit not just factory jobs but our next generation of scientific leadership.

The economic impact is staggering. According to HHS estimates, shortages cost U.S. health systems over $500 million a year in extra labor and substitution expenses. That is money that could fund new manufacturing lines, training programs, and research partnerships in communities that have lost their industrial base. Instead, it bleeds out through supply inefficiencies and foreign mark-ups.

Investing in domestic pharmaceutical production means investing in America's capacity to invent. It means partnering our manufacturing plants with universities and vocational schools, recruiting a new generation of chemical engineers and technicians, and using technology like AI-driven supply-chain platforms to keep U.S. plants competitive. This is how we turn policy into paychecks and innovation into economic security.

Health Security is National Security

Health security is national security. The threat is not hypothetical. China controls 80–90% of the world's supply of key antibiotic ingredients and dominates global API production. India relies on China for most of its inputs, meaning that the U.S. has a single point of failure for critical medicines. Beijing has already proven its willingness to weaponize supply chains, from rare earth elements to medical goods. A strategic embargo or price manipulation could paralyze our health system within weeks.

During COVID, we learned the hard way that there is no "just-in-time" model for public health. The same vulnerability that left our hospitals without masks and ventilators still exists for antibiotics, antivirals, and insulin. We cannot defend our nation if we cannot treat our people. The Department of Defense understands this and so should every civilian agency that procures medicine for veterans, seniors, and first responders.

Domestic drug production is as strategically vital as shipbuilding or semiconductors. The technology exists, the facilities exist, and the need is urgent. Reshoring API manufacture, enforcing trade compliance, and modernizing federal procurement to favor U.S.-made

drugs are not economic preferences—they are acts of defense policy. As Eric Ueland at OMB has stated, "the time for action is now" to restore Made in America and fix procurement.

Our adversaries see the biopharmaceutical sector as strategic terrain. Beijing has declared biotech a pillar industry in its Five-Year Plans and is subsidizing it accordingly. We cannot allow America to be dependent on a competitor for the ingredients of life itself. That is why health security must be written into our national defense planning, our trade enforcement, and our industrial policy.

When the next crisis comes — and it will — our ability to heal, to respond, and to endure will depend not on foreign ports or permissions but on the factories, technologies, and workers here at home. That is the measure of a secure nation. And that is the commitment we owe to the American people.

X. Conclusion

Chairman Scott, Ranking Member Gillibrand, and Members of the Committee — throughout this hearing, we have examined the hard truth that America's medicine cabinet is not its own. The crisis we face is not theoretical; it is human, economic, and strategic. It is the story of seniors rationing prescriptions, hospitals waiting on shipments from Shanghai, and manufacturers in Alabama losing contracts to shell companies importing APIs from China and India. Our dependence has become so normalized that we now treat supply disruptions and contamination as unavoidable facts of life rather than preventable failures of policy.

The first step in solving any problem is admitting it exists. We can no longer paper over a structural dependency with short-term fixes. For too long, the United States has relied on what I would call "band-aids" — temporary measures meant to manage crises rather than cure the underlying disease. Emergency stockpiles, pre-announced inspections overseas, and subsidies offered without transparency have each bought us a little time, but none have restored our capacity to produce what Americans need to survive. These measures are essential in the short term, but they are not the cure.

The cure is to rebuild a fully domestic, technology-enabled, and competitively fair manufacturing base for essential medicines and medical supplies. That means aligning every element of federal policy — trade, procurement, taxation, and regulation — around a single strategic goal: American resilience. It means enforcing unannounced FDA inspections abroad today, while investing in domestic facilities that make those inspections unnecessary tomorrow. It means moving from a fragmented procurement

model to a unified national strategy that rewards quality, transparency, and allied sourcing. And it means harnessing the power of technology — platforms that can map, verify, and modernize our procurement systems — to ensure that future crises are met with data, not panic.

We already know this can be done. Operation Warp Speed proved that when government and industry coordinate with speed and accountability, America can out-produce any nation on earth. Companies like Oxford Pharmaceuticals and our other domestic medical device manufacturing partners have shown that "Made in America" can compete on both quality and cost when the playing field is level. The data are clear: manufacturing costs represent pennies on the dollar of drug prices, while inefficiency and opacity account for the rest. Reshoring will not make medicines unaffordable — it will make them dependable.

To get there, we must move from reactive management to proactive national strategy. Congress should establish a coordinated interagency task force — bridging HHS, DoD, Commerce, and OMB — to execute a 10-year blueprint for pharmaceutical independence. That blueprint must include federal advance-purchase commitments for domestically made generics, tax incentives for U.S. API facilities, and trade enforcement that stops subsidized foreign dumping. It should pair public-private investment in automation, AI, and supply-chain transparency to guarantee that the next generation of American manufacturing is not only cheaper but smarter.

President Trump has demonstrated strong leadership and commitment to prioritizing American-made medicines. I am enthusiastic about his level of engagement and the fact that his administration is open to our ideas and perspective. We need an all-government response involving regulation, legislation and procurement.

This is more than an economic imperative; it is a moral one. Every vial, pill, and syringe we fail to make at home is a potential point of failure in the life of an American senior, soldier, or child. Rebuilding this capability is how we honor the people who built our nation's industrial strength and how we protect those who will inherit it.

Mr. Chairman and Members of the Committee, thank you for your leadership in holding this hearing and for your commitment to ensuring that America once again becomes the most reliable source of its own medicine.

I am deeply grateful for the opportunity to testify and to contribute to the Committee's work. Together, we can move from band-aids to cure — from dependence to resilience. America's medicine should be made in America.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

PREPARED WITNESS STATEMENTS

Andrew Rechenberg

Testimony for Senate Special Committee on Aging:
Bad Medicine — Closing Loopholes that Kill American Patients

Andrew Rechenberg, Economist, Coalition for a Prosperous America

Chairman, Ranking Member, and Members of the Committee: Thank you for the opportunity to testify on the vulnerabilities in our pharmaceutical supply chain and to outline solutions to close these dangerous gaps.

American patients—especially seniors—are increasingly at risk from "bad medicine": unsafe imports, chronic shortages, and a broken market that rewards the cheapest foreign supplier over quality and safety.

These are systemic failures: fragile supply chains dominated by imports, single points of failure with no backup, collapsed pricing that has driven U.S. manufacturers out, persistent shortages, and recurring safety lapses from underregulated overseas plants. Together, they leave the United States dangerously exposed—dependent on adversarial nations for essential drugs, and unable to guarantee patients the medicines they need.

However, these problems are solvable. With the right tools, we can rebuild domestic capacity, enforce rigorous safety standards, and restore confidence in our medicines. This testimony sets out five strategic pillars that work in tandem to achieve this:

1. Protecting the domestic market through a Tariff-Rate Quota system.
2. Jumpstarting U.S. manufacturing with production and investment incentives (the PILLS Act).
3. Overhauling FDA oversight of foreign production and imports.
4. Realigning federal purchasing power and market incentives.
5. Securing U.S. biotechnology leadership through research reinvestment, strong trial standards, and protection of American talent and data.

Taken together, these reforms form a comprehensive strategy to secure our medicine supply, protect patients, and ensure that America leads in the discovery and production of future cures.

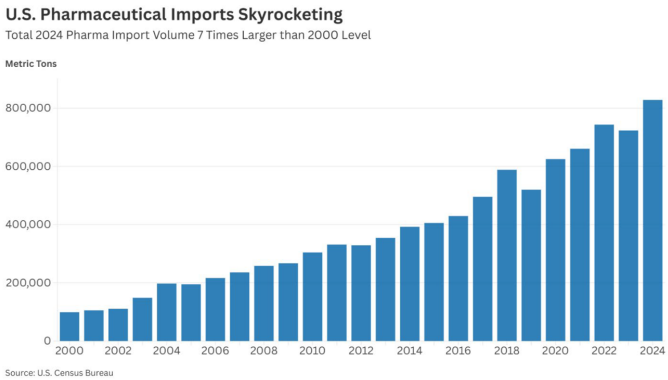
I. Key Failures of the U.S. Pharmaceutical System

Before discussing solutions, it is essential to understand how the United States arrived at this precarious moment. Over two decades of unguarded trade liberalization, relentless price pressure, and weak foreign oversight have hollowed out domestic pharmaceutical production and left our supply chain dangerously exposed and over reliant on underregulated foreign producers. What was once a resilient, U.S.-led system has devolved into one defined by foreign dependence, fragile chokepoints, chronic shortages, and unacceptable safety risks. These failures are not isolated problems. Together, they form a systemic breakdown that threatens both public health and national security.

Fragile Foreign Supply Chains — Extreme Import Dependence

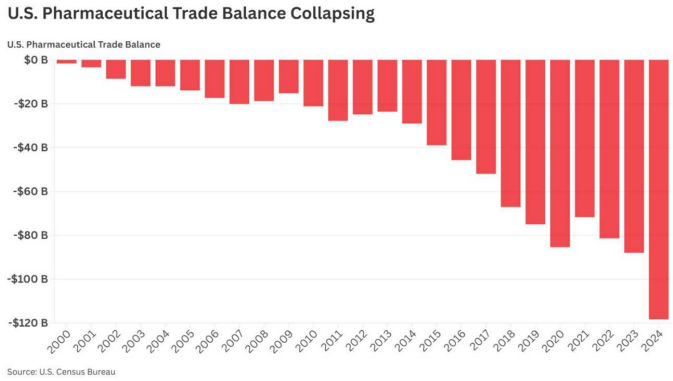
The American pharmaceutical supply chain has become dangerously dependent on imports and foreign-controlled supply chains. Over the past 20 years, the country has experienced a skyrocketing rate of pharmaceutical imports and increasing foreign reliance. In 2024 alone, the United States imported over 828,000 metric tons of pharmaceutical products—more than seven times the volume in 2000 [1].

Figure 1:



This surge doesn't reflect simple domestic demand growth but a complete surrender of U.S. production in pursuit of cheaper and riskier foreign drug alternatives. The result is not only a collapsing pharmaceutical trade balance—amounting to a record $118.3 billion pharmaceutical trade deficit in 2024 [1]—but also an erosion of U.S. sovereignty over one of its most essential industries.

Figure 2:



China and India now dominate our supply of essential drugs: China produces 80—90% of the world's key antibiotic ingredients [2], and India supplies about half of U.S. generic finished drugs, while India itself relies on China for up to 80% of their active ingredients [3]. In practical terms, the U.S. lacks a domestic source for over 80% of the active ingredients used in critical medicines [4]—if foreign shipments stop, Americans simply go without.

Such overreliance on foreign suppliers—many in geopolitically unstable or adversarial regions—is a profound strategic vulnerability. Supply vulnerabilities do not even have to be malicious. During COVID-19, for example, India banned exports of certain drugs and Chinese lockdowns disrupted shipments, triggering shortages here in the U.S. [5]. We cannot allow adversarial regimes or global upheavals to dictate whether Americans can get life-saving medicines.

Highly Concentrated Sourcing — Single Points of Failure

Our drug supply chain is not only over reliant on foreign supply, but highly concentrated in just a few sources, creating single points of failure with no backup. According to an analysis by the HHS' Office of the Assistant Secretary for Planning and Evaluation, among nearly 1,840 small molecule drugs in 2022, 43% had only one approved manufacturer in the U.S. [6]. Similarly, U.S. Food and Drug Administration (FDA) data from 2020 show that about 40% of generic drug markets are supplied by a single manufacturer [7].

Even critical medicines often depend on only one or two overseas factories. This concentration means that if one facility fails, the entire nation faces a shortage.

We are already seeing this happen: In 2023 the FDA shut down an Indian plant (Intas Pharmaceuticals) that made 50% of America's supply of the chemotherapy drug cisplatin [8]. Inspectors uncovered a "cascade of failure" in quality control—shredded and acid-doused documents meant to conceal falsified records [9]. With that single foreign plant offline and no U.S. producer to fill the gap, hospitals nationwide were forced to ration cancer treatments and delay care for thousands of patients [8].

We have seen this before with China as well. In 2016, a single factory explosion in China crippled global supplies of the critical antibiotic piperacillin-tazobactam, forcing rationing and treatment delays around the world [10]. The reason was simple: China was the only source of the active pharmaceutical ingredient. This is not an isolated case. Today, China remains the sole supplier for 20% of the active ingredients in America's most essential medicines [11]. When one plant falters, the entire chain snaps. Just as with the Intas shutdown in India, we are left exposed, with no domestic fallback and no redundancy. This is not a resilient supply chain—it's a house of cards.

Many antibiotics, sterile injectables, and other vital drugs come from only a couple of factories worldwide. A fire, a contamination, or a political decision in one country can instantly cripple America's access to an entire class of medicines. We've built a system where a single plant shutdown overseas has already caused nationwide shortages. These chokepoints are unacceptable for a nation's health security.

Collapse of Drug Pricing — U.S. Manufacturers Driven Out

Underpinning this fragile supply chain is a market failure in generic drug pricing that has allowed imports to drive U.S. producers out of the market. Generics make up 90% of U.S. prescriptions but account for only 17.5% of drug spending [12]. They

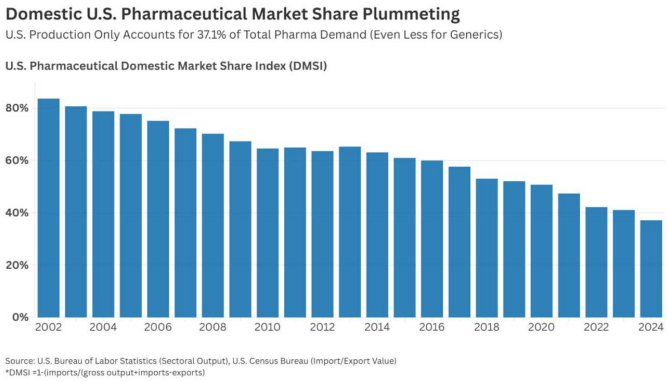
have become ultra-cheap, often just pennies per dose. Decades of unguarded free trade and foreign state subsidies have driven prices so low that U.S. companies cannot compete.

Foreign producers from China and India undercut U.S. and EU manufacturers by an estimated ~42% cost advantage [13]. But this is not through superior efficiency, but through intentional government policies in China and India. These countries have made the pharmaceutical industry a priority via government subsidies [14] [15], lower labor standards [16], lax environmental regulations [17], and corner-cutting on quality and testing [18] [19].

American firms have been squeezed out of the market as a result. As prices plunged to "rock-bottom" levels, we saw a wave of plant closures and bankruptcies among U.S. generic manufacturers [20]. For example, Akorn Pharmaceuticals, a major domestic generic producer, went bankrupt and abruptly shut all four of its U.S. plants in 2023 [21].

These closures weren't just isolated business failures. They were casualties of the gradual hollowing out of America's production base by imports. In 2002, U.S. manufacturers produced 83.7% of the pharmaceuticals consumed domestically. By 2024, that number plummeted to just 37.1%, with a corresponding $157.8 billion loss in potential domestic production value.

Figure 3:



**DMSI Calculations made using BLS Sectoral Output for Pharmaceutical and Medicine Manufacturing data [22] & Census Bureau HTS Chapter 30 Pharmaceutical Product Import/Export Value [1]*

The economic "race to the bottom" on drug prices has hollowed out our industrial base. Essential medicines are now often so cheap that no one in America is willing or able to make them. This pricing collapse also is not a victory for consumers. It is a long-term disaster.

Initially, hospitals and buyers saved money through cheap imports, but once domestic capacity disappeared, the U.S. became hostage to those foreign suppliers. The instant those suppliers have a production problem or raise prices, we have no domestic alternatives. The supposed savings of cheap imports evaporates in a crisis. Shortages force hospitals to pay exorbitant prices on the gray market, far more than any "savings" accrued by the initially cheaper imports. The U.S. pursued short-term lowest-cost drugs at the expense of long-term supply resiliency, and now we are paying the price.

Persistent Drug Shortages — A Production Crisis Endangering Patients

America is now mired in chronic drug shortages at a scale never seen before. In any given month, the United States has about 250-320 active drug shortages nationwide, spanning antibiotics, emergency sedatives, oncology drugs, cardiac medications [23]. These are staples of care in hospitals. Shortage levels hit a record high of 323 drugs in early 2024, the most in over two decades.

This is not normal volatility; it is a systemic breakdown. Over 99% of hospital pharmacists report facing drug shortages, and 85% say these shortages are critically or moderately impacting patient care [24], leading to rationed or delayed treatments. Drug shortages are disrupting frontline care—forcing oncologists to delay cancer treatments [25], hospitals to scramble for scarce medicines [26], and patients to face higher risks when doses are stretched or substituted [27]. For vulnerable and elderly patients, drug shortages can be life-threatening. Treatment delays and interruptions caused by shortages can adversely impact health and increase the risk of morbidity and mortality [28].

These shortages are not just caused by brief logistical glitches or sudden demand spikes. They stem from long-term collapse in domestic manufacturing capacity, driven by razor-thin profit margins, overreliance on foreign-sourced APIs, and insufficient incentives for U.S. firms to maintain redundant, high-quality production [29]. The drive for cheap imports actually created many of these

shortages. Up to 83% of drug shortages are in generics [30], and a primary driver is manufacturers exiting the market because prices fell below sustainable levels [29]. In other words, when foreign competitors undercut U.S. producers and force them out, no one is left to make the medicine if the import supply falters.

Hospitals have learned the hard way that free trade's "low prices" vanish in a shortage. Drug shortages drive up hospital error rates by 1—5%, create unsafe conditions in 60% of cases, and often force hospitals to pay 300—500% markups to obtain critical medicines [31]. The cheap drug from overseas turns into an expensive drug—or no drug at all—when the supply chain breaks. This shortage epidemic is a public health emergency and a national security threat.

It should be seen for what it is: a national economic breakdown with direct implications for public health, military readiness, and national security. In sum, America doesn't just have a drug shortage problem—it has a drug production problem. Without rebuilding manufacturing, the next shortage will be even worse.

Safety Risks from Substandard Imports — Loopholes in Oversight

Perhaps the most alarming loophole in our drug supply system is that Americans are often unknowingly receiving unsafe medicine. Heavy reliance on overseas factories—many in countries with weak oversight and poor compliance records—has allowed substandard and even dangerous drugs to reach U.S. patients.

The FDA has repeatedly documented widespread violations of Good Manufacturing Practices abroad, ranging from falsified test results to unsanitary conditions. These lapses have already had deadly consequences. At Glenmark Pharmaceuticals' plant in India, inspectors found repeated dissolution failures in potassium chloride capsules, poor cleaning, and inadequate investigations [32]. The company recalled more than 100 batches in 2024, and FDA records linked the product to at least eight U.S. patient deaths [32].

Other high-profile cases demonstrate the same dangers. In 2008, adulterated heparin from China killed dozens of Americans after the active ingredient was deliberately cut with a cheaper substitute, triggering fatal allergic reactions in hospitals and dialysis centers [33] [34] [35]. In 2013, Indian generic giant Ranbaxy pled guilty to felony charges and paid $500 million in penalties after admitting it manufactured adulterated drugs, falsified stability test results, and made false statements to the FDA [36]. The company knowingly submitted unreliable data and released unsafe products into the U.S. market, showing how systemic fraud abroad can directly endanger American patients.

Broader data confirms that these cases are not isolated. A recent study found that generic drugs made in India carry a 54% higher risk of severe adverse events than those made in the United States [19]—clear evidence that cut-rate overseas production often translates to cut-rate safety.

Current FDA enforcement actions reveal the same pattern. In China, inspectors cited Nuowei Chemistry for unreliable impurity testing, inadequate stability data, and a broken quality system [37]. In India, inspections at Granules India uncovered microbial contamination risks, poor cleaning and maintenance, and serious quality-control failures [38]. Even when the FDA does inspect, the process is hamstrung: until recently, nearly 90% of foreign inspections were pre-announced [39], giving plants time to conceal problems. Inspectors have found facilities literally shredding quality control records ahead of scheduled FDA inspections [40].

There is also a deep issue of a lack of transparency. Manufacturers are not required to disclose where a drug's active ingredients are made. Even FDA and GAO have acknowledged that the agency cannot determine the source country for many APIs used in U.S. medicines [41]. The Department of Defense admits that for 22% of essential medicines they cannot determine the source country at all [42]. That means hospitals, physicians, and patients have no way to know whether their base medicine ingredients were produced in a world-class facility or a high-risk plant on the other side of the world.

The consequences are sub-potent or unsafe medications, higher rates of adverse reactions, and treatment delays that erode trust in the very system meant to keep patients safe. No American should have to wonder whether their blood pressure pill or chemotherapy dose is safe, effective, and available. Yet that is where we are today. By outsourcing production, we have also outsourced oversight—surrendering control over the integrity of the medicines our patients rely on.

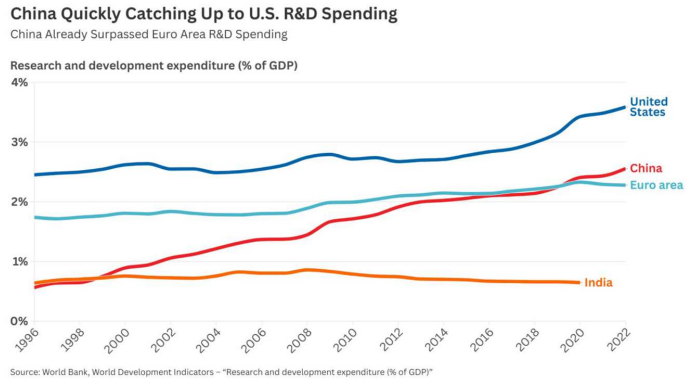
Biotechnology at Risk — How We Lost the Lead

The vulnerabilities in our drug supply extend beyond generics and APIs. America's leadership in biotechnology—once an unquestioned pillar of our medical strength—is now being eroded by a deliberate foreign strategy. Over the past two decades, the U.S. allowed core capabilities in manufacturing to move offshore, and critical research followed.

Beijing made biotech a key priority as part of *Made in China 2025* [43], resulting in billions of industrial investments and subsidies. In 2024, national R&D spending reached ¥3.6 trillion (around $500B), or 2.68% of GDP [44]—already surpassing

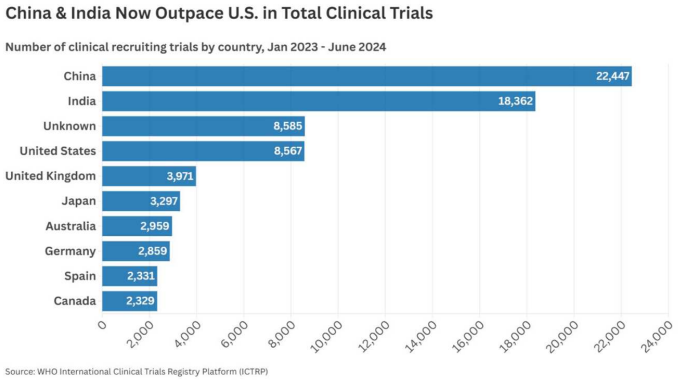
Europe's share and closing rapidly on America. China's biopharmaceutical R&D spending alone climbed to about $15 billion by 2023 [45].

Figure 4:



Driven by heavy investments in research and development, China has caught up to and in many areas surpassed the United States in critical biotechnology measures. By 2024, China logged over 7,100 registered clinical trials, surpassing the U.S. tally of around 6,000 [46]. China now accounts for about 39% of all global Phase I—IV clinical trial starts [47]—a dramatic rise over the past decade. Moreover, as shown in Figure 5, both China and India far outpace the United States in clinical recruiting trials over the past two years [48].

Figure 5:



These trials are not an end in themselves—they have fueled a broader strategy of innovation. China seized the opportunity by treating biotechnology as strategic infrastructure while the United States treated it as just another industry. This deliberate approach has translated into a rapid acceleration of discovery and commercialization. Biotech patent filings from China jumped from 119 in 2010 to 1,918 in 2023 [49], and by 2025 nearly 40% of global licensing deals involved Chinese-origin drugs [50].

This all has translated into research leadership: 7 of the world's top 10 research institutions in global research rankings are now Chinese, with Harvard as the lone U.S. entry [51].

Table 1:

Rank	Institution	Country
1	Chinese Academy of Sciences (CAS)	China
2	Harvard University	United States of America
3	University of Science and Technology of China (USTC)	China
4	Max Planck Society	Germany
5	University of Chinese Academy of Sciences (UCAS)	China
6	Peking University (PKU)	China
7	Nanjing University (NJU)	China
8	French National Centre for Scientific Research (CNRS)	France
9	Tsinghua University	China
10	Zhejiang University (ZJU)	China

Source: Springer Nature Index, Research Leaders 2024: Leading Institutions

Yet China's rapid rise has not been built on efficiency alone. Its edge comes from heavy state subsidies, tax rebates, and state-backed loans [52]—paired with low labor and safety standards [53] and weak environmental enforcement [54].

The FDA has rejected drugs like surufatinib and sintilimab [55] [56], pointing to outdated comparators, weak oversight, and homogeneous Han Chinese cohorts that do not reflect U.S. patients. Other headline therapies, such as ivonescimab, showed promising results in Chinese trials but far weaker outcomes in Western patients

[57]—demonstrating how speed-driven, low-quality designs can mislead regulators and endanger patients.

Meanwhile, NIH funding in the United States has been essentially flat. By 2024 the NIH budget was about 7% below the 2003 peak when adjusted for inflation [58], leaving our labs under-resourced just as China accelerated investment.

If America cedes biotechnology leadership, the consequences will not be limited to economics. We risk a future where the most advanced therapies are invented elsewhere, clinical trials are designed under looser standards, and our supply of lifesaving biologics and cell therapies is dictated by Beijing. This is not a theoretical risk—it is the trajectory we are on today.

II. Policy Solutions — A Five-Pillar Strategy to Secure America's Medicine Supply

The first pillar is to shield and rebuild the U.S. generic drug market using a Tariff-Rate Quota (TRQ) system. For example, Section 232 of the Trade Expansion Act empowers action when imports threaten national security [59]—and our current pharmaceutical import dependence clearly qualifies. This policy would set targeted limits on foreign generics that undermine our security, without sacrificing patient access or affordability.

National Security Rationale — Ending Dangerous Import Dependence

The TRQ is justified by the urgent need to secure our medicine supply. The Department of Commerce has already launched a Section 232 investigation into pharmaceutical imports [60], recognizing that overreliance on China and India is a national security risk. The Department of Defense reports that more than one in four essential medicines for the military are at "very high risk" of supply disruption due to foreign dependence [42].

A carefully designed TRQ directly strengthens national security by:

- **Reducing adversarial leverage.** It prevents hostile regimes from "weaponizing" drug exports to cripple our healthcare system.
- **Mitigating unintentional shocks.** COVID lockdowns in China and export bans from India showed how fragile import supply is under global upheavals.

- **Ensuring domestic fallback.** TRQ space ensures U.S. firms can scale to provide redundancy, not leave America hostage to single suppliers abroad.

Stable access to safe medicines is as fundamental to national security as an adequate defense stockpile. Trade policy is a powerful tool that Congress intended for precisely this scenario: defending the nation when imports undermine vital industries.

How a TRQ Would Work — Targeted Protection Without Shortages

Unlike across-the-board tariffs, a Tariff-Rate Quota (TRQ) allows a limited volume of product to enter the country at a low or zero tariff. Once imports exceed that quota volume limit, much higher tariffs automatically apply. This makes the TRQ a calibrated mechanism that balances security with patient access.

- **Quota setting:** Annual TRQ thresholds for critical generics and APIs would be set by the Departments of Commerce, Health and Human Services, and Defense together, based on demand, shortage data, and production capacity.
- **Quota calculation:** Allowances would equal U.S. demand minus what domestic manufacturers can supply, leaving a margin for market fluctuations. Imports within the quota face low or zero tariffs to guarantee supply of drugs not yet produced domestically.
- **Quality filter:** To qualify for quota-free treatment, both the API and finished drug must come from countries with strong regulatory systems under FDA Mutual Recognition Agreements (MRAs) [61]—such as the EU, UK, and Switzerland. This ensures only high-quality, trusted sources with equivalent safety standards are tariff-free.
- **Penalizing risky supply:** Imports from non-qualified countries (e.g., China, India, or those lacking equivalent MRA standards)—or imports above the quota—face steep tariffs (200—300% equivalent). Duties would be specific tariffs, assessed per-dose or per-kilogram, neutralizing the unfair advantage of subsidies and poor standards abroad.
- **The Need for Specific Tariffs:** One key element of the TRQ design is that duties should be assessed as specific tariffs (based on weight or dosage) rather than ad valorem percentages. In the world of ultra-cheap generics, even a 100% value tariff may add as little as a few cents per pill—far too little to change market dynamics or offset foreign subsidies. A per-dose or per-kilogram tariff structure ensures that penalties on unsafe or subsidized imports are meaningful in practice. This approach also helps guard against

invoice fraud—where exporters understate customs values to evade ad valorem duties—by tying tariff liability to physical volume rather than declared value.

- **Dynamic adjustment:** Quotas are adjusted each year to account for changes in domestic capacity and demand. As U.S. production ramps up, quotas narrow, nudging the market toward self-reliance and rewarding increased domestic supply capacity. During emergencies (pandemics, shortages), quotas can temporarily expand or tariffs be waived to keep patients supplied.
- **Strict enforcement:** Customs and FDA will require origin documentation and real-time monitoring to prevent transshipment or fraud. Any company caught falsifying data faces severe penalties or exclusion. Repeat offenders are barred outright.

In short: America will import what it needs, but on our terms—safe imports prioritized, bad actors penalized, and quotas adapted in real time.

A Proven Precedent — The U.S. Sugar TRQ

The United States already operates a long-standing TRQ system in another sensitive sector: sugar. Each year, the Department of Agriculture sets access levels of raw and refined sugar that can enter at low tariff rates, while imports above those amounts face prohibitive over-quota tariffs [84]. This system has balanced supply and price stability, ensured domestic producers a secure market, and maintained a reliable flow of imports from trusted partners. The pharmaceutical TRQ would follow the same proven model — but with far higher stakes in an even more critical sector. If TRQs can work to secure sugar, they can and must be applied to medicines essential to national health and security.

Protecting Patients — Why Tariffs Won't Raise Drug Prices

A common concern is whether TRQs and tariffs could make drugs more expensive, especially for seniors and vulnerable patients. The evidence shows they will not.

- **Middlemen capture most of the price.** Only ~36% of a generic's retail price reflects manufacturing; the other 64% goes to middlemen in the supply chain, including wholesalers, Pharmacy Benefit Managers (PBMs), pharmacies, and insurers [62]. Tariffs on manufacturers affect only a fraction of the end price at most.

- **Insurance absorbs costs.** Medicare and Medicaid already index reimbursement to acquisition costs:
    - *Medicare Part B*: pays Average Sales Price (ASP) + 6% [63], [64]. If tariffs raise costs, ASP rises, and providers are reimbursed accordingly. Patients' coinsurance stays fixed at 20% [65].
    - *Medicaid & Part D*: use Maximum Allowable Cost (MAC) and National Average Drug Acquisition Cost (NADAC) benchmarks updated weekly [66], [67], [68]. Therefore, pharmacies are compensated almost immediately. Part D's new $2,000 annual out-of-pocket cap (2025) further shields patients [69].
- **Commercial markets adjust similarly.** PBMs and insurers spread out cost upticks, and their large margins—long inflated by cheap imports—provide room to absorb modest increases.
- **Contracts already anticipate tariffs.** Most hospital GPO contracts include "change-in-law" clauses allowing modest price adjustments if tariffs apply. Drugs are so inexpensive that even doubling manufacturing costs often adds only cents to a pill.
- **TRQ reduces real costs.** By eliminating shortages that frequently cause 300—500% surge pricing [70], the TRQ saves hospitals money. Long-term stability beats dependence on a sole foreign supplier that can collapse or price-gouge.

TRQ tariffs are essentially "tariff-proof" at the pharmacy counter. Patients and hospitals are shielded by reimbursement systems, middlemen margins, and contract structures. The only losers are foreign producers and intermediaries who profit from unsafe, subsidized dumping.

Why TRQ is the Cornerstone

The Pharmaceutical TRQ system fortifies America's medicine supply by:

- Excluding unsafe, subsidized imports.
- Resetting the playing field so U.S. firms can compete on quality, not against state-backed dumping.
- Maintaining stable patient access through flexible quotas.
- Ensuring enforcement is adjustable, traceable, and enforceable.

- Doing all this without raising drug prices or causing shortages.

The TRQ is the cornerstone of reform. Trade tools exist to defend U.S. national security, including public health. American lives now depend on using them.

Pillar 2: Jumpstarting U.S. Pharmaceutical Manufacturing — The PILLS Act (Production & Investment Incentives)

The second pillar tackles the other side of the equation: we cannot just curb bad imports; we must actively rebuild the U.S. pharmaceutical base. That requires strong production and investment incentives to make domestic manufacturing economically viable again, and quickly.

The PILLS Act Framework

The Producing Incentives for Lifesaving Medicines Supply (PILLS) Act [71] is modeled on successful manufacturing incentives such as the CHIPS Act. It would provide targeted tax credits that directly address the cost disadvantages that drove production offshore.

Production Tax Credit (PTC).

- 35% tax credit on sales of U.S.-made finished generics, APIs, and licensed biosimilars.
- 30% credit for U.S.-made inputs such as intermediates, excipients, sterile diluents, packaging, and testing materials.
- A "domestic content bonus" worth up to 20%. The more of a company's supply chain that is U.S.-sourced, the larger the bonus. For example, if 80% of a drug's ingredients, packaging, and components are made in America, the manufacturer would qualify for an additional 16% tax credit on top of the base credit. Firms that fully source domestically could receive the full 20% bonus.
- Together, credits could offset up to half of costs, erasing much or all the foreign cost advantage.

Investment Tax Credit (ITC).

- 25% credit for building or upgrading pharmaceutical facilities and equipment.

- Covers new API plants, sterile injectable lines, and modernized fill-finish capacity.
- Structured as direct-pay or transferable to benefit startups as well as incumbents.
- Lowers the upfront barrier that often pushes investment overseas.

Both credits would phase down gradually between 2030—2033 to give firms planning certainty while preventing long-term dependency.

Why It Matters

The PTC makes U.S. production profitable where it currently operates at slim margins or even a loss, while the ITC lowers capital costs to build capacity. Together, they neutralize foreign subsidies, environmental and labor cost arbitrage, and quality-cutting advantages in China and India.

This is not abstract—it matters for critical U.S. firms like Coherus Biosciences, one of the few U.S. players in biosimilars. Coherus has brought important products such as *Udenyca* (for cancer patients) [72] and *Cimerli* (for vision loss) [73], but like other U.S. biosimilar firms it faces relentless pricing pressure from subsidized imports. Razor-thin margins leave little room for reinvestment or expansion. With a Production Tax Credit and investment incentives, companies like Coherus would finally have the foundation to expand capacity, hire American scientists, and secure a U.S. foothold in a sector we cannot afford to lose.

The Synergy with TRQ

The TRQ and PILLS Act are designed to work together. Tariffs create market space by curbing predatory imports; incentives make it attractive for U.S. firms to fill that space with real production. One without the other risks failure. Together, they form a classic industrial strategy: demand protection and supply stimulation. Within a few years, this combination could put new U.S. plants online making the medicines Americans need—under high standards, with American workers.

Pillar 3: Overhauling FDA Oversight of Foreign Manufacturing — Ensuring Safety for Imports

Even as we rebuild domestic capacity, the reality is we will continue to import some pharmaceuticals in the near term. To protect patients, we must close the regulatory loopholes that have allowed unsafe and substandard imports into the U.S. market. The U.S. must strengthen FDA oversight so that any drug sold in America meets the same gold-standard requirements as if it were made here.

Unannounced, Frequent Inspections

Foreign plants must face the same scrutiny as U.S. facilities. Today, many overseas facilities have gone five years or more without inspection [74], and until recently nearly 90% of those inspections were announced in advance [75]—giving companies time to conceal violations, as some have been caught doing [76]. Surprise visits should become the norm. Congress should provide FDA the resources for more inspectors abroad and mandate inspection frequency on par with domestic plants. Countries that refuse unannounced inspections should see their shipments restricted until compliance is restored.

Independent Batch Testing

The U.S. also needs to verify the safety of imported medicines, not just trust manufacturer paperwork. Each batch—or a statistically valid sample—of critical imports should be tested in certified U.S. labs for identity, potency, and impurities. This closes the loophole that allowed dangerous contaminants like NDMA in blood pressure drugs [77] to be discovered only after patients had already taken them. In the European Union, routine batch release testing by certified labs is standard [78], giving patients assurance that unsafe products are caught before reaching pharmacies. U.S. patients deserve no less. Independent testing can be financed through modest importer fees and would cost far less than the billions lost in recalls, shortages, and adverse events.

Tougher Enforcement for Repeat Offenders

Serial violators cannot be allowed to treat FDA warnings as a cost of doing business. If a manufacturer has multiple major violations—falsified data, contamination, or unsafe practices—FDA should be required to act swiftly. A “two strikes” rule could automatically suspend imports for a year, and a third violation

would trigger a five-year or permanent ban. Repeat offenders would also lose tariff-free access under the TRQ system and potentially face total exclusion from the U.S. market. Enforcement must have teeth—firms that cheat should lose the privilege of supplying the world's largest medicine market.

Supply Chain Transparency

A glaring weakness today is opacity. Hospitals and regulators often cannot determine where drugs or their active ingredients are produced. Congress should require full disclosure: API country-of-origin on labels, finished-drug site information, and a public FDA database tracking supply chains. Transparency allows buyers to avoid risky sole sources and enables policymakers to anticipate vulnerabilities before they trigger shortages. It is a low-cost reform that delivers accountability and security.

These reforms ensure that even as we import, those imports are held to U.S. standards. Stronger inspections, independent testing, strict enforcement, and transparency will restore trust in the drug supply. Safety can no longer be an afterthought—it must be embedded in the system.

Pillar 4: Realigning Federal Purchasing Power and Market Incentives — Putting Quality and Security First

The final pillar recognizes that the U.S. market itself—especially the largest buyers—must be part of the solution. The federal government, through Medicare, Medicaid, Veterans Affairs, Defense Department, and the Strategic National Stockpile, is the single largest purchaser of medicines [79]. Meanwhile, a handful of private buying groups—Group Purchasing Organizations (GPOs) and Pharmacy Benefit Managers (PBMs)—dominate hospital and pharmacy contracts. For too long, these buyers have rewarded only the lowest price, inadvertently reinforcing offshoring, squeezing out domestic firms, and leaving America dangerously exposed. The U.S. must realign incentives so that both federal programs and private intermediaries reward quality, redundancy, and security—not just pennies-per-pill.

Buy American in Federal Programs

- Medicare, Medicaid, DoD, and VA should explicitly favor U.S.-made or allied-sourced drugs.
- The Centers for Medicare & Medicaid Services (CMS) could provide enhanced reimbursement for U.S.-made generics, modeled on the COVID-era add-on for American-made N95 masks [80].
- DoD and VA should use TRICARE and procurement contracts to prioritize U.S.-sourced medicines vital to military readiness.
- Pilot programs in Medicare Part D, Medicaid formularies, and DoD acquisition can test domestic preference rules.
- Even a modest preference margin (5—10%) could tip contracts away from imports, sending a strong demand signal to U.S. producers.

Strategic Stockpiles and Anchor Contracts

- Expand the Strategic National Stockpile from a narrow reserve into a tool that anchors domestic production.
- Establish a Strategic API Reserve (SAPIR) and expand finished drug reserves sourced from U.S. plants.
- Use long-term federal procurement contracts to guarantee demand—making the government a buyer of first resort.
- The Defense Production Act (DPA) showed during COVID that federal purchasing can jumpstart capacity [81]; this should be institutionalized.
- Stockpiling also saves money: shortages cost hospitals hundreds of millions annually in labor and substitutes.

Reforming GPOs and PBMs

- Three Group Purchasing Organizations (GPOs)—Vizient, Premier, and HealthTrust—control ~90% of hospital generic contracting [82]. Moreover, ~90% of retail generic purchasing is concentrated in three PBM-aligned alliances—AmerisourceBergen, Cardinal, and McKesson [83].
- This concentration gives a handful of buyers overwhelming leverage in drug contracting. To win access to those contracts, manufacturers must accept rock-bottom prices. Subsidized imports from China and India can sustain

those margins, but U.S. producers cannot—and are driven out of the market. Once domestic firms exit, the only suppliers left are the foreign manufacturers, leaving hospitals dependent on single overseas sources.

- Congress should revisit the anti-kickback safe harbor that allows GPOs to collect vendor fees (42 C.F.R. §1001.952(j)), which biases contracts toward large incumbents.
- Require contracts to weigh FDA compliance history, redundancy of supply, and domestic sourcing—not just price.
- Encourage dual sourcing and shorter contract terms to avoid lock-in.
- The FTC and DOJ should investigate exclusionary practices—from bundled rebates to monopsony (buyer-side monopoly) power—that block new domestic entrants.

By harnessing the immense purchasing power of the federal government and the dominant leverage of GPOs and PBMs, the U.S. can reset incentives across the system. If Medicare, Medicaid, DoD, VA, and major buyers all prioritize secure supply, the entire market will follow. Hospitals will know that choosing the safer supplier is financially viable. Manufacturers will finally have customers willing to pay a fair price for reliable medicines. This ensures that the way America buys its drugs supports resilience, not collapse.

Pillar 5: Securing U.S. Biotechnology Leadership — Research, Trials, and Talent

Protecting today's medicine supply is essential, but the U.S. must also secure long-term leadership. The next frontier is biotechnology: advanced biologics, innovative therapies, and cutting-edge clinical research. China has treated biotech as strategic infrastructure, pairing subsidies with loose standards to seize global market share. Meanwhile, U.S. investment has stagnated and our research base risks erosion. The U.S. must ensure that it is not playing catch up to China—it must lead.

Strengthening Clinical Standards

- Require multi-regional trial data with diverse patient cohorts and modern comparators before FDA approval, ensuring U.S. patients are not exposed to therapies validated only on narrow overseas populations.
- Expand FDA capacity to monitor foreign trials and manufacturing sites with advanced analytics and risk-based inspections if these products seek U.S. approval.
- Mandate independent verification of site quality and data integrity to prevent shortcuts and systemic fraud in overseas studies.

Reinvesting in Research and Talent

- Reverse NIH stagnation by restoring real growth in research budgets, especially for early-stage discovery.
- Direct a share of federal R&D funding to biotech startups and translational research, using matching grants, loan guarantees, and dedicated commercialization funds to bridge the gap between university discoveries and market-ready therapies.
- Retain U.S.-trained PhDs and postdocs with competitive fellowships and permanent opportunities, while selectively recruiting top global scientists to ensure the most advanced cures are discovered and made in the United States.

Protecting U.S. Biological Assets

- Prohibit export of U.S. patient cells, genomic data, and biological samples to adversary countries without consent, traceability, and federal oversight.
- Establish penalties for unauthorized transfers and require transparent review of partnerships involving sensitive biological material.

These policies secure America's future edge in biotechnology by tightening trial standards, rebuilding research capacity, investing in startups and talent, and protecting patient data. Without these steps, tomorrow's cures may be discovered and manufactured in Beijing—not in Boston, San Diego, or North Carolina's Research Triangle. With them, the U.S. ensures that innovation, safety, and supply resilience remain firmly in American hands.

Conclusion

America's medicine supply chain is failing patients. We have built a system that prioritizes the cheapest offshore pill over secure access and quality. The result has been chronic shortages, shuttered U.S. plants, dangerous dependence on adversarial suppliers, and repeated safety lapses that cost lives. Today, 80% of essential medicines have no U.S.-based source, and many rely on a single foreign factory. When that chain snaps—whether by contamination, political decision, or accident—Americans go without care. This is not a temporary problem; it is a systemic breakdown with direct consequences for public health, seniors' care, and national security.

But this crisis is solvable. This testimony outlines five interlocking pillars that together can close the loopholes that kill American patients:

- **Protecting the Domestic Market (TRQ):** A Section 232 Tariff-Rate Quota system will end the flood of unsafe, subsidized imports while ensuring patients still have access to trusted allies' supply. It creates breathing room for U.S. firms to re-enter the market.
- **Jumpstarting Manufacturing (PILLS Act):** Production and Investment Tax Credits will make it profitable to manufacture generics, APIs, and biosimilars in America again, backed by a clear planning horizon that would catalyze capacity investments.
- **Overhauling Oversight (FDA Reform):** Independent batch testing, unannounced inspections, tougher enforcement, and supply chain transparency will ensure that any imports Americans do take meet our gold-standard safety expectations.
- **Realigning Purchasing (Federal Power & GPO/PBM Reform):** By directing Medicare, Medicaid, DoD, and VA to prioritize resilient domestic supply, and by reforming distorted GPO and PBM contracting, we can reset the market so it rewards reliability and quality, not just the lowest foreign bidder.
- **Securing Biotechnology Leadership:** By raising trial standards, reinvesting in NIH and biotech startups, protecting research talent, and safeguarding U.S. biological data, we ensure the cures of tomorrow are discovered and manufactured in the United States—not dictated from Beijing.

Taken together, these pillars rebuild both today's supply of generics and tomorrow's pipeline of advanced therapies. They are designed to reinforce one another: trade tools create the market space, incentives fill it, oversight guarantees safety, purchasing power sustains it, and biotech leadership secures the future.

Importantly, these reforms do not raise costs for patients. In fact, they lower them over time by eliminating shortages, preventing gray-market price spikes, and avoiding the hidden costs of unsafe imports. Seniors on Medicare and patients on Medicaid will remain protected, while hospitals will save from greater stability and fewer emergency markups.

We are at a historic inflection point. Congress now has the chance to transform supply security before the next crisis costs lives. With bipartisan leadership, we can move from a fragile, import-dependent system to one where every American can trust that their medicine is safe, available, and made under standards worthy of this country.

Let us act now. By enacting these five pillars, Congress can save lives, restore American manufacturing, revive research leadership, and ensure that our seniors—and every patient—never again suffer from "bad medicine."

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U.S. Senate Special Committee on Aging

"Bad Medicine: Closing Loopholes That Kill American Patients"

October 8, 2025

Prepared Witness Statements

Dr. Marta E. Wosińska

Testimony of Marta E. Wosińska, Ph.D.
Senior Fellow at the Center on Health Policy
at the Brookings Institution

Before the
U.S. Senate Special Committee on Aging
hearing titled

"*Bad Medicine: Closing Loopholes that Kill American Patients***"**

October 8, 2025

Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee, thank you for the opportunity to testify on generic drug supply and quality.

My name is Marta Wosińska, and I am a senior fellow at the Center on Health Policy at the Brookings Institution. I am an economist specializing in prescription drugs and pharmaceutical supply chains. Before coming to Brookings, I spent 12 years conducting policy work at three federal agencies with law enforcement responsibilities: the Food and Drug Administration (FDA), the Office of Inspector General at the Department of Health and Human Services, and the Federal Trade Commission. My time at these agencies gave me unique insight into enforcement dynamics that inform the Qualified Person proposal I present today.

Today, I am testifying solely in my personal expert capacity. The views I share are my own, reflecting nearly 15 years of studying drug supply chain issues both inside and outside government, with no financial stake in the outcome.

Introduction

Drugs, especially generic drugs, are a key component of medical care for seniors. Nearly nine in ten adults aged 65 and older use at least one prescription medication, and more than half take four or more on a regular basis, with the share increasing steadily with age. These medications are commonly used to manage chronic conditions that become more prevalent as people get older, such as hypertension, diabetes, heart disease, arthritis, high cholesterol, and depression.

Generic drugs account for the large majority of prescriptions filled for older adults—about 90% of all retail or mail pharmacy prescriptions in the United States are dispensed as generics.

Generics contain the same active ingredients and must meet the same FDA standards for safety, quality, and efficacy as brand-name drugs, but typically cost much less. For seniors, the widespread availability and affordability of generics supports medication adherence and helps limit out-of-pocket costs, both for individuals and for public programs such as Medicare.

Because most major categories of chronic disease medications have generic options available, the majority of what seniors take each day is likely to be a generic product. This allows older adults to better manage multiple conditions as their needs increase with age, with important implications for quality of life and long-term health outcomes.

It is therefore fitting that the Senate Aging Committee is considering how best to assure that the generics seniors rely on remain safe, effective, and available. I appreciate the Committee's attention to this issue and the opportunity to testify on steps we can take to strengthen those assurances.

My testimony proceeds in three steps. First, it explains how intense price competition shapes today's generic markets and why those economics contribute to quality lapses and shortages. Second, it evaluates commonly proposed solutions through a fit-for-purpose and budget-conscious lens, highlighting where onshoring helps and where upstream China risks and hospital shortages merit higher priority than Indian finished dosage forms (FDF). Third, it turns to direct, scalable measures to strengthen Current Good Manufacturing Practice (CGMP) oversight—concluding with a Qualified Person (QP) certification model and targeted import testing to improve detection, deterrence, and accountability without destabilizing supply.

The race to the bottom

Generic drugs are prescription drugs that contain the same active ingredients, dosage form, strength, safety, quality, and intended use as their brand-name counterparts, but are typically sold at a significantly lower price than the brand they copy once sold at. In this section, I describe what drives this competition.

To be approved, generic drugs follow an abbreviated pathway that allows applicants to rely on existing clinical data from the brand-name product to establish safety and efficacy. The abbreviated pathway does not, however, waive manufacturing quality requirements: applicants must still prove to the FDA that their manufacturing processes can consistently replicate the approved product, ensuring each batch matches the quality, safety, and efficacy of the original drug.

While minor differences such as inactive ingredients, appearance, and packaging are permitted, generic drugs are regarded as interchangeable with their brand-name originals. This means that pharmacists can substitute a generic drug for the brand-name version without needing a new prescription, and patients can expect equivalent safety, efficacy, and clinical effects from either product. By extension, pharmacists may substitute one generic version for another.

Leveraging the therapeutic equivalence of generic versions, payers structure reimbursement systems—including Maximum Allowable Cost (MAC) lists, discounts off Wholesale Acquisition Cost (WAC), Average Sales Price (ASP) formulas, and Diagnosis Related Group (DRG) payments—to promote the selection of the least expensive option. In all these systems, providers and pharmacies are strongly incentivized to seek out the lowest-cost product that meets therapeutic equivalence requirements because reimbursement typically does not vary with the acquisition cost of different generic versions.

In the retail pharmacy setting, payers often reimburse pharmacies based on MAC lists, which set a fixed upper limit (the maximum allowable cost) for what the payer or pharmacy benefit manager will pay for a

given generic drug, regardless of which manufacturer is chosen. Pharmacies may also be reimbursed using payment formulas (such as discounts off WAC) or other fixed amounts. In all cases, selecting a lower-cost generic increases the pharmacy's margin, since reimbursement is not tied to the actual purchase price.

In inpatient hospital settings, commercial and government payers frequently bundle input costs into a single payment determined by DRG, so hospitals have a strong incentive to minimize input costs—including drugs—by using the least expensive generic version. For drugs administered in outpatient clinics, reimbursement may be bundled or based on ASP across all versions of the same generic drug. In this scenario, the payer's outlay is not adjusted for which generic is sourced, again driving providers to select the lowest-priced option.

To obtain the best prices, major retail pharmacy chains participate in one of the four buying groups that represent over 90% of generic drug volume purchased. The four main joint ventures are: Red Oak Sourcing (CVS Health and Cardinal Health), Walgreens Boots Alliance (Walgreens and Cencora), ClarusOne (Walmart and McKesson), and Econdisc Contracting Solutions (Express Scripts and Kroger, among others). These joint ventures consolidate the purchasing power of their members, enabling them to negotiate deeper discounts and more favorable terms.

Similarly, hospitals pool their bargaining power using group purchasing organizations (GPOs). The top three GPOs collectively represent hospitals that account for over 80% of hospital beds, giving them substantial collective purchasing power to negotiate prices. Vizient holds the largest share of the market with 37% of hospital beds, followed by Premier with 28%, and HealthTrust with 15%.

Empirical data confirms continued price pressure resulting from concentrated purchasing power among retail chains and hospital network.

There is continued deflation in the generic retail markets. Industry analyses report annual deflation rates of -10% to -15% for most generic drugs from 2017 to 2018, moderating somewhat to -5% to -10% by 2021. One analysis of pharmacy acquisition costs for top-selling generics found that many now cost pharmacies less than $1.50 for a 30-day supply. Most recently, a 2024 analysis found year-over-year acquisition cost deflation for generic oral solids as high as 25%—an unprecedented drop likely amplified by recent National Average Drug Acquisition Cost (NADAC) survey methodology changes. But recent manufacturing earnings reports reference continued price erosion, especially for older generic products.

Generic drug prices in hospital markets are also at historic lows. Analyses of FDA and US Pharmacopeia (USP) shortage databases show that over half of sterile injectables and 66% of solid oral medicines in shortage were invoiced at the pharmacy level for less than $5 and $3, respectively, in 2024. A recent IQVIA report found that while only 1% of drugs invoiced at $500 or more are in shortage, 11% of drugs priced under $1 are in shortage. As provided for this testimony by QuickSortRx Inc., among the 20 most commonly used generic injectables, eight had options with list prices below $1, another with options listed between $1 and $1.50, and only four had list prices of at least $5. In addition to list prices, some generics may also be providing GPO discounts or 340-B discounts. One 2018 analysis listed those in the range of discounted about 15% to 20% for GPOs and 25% to 50% for 340B. Those discounts have since had 7 more years to deepen.

Generic drug prices in hospital markets are also at historic lows. Analyses of FDA and USP shortage databases show that over half of sterile injectables and 66% of solid oral medicines in shortage were invoiced below $5 and $3, respectively, in 2024. A recent IQVIA report found that only 1% of drugs invoiced at $500 or more are in shortage, compared to 11% priced under $1. As provided for this testimony by QuickSortRx Inc., among the 20 most commonly used generic injectables, eight had list prices below $1, one ranged from $1 to $1.50, and only four were priced at $5 or more. Generics also

often receive GPO or 340B discounts, which a 2018 analysis estimated at about 15% to 20% for GPOs and 25% to 50% for 340B — discounts that have likely grown deeper since.

The race has consequences

The high leverage of drug buyers leads to demand instability, which, when coupled with persistent price pressure, leads to significant pressure to cut costs. This can then lead to reduced supply chain resilience and may compromise the ability or willingness of manufacturers to maintain strict CGMP standards. Both can then lead to drug shortages. This section explores these operational realities and their consequences.

Demand instability

In the retail generics market, manufacturers often lack predictability over how much product they can sell while at least breaking even on production costs. Long-term contracts exist but frequently include best price guarantees that force manufacturers to match uncontracted competitors' discounts—sometimes weekly and without knowing the quantities sold at those lower prices. In the hospital setting, similar clauses exist in GPO contracts but are triggered less often, likely because fewer manufacturers produce a given generic sterile injectable. However, hospitals can still source off-contract, further reducing the predictability of order volume.

Unstable demand makes production planning difficult for generic drug manufacturers. With lead times for raw materials and manufacturing often measured in months, companies must choose between producing larger, more efficient batches—risking unsold inventory if demand falls—or smaller, more costly ones to avoid losses.

The large product portfolios, coupled with uncertain demand, also create manufacturing control challenges. Unlike a branded production line, which may be dedicated to the same product for several years in a row, generic production lines may switch between 20 to 30 products in a year. For generic products first to market, batch runs may last a couple of months, but will shorten to three to ten days once the market settles and competitors emerge. These frequent changeovers not only increase labor and equipment downtime but also require rigorous regulatory documentation and validation, adding further complexity and cost to manufacturing operations. But if not conducted properly, changeovers can lead to cross-contamination between products.

Greater relative shock size

Faced with price pressure and unpredictable demand, manufacturers of generic drugs have a strong incentive to cut costs. Two of the ways that manufacturers can cut costs directly affect shock size: create scale and offshore. These are important from a supply resilience perspective, and therefore the risk of shortages, because the greater the shock relative to the market, the harder it is for supply chains to recover.

As described in the unstable demand section, manufacturers have a strong incentive to leverage economies of scale to minimize per-unit cost. However, the lack of predictability over demand tampers with those incentives. But if market structure allows for it, for example, sterile injectable facilities have high entry barriers and fewer competitors, scale wins. It is therefore why we see sterile injectable

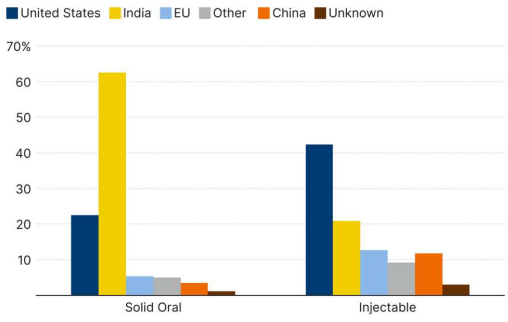
markets with single facilities representing 60% market share of 1L saline bags, 50% market share of injectable morphine, and a 50% market share of carboplatin.

Another market structure factor that may create disproportionately large shocks is the co-location of facilities. Economic incentives have a lot to do with it—moving facilities to lower-cost environments. For example, tax policies implemented in the 1950s encouraged significant expansion of the U.S. pharmaceutical industry in Puerto Rico. When Hurricane Maria hit the island in September 2017, most, if not all, of the 50 pharmaceutical facilities on the island were affected. Similarly, the low cost of labor and capital in East Asia, coupled with government subsidies in some of these countries, has shifted parts of pharmaceutical production to those countries, creating a potential geopolitical threat.

The impact of offshoring FDF production is clearly visible in Figure 1: 61% of the FDF of generic solid oral drugs sold in pharmacies are now primarily made in India. The U.S. makes 22% unit share of generic solid oral dose drugs, a big share of which are controlled substances such as opioids and ADHD medications, due to Drug Enforcement Agency requirements that those products are domestically produced. China represents a 3.5% unit share, which is less than Europe's 5.4% unit share.

Sterile injectable generics, such as IV antibiotics, saline, chemotherapy agents, lidocaine, and epinephrine, are still largely made in the U.S. (Figure 1). Part of it has to do with the complexity of production relative to oral dose products and the much higher transportation costs for such drugs. But offshoring has followed, with India taking a leading role in the trend, currently at 20.9% unit share. China and Europe are almost on par when it comes to generic injectables, 11.8% and 12.7% respectively.

Figure 1: Unit volume share of generic finished dosage drug production (2024)



Source: Wosińska (2025) using USP Medicine Supply Map

Note: Solid oral dose volume is measured in tablets/capsules; injectables are measured in dispensing units (vials, syringes, or IV bags)

The upstream supply chains for pharmaceuticals—especially for active pharmaceutical ingredients (APIs), key starting materials, and certain bulk chemicals—have even greater exposure to international risk, with significant dependencies on India for active ingredients and on China for chemical precursors. However, when considering the physical product quality concern at the heart of this analysis, it is the FDF production stage that matters most. This is because CGMP compliance requires that manufacturers thoroughly test and document the quality of all inputs, regardless of where those inputs originate. If manufacturers are meeting their CGMP obligations, any product defects reaching the market, even if they originate with inputs, represent a breakdown at the final production stage.

Diminished ability to respond to shocks

When supply chain shocks occur, shortages result if the supply chains lack resilience to absorb or recover from them. If recovery is slow, shortages persist.

Branded drug manufacturers pay attention to supply chain resilience because high margins earned by their products provide manufacturers with strong incentives to invest in trying to prevent disruptions to those products. The risk of forgoing these margins and profits give them a greater incentive to invest in quality systems and to maintain spare capacity in case production unexpectedly must shut down. When production disruptions of this kind occur, they tend to resolve faster.

For generics, low margins create little incentive to invest in resilience efforts, but actual resilience across generic drug markets differs because of market structure and technological differences.

Generic injectables often require specialized production lines (you cannot make one-liter IV bags on a line that only makes 250-milliliter IV bags). In other cases, it is because production lines are often dedicated to specific products (as with cancer drugs and antibiotics), as process requirements make switching lines either costly or impossible. Ramping up production can take weeks, even on a production line fitted for the drug. The market concentration described in the previous subsection also means that the gap to recover from can be substantial, e.g., half the market production that has ceased overnight.

Generic drugs that are formulated as tablets or capsules face possibly greater price pressures from pharmacies, but they are less vulnerable to shortages because they face a different manufacturing environment and market structure. Manufacturing of those products is less complex, not requiring specialized facilities with employees following complex manufacturing processes and controls. Generic oral dose product markets are also less concentrated than sterile injectable ones, and there is more fungibility in oral dose production lines that can also be ramped up faster.

However, common shocks can still be quite consequential in the oral solid dose market, despite these advantages. For example, when many manufacturing facilities are co-located in a single region, they may all be vulnerable to the same natural disaster or local infrastructure failure. Similarly, reliance on common sources for raw materials or key ingredients, or siting production in countries that may impose export bans, can create systemic supply risks. Such vulnerabilities mean that even the relatively resilient retail generic market is not immune to wide-ranging disruptions.

While geographic concentration and upstream supply chains are important risks, it is important to note that much of the fragility in the generic drug supply chain is associated with manufacturing quality failures in the production of the FDF (i.e., tablet or vial of medicine). This, in turn, is closely associated with adherence to CGMPs.

Challenges to upholding CGMPs

High-quality, safe, and effective generic drugs depend on robust compliance with CGMPs. CGMPs are essential safeguards, ensuring that medicines meet strict standards for identity, strength, quality, and purity in every batch produced, minimizing risks of contamination, error, or deviation. Because neither patients nor clinicians can readily assess the quality, safety, or efficacy of medicines themselves, the public relies on manufacturers to maintain these rigorous standards and on FDA to enforce them through an established regulatory framework.

Manufacturers bear primary responsibility for following CGMPs, which require oversight at every step of production—monitoring equipment, verifying staff credentials, supervising processes, testing samples, and thoroughly investigating any problems that arise. This is especially critical for complex products like sterile injectables, where lapses in quality control can result in serious contamination risks.

Yet, significant price competition and unstable demand often pressure manufacturers to cut costs in ways that undermine CGMP compliance. Thin margins and unpredictable markets can lead to reductions in Quality Unit staffing, less independence for those responsible for quality assurance, and the blending of production and quality roles. Manufacturers may also limit routine controls, such as audits and investigations, weakening the systemic safeguards needed to ensure each product's safety and reliability.

As pharmaceutical supply chains grow more global and complex, FDA's oversight is more important—and more challenged—than ever. The agency must hold manufacturers accountable for consistently upholding these essential practices in the face of ongoing operational and economic pressures.

FDA enforcement faces headwinds

To ensure consistent drug quality, FDA relies on a combination of prescriptive regulatory requirements, facility inspections, and various compliance tools. FDA requires manufacturers to have strong quality systems that follow CGMPs, including oversight of every production step, checking samples during production, and keeping thorough records. FDA investigators then verify compliance with standards through both scheduled and unannounced inspections, during which they review everything from personnel training and equipment maintenance to contamination control and recordkeeping. When serious violations are uncovered, FDA can act through warning letters, drug recalls, import refusals, and import alerts.

But the FDA oversight system is imperfect. FDA struggles with persistent staffing shortages and inspection backlogs, especially for foreign facilities in countries such as India and China. Many inspections abroad are still announced in advance, which weakens the detection of compliance issues. Driven by economic forces, some pharmaceutical manufacturers of low-cost generics often have weak quality management systems that lack the authority and resources to enforce CGMP compliance effectively. Perhaps most concerning, decisions not to release a batch or to initiate a recall are often judgment calls. For low-margin products, manufacturers face strong incentives to release a questionable product rather than bear the financial hit of withholding it from distribution.

The consequences of manufacturing quality problems can require costly remediation, but shortages also invite government support. Here is what might be referred to as a "too important to fail" problem: FDA does not want shortages, so it will be flexible with its rules when problems arise, especially for medically necessary drugs where the manufacturer, in violation of FDA standards, also holds a large market share.

That dynamic, however, undermines the deterrence effect of fines, just like a traffic cop giving out warning tickets for speeding will have a lesser deterrence impact than a cop giving out fines.

In such an environment, manufacturers may function at a "lowest common denominator" level of compliance, where CGMP principles are not fully enforced and quality systems lack the independence or resources to reliably detect, investigate, and prevent errors.

Analyses of FDA enforcement trends and warning letters identify recurring failures in quality unit authority, documentation practices, change control, and batch record review—especially among overseas and generic manufacturers. FDA data show that in recent years, many facilities inspected—particularly in China, India, and Southeast Asia—received citations for inadequate quality management, data integrity lapses, and insufficient oversight of outsourced production. Systemic noncompliance at these facilities increases the risk that substandard or contaminated drugs will reach patients, with potentially serious health consequences.

At the same time, the detection of such quality oversight problems can force manufacturers or regulators to delay or withhold release of affected products. This restriction—while essential to protect patients—often leads directly to drug shortages. Manufacturing quality issues are a leading cause, responsible for 56% in 2011, 62% between 2013 and 2017, and 46% in 2022 of shortage events.

The illusion of easy fixes

Policy solutions must be fit for purpose. Measures that don't match the failure they target risk being inadequate—or even counterproductive—in a market defined by intense price competition and thin margins.

For supply chains, there is one overarching goal: ensuring patients can access safe and effective drugs when needed. To achieve this, it is important to distinguish four related but distinct concepts:

- **Physical product quality**: reducing product defects in the drug itself, including contamination, mislabeling, and potency failures.
- **Quality assurance:** strengthening systems that prevent defects—manufacturing controls, process capability, data integrity, and ongoing monitoring—because unit-by-unit verification is infeasible and CGMP is the principal assurance tool.
- **Supply chain resilience:** improving the ability to withstand disruptions—manufacturing problems, input shortages, plant closures, or geopolitical shocks—regardless of origin.
- **Supply chain reliability:** the broadest outcome, encompassing both quality assurance and resilience, to deliver dependable, on-time availability of medicines.

In this section, I evaluate policy options to address manufacturing quality concerns identified by this Committee, assessing them on how well they advance each of the four concepts outlined above, with attention to whether the costs are justified by the benefits for patients and taxpayers.

Transparency for consumers

At the September 17th hearing, patient-facing transparency around drug quality drew genuine interest from several senators, who were intrigued by its potential for empowering consumers and strengthening trust in the pharmaceutical system. The underlying idea is straightforward: studies show consumers would value drug quality information, and if prescription labels included measures like a five-

star rating based on product testing, patients could express preferences at the pharmacy, potentially steering demand toward products with higher ratings.

However, what this idea overlooks is that pharmacies have little economic incentive to accommodate such requests. Pharmacies are reimbursed the same amount regardless of the manufacturer's quality rating, meaning they earn no more for dispensing a higher-rated product. In fact, sourcing a non-preferred or specially ordered product often carries additional costs, including time, administrative burden, and inventory risk, without any offsetting revenue—a challenge for what is already a low-margin business.

Patients, meanwhile, have only one real choice at the pharmacy counter, which is to take the medication offered or forgo treatment altogether. This means the only way to express preference in the current system is through non-adherence—a harmful and unacceptable outcome.

Even if drug quality scores were printed on labels, pharmacies would be unlikely to change procurement patterns unless reimbursement models tied payments to quality ratings, making it economically viable to stock or special-order higher-rated products. Without correcting this misalignment, consumer-driven quality improvement could make things worse, not better. Policymakers should therefore proceed carefully with the idea, either by addressing pharmacy reimbursement first or by turning to other tools to accomplish the same goal of improved drug quality of drugs sold in retail pharmacies.

That is not to say transparency is all bad. For example, with greater visibility into supply chains, the federal government can assess which supply chains are most vulnerable, prioritizing those for intervention. Quality metrics can also be critically important for institutional buyers—an issue I turn to next.

Transparency for institutional buyers

Unlike individual patients, institutional buyers such as hospital pharmacies, mail-order, and retail pharmacies have real choices when it comes to generic manufacturers from whom they procure. This makes transparency around supply reliability and manufacturer quality an especially valuable area to explore.

The early development and application of these ideas have focused heavily on the hospital setting, where drug shortages have been particularly common and acute.

The central goal of these transparency initiatives is to equip institutional buyers with metrics that help them identify manufacturers capable of reliably delivering products. This focus is distinct from typical product quality measures; it is about shifting demand toward manufacturers with stronger records of supply chain reliability. By doing so, the overall stability and resilience of the pharmaceutical supply chain can be strengthened as demand incentivizes better performance.

Efforts to create such metrics are not new. As early as 2012, the concept was first proposed in a research paper I coauthored with then-FDA Drug Center Director Janet Woodcock. This work has since evolved into three key programs aimed at measuring and reporting on manufacturer quality and supply reliability, including the FDA Quality Management Maturity (QMM) assessments, Healthcare Industry Resilience Collaborative (HIRC), and US Pharmacopeia's (USP) quality testing and resiliency benchmarking programs. All these remain in early or pilot phases. Their eventual adoption, implementation, and influence on the market are not yet certain. Nevertheless, their shared aspiration is to drive market incentives toward a more robust and reliable drug supply.

Addressing this gap, some entities like Civica Rx operate with a different model, vetting manufacturers rigorously before entering into long-term supply agreements, thereby providing member hospitals with a dependable drug supply as well as encouraging manufacturers to maintain high reliability standards.

Ultimately, transparency about supply reliability alone will not transform institutional purchasing behavior unless accompanied by changes to the underlying incentives faced by hospitals and GPOs. Even now, GPOs cold use their size and collective purchasing power to assess supply chain vulnerabilities, including by compelling confidential information about manufacturers' supply reliability. But GPOs are only paid if hospitals buy through their contract, and with hospitals seeking the best prices, neither GPOs nor hospitals have sufficient incentive to pursue such initiatives aggressively.

In other words, no matter how much transparency there is about suppliers, if there is no financial reward or accountability on the hospital's part for not having a drug available, transparency reforms will falter.

This discussion, therefore, turns to the bipartisan Senate Finance proposal put forward in May 2024, which aims to reform the hospital incentives to select more reliable manufacturers.

Senate Finance proposal

Because the Senate Finance legislative drug shortage proposal addresses the fundamental incentives hospitals face, it stands as perhaps the most consequential attempt to correct the persistent equilibrium of manufacturing quality issues that trigger a disproportionate share of shortages.

The Senate Finance Committee's approach focuses on generic sterile injectable drugs where the shortage risk is the greatest. The proposal has two pillars.

First, the legislative proposal provides for Medicare add-on payments to hospitals and physicians who sign long-term contracts for qualifying generic sterile injectables with more reliable supply chains. The proposal would require providers and GPOs to sign minimum three-year contracts, bind themselves to meaningful purchase volumes, and maintain contingency agreements with alternate manufacturers. The premise is that such stable purchasing will help ensure continuous drug supply and encourage manufacturers to invest in quality and capacity, knowing they will have committed buyers.

The program's success hinges on the practicality of participation costs for hospitals and having a reliable way to identify which manufacturers are trustworthy, meaning that they can consistently deliver drugs that meet specifications to hospitals. Efforts to develop quality metrics for reliability are important, but an alternative approach is simply to pay based on whether the contracted drug was delivered to specification, sidestepping the challenge of metric precision.

The second major component is reforming the ability of generic manufacturers to increase prices. Current Medicaid policies—particularly the inflationary rebate system—cap how much manufacturers can pass costs onto the Medicaid program. The same rebates extend to the 340B in which about half the hospitals participate. The inflation rebate, while designed to prevent price gouging, caps all price increases, even when those increases could fund investment in better quality or redundancy. To address that, the Senate Finance proposal eliminates Medicaid inflation rebates and, by extension, addresses the same problem in the 340B program.

Since the proposal has come out, many stakeholders have raised concerns that adjusting the inflation rebate and 340B interactions would harm hospital finances. But for shortage-prone generics, the dollars at issue are small not only to overall hospital pharmacy budgets but also the intake from the branded-side of the 340B program. It is also not realistic to fund multi-year quality investments by 'raising price

elsewhere.' Attempting to pass the full share of quality improvements to non-340B buyers is likely to run up against what is effectively a price-cap that is an add-on payment, risking loss of participation by those buyers if the potentially doubly higher prices would not be worth the add-on.

Overall, the Senate Finance proposal is a promising framework, but it requires significant refinement to offer true relief from drug shortages without creating new inefficiencies. It addresses the market most vulnerable to shortages, the generic sterile injectable market. This leaves the retail market concerns still to be addressed.

Domestic manufacturing

Onshoring production could indeed help improve CGMP compliance by lowering the rate of product defects for generics. One benefit of shifting production domestically is the likelihood of building new facilities that incorporate more advanced manufacturing methods and process automation. Such upgrades can lower the risk of human error and increase operational consistency, reducing the potential for product defects. Modern systems also enable better and faster detection of problems through real-time monitoring, robust documentation, and integrated quality management protocols. FDA faces fewer barriers to robust facility oversight within the U.S., further reinforcing CGMP compliance.

But a reality check is needed: using domestic manufacturing as a systemic fix for CGMP shortcomings runs straight up against powerful economic headwinds. The offshoring of generic drug production has been shaped by the market forces I described earlier. Reversing this trend and building up domestic supply chains at scale would require a major government intervention—meaning sustained new spending on subsidies, direct investment, or tax credits to counteract those underlying economic pressures.

Recent data highlight the immensity of the foreign footprint. As Figure 1 indicates, India supplied 61% of over 187 billion generic pills dispensed in U.S. retail and mail pharmacies in 2024. This volume came from a combination of 179 sites in India making FDF drugs. In addition, up to 236 Indian sites supplied APIs. China's role in FDF generics is smaller, with 60 facilities paying generic facility fees in 2024, but it dominates further upstream, including 148 API sites and a large presence in critical starting materials, reagents, solvents, and intermediates used across the pharmaceutical manufacturing chain (see Wosinska 2025).

Replicating this fully onshore would require hundreds of billions of dollars of new construction, supplemented by ongoing operational subsidies to overcome persistent cost, scale, and policy disadvantages vis-à-vis India and China (see Wosinska 2025)—the same factors that drove manufacturing out of the U.S.

If Congress authorizes less than what is required to fully onshore supply chains, including the chemicals that supply the pharmaceutical production, policymakers will face difficult trade-offs in allocating limited funds. They will need to weigh risks such as persistent drug shortages, dependence on a small number of foreign suppliers for APIs and chemical inputs, vulnerability to geopolitical disruptions, and the challenge of scaling U.S. manufacturing capacity efficiently and promptly.

Government onshoring initiatives should explicitly prioritize the highest-risk segments first—or risk spending heavily and achieving little improvement in supply reliability. Without clear prioritization under tight budgets, funds will diffuse across too many targets, yielding marginal resilience gains while wasting taxpayer and patient dollars. Policymakers should therefore concentrate investments on essential APIs, lifesaving hospital injectables prone to recurring shortages, and upstream chemical inputs with the greatest China-dependence, sequencing other categories only after these choke points are secured.

Generic FDFs sourced from India—such as common oral tablets like statins and antihypertensives, produced at massive scale—are not at the top of the onshoring priority list. For this reason, we should look for alternative solutions that directly address persistent CGMP shortcomings in Indian facilities.

Tariffs

Before turning to alternative solutions to CGMP concerns in Indian (and Chinese) facilities, it is important to discuss tariffs as an onshoring tool because of the unintended consequences that tariffs may have on generic drug supply availability and quality.

The implied mechanism for how tariffs lead to onshoring begins with tariffs increasing the prices that foreign firms can charge, making their products less competitive in the U.S. market. As these prices rise, demand naturally shifts away from the now more expensive foreign suppliers toward existing domestic manufacturers. This shift allows domestic firms not only to gain market share but also to raise their own prices, thereby increasing their profitability. As domestic firms become more profitable, they are incentivized to expand production capacity, and the improved business environment attracts new manufacturers to establish operations in the U.S.

This mechanism, however, requires that prices can adjust, with it shifting demand. This, however, is limited in the case of generic drugs by several key market and regulatory features. Medicaid inflation rebates create a cap on how much manufacturers can increase prices, with any additional price increases rebated to Medicaid. Additionally, the 340B program—whose discounts are pegged to Medicaid prices—extends these caps to outpatient drugs used by about half the hospitals. Beyond outpatient 340B use, hospitals may also use contracts that cap for one to three years, preventing price hikes even when input costs rise.

But with margins low, the inability to recover now higher costs means manufacturers affected by tariffs will face a choice: either further cut costs or exit the market.

The potential for further cutting costs is concerning because it can adversely affect product quality if cost-cutting happens through equipment maintenance, quality of materials, process control, or quality assurance. If problems arise, for example, the product is contaminated with other API, bacteria, or metal shavings (all actual examples), manufacturers may temporarily shut down or slow down production, leading to a potentially dramatic drop in output. But if FDA oversight is concurrently weakened, economic theory and experience suggest we should expect product quality to decrease.

Another bad option is to discontinue production of the unprofitable drug. Historically, discontinuations have not been a major driver of shortages, partly because manufacturers have tended to decrease production before exiting, leaving a more vulnerable market but not triggering a shortage. But the optics might change here – companies may be less shy about exiting the market with a higher market share due to tariffs they cannot control. There is also a concern that discontinuations of smaller share markets can occur in close succession, combining the impact of each.

This disruption in supply would not be as problematic if the share of the affected market is small or if the affected markets do not have substantial exposure to either the Medicaid program or the hospital market. For example, Chinese products are already facing a 20% tariff, but no shortages have resulted. This is likely a combination of the relatively small presence of Chinese products in the U.S. market (3.5% for oral dose and 11.8% for injectables, per Figure 1), the types of drugs that Chinese manufacturers are making and therefore the exposure those drugs have to price caps, and the margins that those manufacturers might have (including through potential Chinese government subsidies).

However, depending on the size of the tariff, a tariff on Indian pharmaceuticals plays out differently because many markets would face little alternative to Indian supplies. In particular, there is limited ready-to-activate domestic manufacturing capacity to quickly replace lost production. However, onshoring generic drug production faces substantial obstacles. Building or expanding pharmaceutical manufacturing in the U.S. involves high capital costs, reaching hundreds of millions of dollars per facility, and construction plus regulatory approvals can take three to five years or more.

Without substantive payment reform, generic drug margins will continue to be thin. Even with tariffs, the incremental gain from domestic production is unlikely to offset these substantial costs. Firms and investors remain hesitant to pursue capital-intensive investments, given persistent uncertainty about the duration of tariff protection—especially considering President Trump's recent use of pharmaceutical tariffs as a threat for concessions against branded manufacturers rather than a predictable policy tool.

Margins and market exposure may vary across products, but the evidence is clear that unless pass-through of tariff costs is addressed, higher tariffs on generics will increase the risk of shortages in markets with Medicaid or 340B exposure—particularly if a large enough share of the market is affected by these tariffs.

Strengthening FDA enforcement

Over the years, various proposals have been put forward to address the gap in oversight between foreign and domestic facilities, which by law had to be inspected every two years, in contrast to foreign facilities, which had no such requirement.

After two decades of faltering foreign inspections, the onset of the Generic Drug User Fees Amendments (GDUFA) provided a much-needed infusion of funding for foreign inspections. However, FDA continued to struggle with leveling the playing field between domestic and foreign facilities, especially those located in India and China, partly because GDUFA also fueled the number of generic drug approvals, which in turn increase demand for foreign inspections.

Since the onset of GDUFA, FDA and outside observers such as the Government Accountability Office (GAO) have called for a number of changes to FDA's foreign facility oversight in countries without comparable regulatory oversight and therefore within Mutual Recognition Agreements (MRA) with FDA. Recommendations include expanding unannounced inspections, increasing inspection frequency, improving policies to ensure inspector independence, addressing inspection workforce and backlog challenges, and exploring alternative monitoring tools, such as remote access to documents, information from foreign regulators' inspections, or third-party audits.

Due to time constraints in preparing this testimony, I am not reviewing the specific proposals or initiatives individually. What can be said is that each one of them strengthens the probability of detecting CGMP problems. FDA has been acting on those recommendations, but they all collectively require additional resources and, therefore, support from Congress. But it is important to say that they focus on increased detection, without changing any rules of the game when it comes to accountability. I turn to that concept next.

Raising the bar on accountability

An alternative but complementary path to enhance U.S. drug quality assurance involves requiring every importer to designate a qualified individual—located in the U.S.—who certifies that each batch meets CGMP standards, and to ensure that mandatory testing of imported products is also conducted in the

U.S. This system already exists in the EU for drugs and has precedent under the Food Safety Modernization Act, specifically with the Foreign Supplier Verification Program (FSVP) and Preventive Controls rules, which each designate a "Qualified Individual" or a "Preventive Controls Qualified Individual" to oversee compliance activities.

Under the Qualified Person (QP) system, each EU importer designates a QP with specialized credentials and formal authority to personally certify that every drug batch meets GMP and regulatory requirements before release. The QP reviews all relevant batch data, including manufacturing and quality control records, and ensures compliance with the marketing authorization. They may rely on audits or testing within the EU but bear personal legal responsibility for certification.

For drug imports from countries lacking a Mutual Recognition Agreement (MRA) with the EU, the QP must, before certifying any batch, must also conduct mandatory re-testing of each batch at EU-registered, GMP-compliant laboratories. This further ensures product quality and reduces reliance on the exporting country's regulatory system.

Layering a QP system onto FDA's existing system would change both the probability of problems being detected and the consequences once they are uncovered. Detection probability would increase through required import testing and the additional review conducted by QPs, whether through documentation checks or site audits. Consequences would increase because—in addition to the legal responsibility of the firm—the QP would now be personally responsible for certifying each batch and, therefore, unwilling to approve products whose CGMP compliance is in doubt. Conversations with current and past QPs confirm that dynamic.

The QP system, paired with targeted import testing, directly addresses the underlying CGMP challenge: ensuring that only medicines meeting robust manufacturing standards can enter the U.S. supply chain. This approach is more efficient and focused than indirect levers like tariffs or wholesale onshoring, which may impose far greater costs but do not directly improve product quality assurance. Compared to indirect levers like tariffs or broad onshoring, the QP testing approach provides a direct, efficient, and scalable path to enhanced product quality assurance.

In the broader policy context, the QP testing approach is distinct from, but works alongside, other interventions such as the Senate Finance proposal's hospital reliability incentives. The QP testing model is not a replacement for supply-focused solutions: rather, it fills a critical gap in product-level quality assurance, especially for generic drugs in the retail channel, where reliability incentives cannot prevent substandard products from reaching patients. Senate Finance's proposal largely addresses injectable hospital drugs but does not reach the retail segment or guarantee batch-level manufacturing quality.

Well-designed drug quality policy should target known vulnerabilities rather than assume risk is limited to foreign or non-U.S. facilities. Accountability mechanisms like the QP testing proposal must therefore be tailored—fit for purpose, nuanced, and proportional—so that the approach delivers both detection and deterrence, and focuses responsibility precisely where oversight is weakest and consequences for U.S. patients are greatest.

Implementing a QP certification and mandatory batch testing system in the U.S. raises several practical considerations, discussed in detail in the accompanying QP report. Key design decisions include determining the scope of products subject to the requirements (e.g., imports from non-MRA countries), establishing standards for QP certification and liability protections, accrediting U.S. testing labs, and phasing in requirements to prevent supply disruptions. Policymakers should also account for reimbursement barriers in Medicaid, 340B, and other programs, and ensure cost and regulatory burdens

remain proportional to the policy's risk-targeting aims. Attention to these design, resourcing, and rollout challenges will be critical to fully realizing the benefits of accountability-focused reform.

Conclusion

Patients deserve safe, high-quality medicines, and companies are legally required to deliver them by upholding robust CGMP standards. Yet, economic pressures and FDA's expanding oversight constraints have created a system that too often fails to deliver on that requirement. Policymakers are right to seek solutions.

But in identifying solutions, policymakers must be careful that policy interventions are fit for purpose—that is, tailored to the specific problem and designed to achieve the intended outcome without creating new risks or costs. Put simply, the tool should match the failure it aims to fix, not a broader goal that drifts from the underlying cause.

If the goal is simply to increase domestic drug manufacturing, almost any facility will qualify regardless of clinical need or shortage risk, and little attention may be paid to whether tools to drive onshoring could destabilize supply. If China is the central concern, attention should turn upstream—to the raw materials, reagents, and chemical inputs where supply chains are most exposed—while India should be leveraged as a strategic partner to de-risk from China at lower cost than direct U.S. production. If persistent hospital drug shortages are the true priority, durable solutions require shifting hospital incentives, so reliability is valued more than low cost.

Beyond being fit for purpose, policy solutions must also account for costs and budget constraints. With finite resources and competing risks, not every problem can or should be addressed through onshoring; under realistic budgets, Indian FDFs are unlikely to be top priorities compared to essential APIs, hospital injectables prone to shortage, and upstream chemicals with concentrated China exposure. Responsible policy should pursue strategies that deliver the best value not only for patients but also for taxpayers.

For concerns about defective drugs reaching patients from non-MRA countries, the most direct and cost-effective approach is to improve manufacturing quality oversight. Many proposals understandably focus on increasing the probability of detecting problems through expanded and unannounced inspections, stronger overseas enforcement, and increased testing, but accountability has received less attention despite being equally critical.

Introducing a QP system, complemented by mandatory import testing of every batch, provides a stronger safeguard for drug quality. Combining mandatory product testing of imports with batch certification by a qualified U.S.-based person who bears personal sign-off responsibility strengthens both detection and deterrence and underscores that safeguarding drug quality and CGMP compliance is an industry obligation—not a task that can be offloaded to regulators alone.

Questions for the Record

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

QUESTIONS FOR THE RECORD

Tony Sardella

Ranking Member Kirsten E. Gillibrand

I. Current reimbursement models prioritize lower-cost medications. You have made recommendations to improve provider reimbursements for U.S.-made generic products. Could you say more about some improvements that could be made to reimbursement models so that hospitals and other health care providers place more of an emphasis on quality and reliability?

Changes to reimbursement structures can play a pivotal role in reshaping how hospitals, pharmacies, and health systems make purchasing decisions. Adjusting reimbursement to reward higher quality, reliability, and domestic sourcing could help shift buying practices away from the lowest-cost, offshore-dominated model that currently defines the generic drug market. However, for these reforms to be fully effective, they must be paired with greater visibility into the quality and reliability of manufacturing. Without this transparency, even the most well-designed reimbursement incentives risk reinforcing the same price-driven dynamics that have contributed to recurring shortages and fragile supply chains.

To meaningfully strengthen the U.S. pharmaceutical supply chain, reimbursement reform must begin with better visibility into the quality and reliability of drug product manufacturing. At present, hospitals and other healthcare providers operate in a system where the clearest purchasing signal is price. The quality of a medicine—beyond a manufacturer's compliance with current good manufacturing practices (cGMP)—is not transparent or readily comparable across suppliers. In conversations APIIC has had with hospitals and health systems, availability remains their single most important concern. Many have indicated that if they had reliable visibility into quality and assurance of supply, they would be willing to pay modestly more for those medicines.

Without a framework to measure and communicate these attributes, procurement teams must default to the lowest-cost option, reinforcing a system that values only acquisition price rather than resilience, consistency, or domestic sourcing. To strengthen resilience, reimbursement frameworks should evolve to consider cost alongside measurable indicators of quality and reliability. There are several considerations that could help achieve this.

1. A Quality and Reliability Index

Before establishing mechanisms that could improve reimbursement models or have purchasers place more priority on quality and reliability, there must be a clear and transparent process to clearly determine the quality and reliability of a manufacturer.

Although the FDA conducts inspections of drug manufacturing facilities and publishes the results in its inspection database, there remains a lack of consistent, manufacturer-level transparency into the quality of generic drug production. These inspection outcomes are not readily integrated into procurement or reimbursement frameworks, limiting their practical influence on decision-making. Establishing a quality and reliability index—that could serve as

standardized scorecard—would allow providers to compare manufacturers based on metrics such as:

- compliance and recall history;
- adherence to current good manufacturing practices (cGMP);
- delivery reliability; and
- investment in process and system improvements.

Health systems and other purchasing entities (both federal and private) could use this score to inform contracting decisions or tiered reimbursement rates. Manufacturers with higher reliability scores would receive preferential pricing, formulary placement, or bonus payments for consistently maintaining supply and quality. This index would give providers and payers a meaningful basis to differentiate products beyond price. The U.S. Department of Health and Human Services (HHS) 2024 white-paper also proposed a "Manufacturing Resiliency Assessment Program (MRAP)" that could link to hospital procurement and payment decisions.[1]

2. Link Quality and Resiliency to Reimbursements and Incentives

Reimbursement Add-on
As highlighted in APIIC's latest white paper, innovative reimbursement models could encourage healthcare providers to prioritize medications from manufacturers known for their outstanding quality, reliability, and domestic production. [2]

For retail pharmacies, a resiliency reimbursement add-on for drug products with U.S.-based manufactured APIs and strong quality records could be applied to ingredient cost calculations under Medicaid programs. Each state operates its Medicaid program[3] under a CMS-approved plan, which reimburses pharmacies for dispensing outpatient prescription drugs. Pharmacy billing and thereby reimbursement includes:

- Ingredient cost - the acquisition cost of the drug; and
- Dispensing fee - covering handling, storage, and administrative costs.

A drug verified to contain a U.S.-manufactured API could qualify for a small percentage-based premium (e.g., 5–10%) on top of the original ingredient cost. For example:

- Base reimbursement: $20.00 ingredient + $2.50 dispensing = $22.50 total

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[1] U.S Department of Health and Human Services - Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States: https://aspe.hhs.gov/sites/default/files/documents/bd863be8f0aaf5380dc801390440bc3d/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf.
[2] Building a Resilient Domestic Drug Supply Chain: The Path to National Health Security: https://apicenter.org/wp-content/uploads/2025/03/APIIC-White-Paper-2025-Building-a-Resilient-Domestic-Drug-Supply-Chain.pdf.
[3] The pharmacy reimbursement and overall state plan may be managed either directly by the state (fee-for-service) or through managed care organization contracted by the state.

- With (10% add-on): $22.00 ingredient + $2.50 dispensing = $24.50 total

The cost increase could be absorbed by the federal government or cost shared with the state under the established state plan.

While the mechanisms by which a drug product is identified would need to be established—possibly through the National Drug Code and assertion from manufacturers—this could be extended to quality and reliability if the aforementioned index is created.

Preferential formulary placement for resilient products and manufacturers
Hospitals, health systems, retail pharmacies, and payers should align their formulary design so that medicines from manufacturers with demonstrated supply-chain reliability, quality assurance, and domestic sourcing receive preferential treatment in placement. Key approaches include:

- Tiering products such that those made by companies participating in a resilience-assessment program are placed in preferred formulary tiers, thereby signaling that supply reliability and quality are value-drivers.[4]

- Granting formulary "preferred status" to generics and other medicines whose manufacturer has a "strong performance on a quality/reliability" and which could include domestically-sourced product— components of which the Duke-Margolis Center for Health Policy paper in its "Drug Supply Chain Reliability" framework.[5]

Encourage Long-Term, Guaranteed-Volume Contracts
Federal payment policy can help strengthen supply reliability by encouraging long-term, guaranteed-volume contracts between healthcare providers, manufacturers, and other key supply chain partners such as intermediaries (i.e. GPOs, PBMs, distributors). These agreements create stability and mutual benefit across the system — providing manufacturers with predictable demand to justify investments in quality and domestic capacity and giving providers greater assurance of consistent access to essential medicines.

To be effective, these contracts should be designed with flexibility and shared accountability in mind:

- They should promote predictable supply and fair pricing, while ensuring that no participant — manufacturer, intermediaries, or provider — is unfairly penalized for disruptions beyond their control.

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[4] U.S Department of Health and Human Services - Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States: https://aspe.hhs.gov/sites/default/files/documents/bd863be8f0aaf5380dc801390440bc3d/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf.
[5] Duke-Margolis Center for Health Policy: https://healthpolicy.duke.edu/sites/default/files/2025-10/Addressing%20the%20Root%20Causes%20of%20Drug%20Shortages_Updated%2010.27.25.pdf.

- Reliability safeguards such as agreed-upon buffer supply expectations or contingency plans can enhance confidence without adding rigid or punitive requirements.

- Participation should be incentivized through payment alignment, such as modest add-on payments or premium reimbursement for providers that establish multi-year purchasing commitments with qualified, reliable manufacturers.

3. **Support Technology Adoption to Reduce Cost Disparities**
   Underpinning any approach is the need for manufacturers to produce the actual products at high quality, consistency, and domestically. To that end, government must help close the cost gap between U.S. and offshore production. Strategic investments in advanced manufacturing technologies and continued process improvements —through public grants, tax incentives, or private sector co-investment—can make domestic production cost-competitive, improve quality and reliability, and strengthen the supply chain.

II. Your work has involved collaborating with existing American-based, FDA-approved drug manufacturing facilities to produce APIs using advanced production technology. What advanced manufacturing technologies do you recommend U.S. drug manufacturers adopt? How can the federal government encourage U.S. drug manufacturers to adopt these practices?

The U.S. possesses a strong foundation of FDA-approved manufacturing sites, yet most continue to operate systems that were designed for a different era of global competition. To grow domestic competitiveness and supply-chain resilience, a keen focus on adopting advanced manufacturing technologies (AMTs) is vital. Along with opportunities for long-term improved quality, reduce costs, sustainable processing, and production efficiencies, AMTs can play a critical role in rebuilding the U.S.' domestic manufacturing infrastructure.

Continuous Flow Manufacturing

Continuous flow chemistry represents one of the most transformative opportunities for domestic API production. Unlike traditional batch processes, continuous flow reactors allow for uninterrupted production, more precise control of reaction conditions, and real-time monitoring of product quality. This method also can improve reaction yields, minimize waste, and significantly shorten cycle times, thereby reducing manufacturing costs while increasing reliability, reproducibility, and quality.

While common in other industries, continuous flow remains novel in pharmaceutical manufacturing. APIIC is demonstrating its commercial potential through its collaboration with small and large API manufacturers including Sentio BioSciences to produce propofol API and Mallinckrodt Pharmaceuticals for metoprolol API using continuous flow technology. In high

volume products like in the case of metoprolol, the end product can still use batch technology for drug product, but combining these two systems allows efficiency gains throughout the entire process chain. This hybrid model represents a practical and scalable bridge for U.S. companies transitioning to next-generation manufacturing methods.

Improving Existing Batch Operations

Even as advanced systems emerge, most U.S. manufacturers will continue to rely on batch processes for the near future. Significant efficiency and quality improvements can be achieved by applying Process Analytical Technology (PAT) and Quality-by-Design (QbD) principles within these systems.

PAT integrates real-time, in-line monitoring of critical process parameters (CPPs) during production, reducing waste, preventing out-of-specification batches, and accelerating batch release. QbD complements this by embedding risk-based process understanding and control strategies from the outset. Collectively, these approaches modernize existing infrastructure, making them a low-risk, high-impact step toward advanced manufacturing readiness.

Genetic Editing in Fermentation

Many critical APIs and their key starting materials (KSMs) rely on complex microbial or cell-based manufacturing. Advances in genetic editing and synthetic biology enable the engineering of microbial strains for higher yield, reduced impurity formation, and greater process robustness.

Researchers can design fermentation strains capable of producing pharmaceutically relevant molecules with improved productivity, heat and stress tolerance, and consistent performance under GMP conditions. This capability provides a direct route to reshore fermentation-based APIs that are now largely dependent on overseas production.

However, scaling from laboratory development to commercial production remains a significant challenge. Few engineered strains have yet advanced to full-scale cGMP manufacturing. Greater support for translational R&D, including bridging strain engineering to validated, economically viable commercial processes, will be crucial for realizing this opportunity. With proper incentives, these technologies could dramatically expand the domestic bio-manufacturing base for APIs.

Emerging AI-Enabled and Digital Tools

While adopting continuous flow and improve on existing technologies is important, the U.S. must also look towards the future as foreign countries, like China and India, will continue to make investments in new development approach to maintain dominance in API and generic drug

manufacturing. Digital tools, including AI-driven route modeling, digital twins, and 3D printing, offer innovations of the future. Opportunities include:

- Utilizing AI to optimize generic synthesis routes, identifying reaction pathways constrained to raw materials available domestically. Such "U.S.-specific route design" reduces dependence on imported intermediates.
- Developing digital twins—virtual models of real-world manufacturing systems—to enable companies to simulate reactions, test parameter changes, and identify yield improvements before running physical experiments. This can potentially reduce use of solvents and reagents, while lowering energy and environmental costs.
- Creating 3D pharmaceutical manufacturing and additive printing techniques to allow for on-demand production of personalized or low-volume drugs, offering flexibility during shortages or emergencies.

However, without coordinated U.S. investment, the domestic sector risks falling behind in this next technological wave. Further, while there are ongoing efforts to integrate leading technological advances across the broader healthcare sector, these initiatives have largely not extended to pharmaceutical manufacturing, particularly in generic medicines. For example, FDA has collaborated with industry to develop draft guidance on emerging technologies such as 3-D printing for medical devices, comparable frameworks do not yet exist for pharmaceuticals. This gap underscores the need for greater regulatory engagement and targeted investment to de-risk innovation and offset the low return on investment that undermines the generic market, thereby enabling the adoption of advanced manufacturing technologies across the industry.

Federal Government Can Encourage Adoption

Adoption of these technologies requires regulatory assistance coupled with economic and policy incentives. Because AMTs and synthetic biology platforms are not "off-the-shelf," they entail validation costs, extended regulatory timelines, and uncertain near-term return on investment. Federal investments could de-risk these investments and accelerate adoption through several mechanisms:

- **Targeted Financial Grants and Incentives** – Funding under vehicles like the Defense Production Act, tax credits, or grants for companies that invest in AMTs or digital manufacturing infrastructure.
- **Regulatory Acceleration** – Establishing "fast-track" or "front-of-the-line" designation within FDA for reviewing new processes, equipment, and facility retrofits. Time is a critical cost factor; shortened approval cycles would significantly increase private-sector willingness to invest.
- **Public-Private Demonstration Projects** – Support national efforts that allow manufacturers to validate and scale new technologies collaboratively with federal laboratories and academic institutions.

III. <u>You recommended rewarding U.S. manufacturers that demonstrate consistent commitments to quality with priority preference when awarding federal procurement pharmaceutical contracts. How can the federal government determine if a manufacturer has a commitment to quality? Are there different quality control measures you would recommend for different stages of the pharmaceutical supply chain?</u>

A true measure of pharmaceutical quality goes beyond regulatory compliance at the facility level. Current frameworks such as the FDA's cGMP standards set important, minimum standards for safety, quality, potency, purity, and identity. The FDA utilizes spot inspections to verify these standards are met by manufacturers. While a facility may appear fully compliant during inspection, it is a snapshot in time and limited to a component of the supply chain as accessed during the inspection.

To identify and reward high-quality manufacturers, the federal government could assess three interrelated dimensions:

Third-Party Product-Level Verification
The definitive test of quality is in the final drug product, not only the process used to make it. A drug product could undergo independent, third-party verification that confirms the potency or purity results as reported by the manufacturer. This will ensure an addition verification that the product meets its intended label claim.

As the Senate Aging Committee has highlighted, the Pentagon has performed independent testing of generic drugs widely used by U.S. service members.[6] [7]

This effort demonstrates that, if expanded beyond a single agency, a coordinated testing program could reconfirm that drug products meet approved specifications and provide objective data for procurement decisions.

Manufacturer Investment and Continuous Improvement
A manufacturer's proactive investment in modernization—unrelated to an inspection finding or warning letter—is one of the strongest indicators of long-term quality commitment. Federal evaluators could review evidence of voluntary facility upgrades, adoption of Process Analytical Technology (PAT) or Quality-by-Design (QbD) systems, or internal quality metrics that exceed baseline requirements.

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[6] Axios - Pentagon starts independent generic drug safety tests: https://www.axios.com/2023/08/08/pentagon-generic-drug-safety-tests.
[7] Bloomberg - US Military is So Worried About Drug Safety It Wants to Test Widely Used Medicines: https://www.bloomberg.com/news/articles/2023-06-07/drug-safety-fears-spur-pentagon-plan-to-test-widely-used-meds.

These forward-looking activities signal a company's willingness to prevent problems before they occur, not just react to them after inspections.

Reliability and Transparency in Supply Performance
Commitment to quality is inseparable from reliability. Consistent, on-time delivery of conforming product batches over time should factor into quality scoring. Manufacturers that maintain uninterrupted supply, minimal recalls, and transparent reporting of deviations demonstrate maturity in quality culture and should receive preferential weighting in federal contract evaluations.

Differentiated Quality-Control Measures Across the Supply Chain

Quality assurance must extend across the entire supply chain, from raw materials to finished dosage, because weaknesses at any stage can compromise final product quality. Further, quality breakdowns often originate upstream in the sourcing of raw chemicals and KSMs, where oversight is weakest.

Recommended tiered controls could include:

- **Raw and Starting Materials**: Implement supplier-qualification programs that require verification of source origin and impurity profile. Encourage domestic sourcing where feasible to reduce uncertainty.

- **Post-Market and Distribution Monitoring**: Implement periodic re-testing of purchased lots.

These layered measures create a "closed loop" quality system that links raw material integrity, process control, and final product verification.

Supporting these measures is the importance of federal buyers needing to balance quality, cost, and availability when awarding contracts. Approaches such as a weighted-evaluation model could make quality an explicit and quantifiable factor in award decisions, rather than an afterthought to lowest price. Factors that could be considered:

- **Baseline Safety Requirement**: All suppliers must meet basic cGMP safety and potency standards ("safe and effective" threshold).

- **Quality Differentiation**: Beyond this baseline safety requirements, manufacturers could earn additional scoring for demonstrable quality improvements: statistical process controls, reliability records, voluntary modernization investments, and supply-chain transparency.

- **Balanced Trade-Offs**: With greater visibility into verified product quality, hospitals and federal agencies alike can make smarter, evidence-based purchasing decisions that balance quality, cost, and availability and assert pressure on manufacturers to maintain the highest standard of quality and reliability. For critical hospital-administered medicines—such as sterile injectables, oncology drugs, and antibiotics—where potency, sterility, and consistent supply are essential to patient outcomes, modest price premiums for proven, high-quality domestic suppliers are justified. Hospitals rely on these drugs daily for life-saving care, and a single subpotent or contaminated batch can have immediate clinical consequences. In contrast, for lower-risk oral generics dispensed in outpatient or maintenance settings, where a product may be "safe" though minor variations in "efficacy" pose minimal risk, cost can weigh more heavily once the "safe and effective" threshold is met. During shortages, both hospitals and federal purchasers may need to temporarily rely on lower-rated but still safe sources to maintain access, while maintaining long-term incentives that reward reliable, high-quality manufacturers. Ultimately, a balanced trade-off framework recognizes that "safe" and "efficacious" are not synonymous and that hospitals—often on the front lines of patient care—depend on consistent access to high-quality medicines. Federal purchasing policies that reflect these distinctions ensure public funds support affordability without sacrificing the potency, reliability, and clinical integrity of the therapies on which patients and providers rely.

- **Transparency to Market**: Publishing summary quality and reliability scores would allow hospitals and distributors to make informed sourcing decisions, creating market pressure on manufacturers to continuously improve.

IV. <u>You have also been involved in private–public partnerships through your work with the API Innovation Center, which developed the Invest–Contract–Partner Model. Based on your experience, could you describe best practices that could be applied from the Invest–Contract–Partner Model to other private–public partnerships? What role can the federal government take in promoting future public–private partnerships?</u>

The Invest–Contract–Partner (ICP) Model™ developed by APIIC demonstrates how a structured, outcomes-based public–private partnership can accelerate domestic manufacturing and research capacity while maximizing the impact of public funds. The model creates a framework in which public investment, private execution, and collaborative governance align around measurable goals—such as reshoring KSMs, APIs, developing AMTs, and fostering business growth through regional innovation ecosystems.

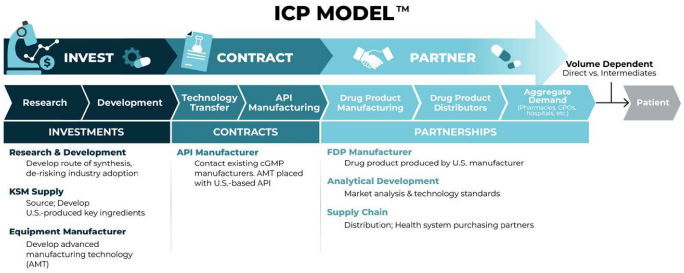
At its core, the ICP Model establishes three pillars:

- **Invest**: APIIC invests in research and development of AMTs, including new methods for producing APIs and KSMs, and modernizing medicines. This involves working

with equipment manufacturers to leverage advanced technologies.

- **Contract**: APIIC contracts with existing U.S.-based facilities that are ready and underutilized to manufacture APIs. This approach leverages existing capacity and can be implemented more rapidly than building new facilities.

- **Partner**: APIIC forms strategic partnerships with health care systems, retailers and drug manufacturers that include revenue-sharing agreements that enable long-term economic sustainability of manufacturer supply and cost for end customers.



Best Practices from the ICP Model

APIIC's experience applying the ICP framework in Missouri and across its partner network highlights several best practices that can inform other public–private partnerships:

- **Align Around a Shared National Mission with Clearly Defined Roles**
  The ICP Model shows that successful public–private partnerships begin with a unified mission and structured accountability. By centering around national health security—reshoring APIs, building advanced manufacturing capacity, and reducing dependence on foreign supply—the ICP Model ensures all partners share a measurable public purpose. Each participant has defined responsibilities: the government sets direction and de-risks investment, industry provides innovation and capacity, and purchasers commit to long-term demand. This clarity fosters trust, speeds implementation, and prevents partnerships from devolving into fragmented or short-term projects.

- **Blend Investment, Contracting, and Partnership to De-Risk Capital**
  A key lesson from the ICP Model is the value of combining upfront investment, secure contracts, and shared risk and reward partnerships to make projects financially sustainable. The ICP model structure deploys public funds for critical items like AMT upgrades,

establishes multi-year contracts to guarantee demand, and forms long-term alliances between government, manufacturers, and purchasers. This approach ensures that every dollar invested is tied to commercial outcomes and shared accountability. By integrating these elements, PPPs can move beyond one-off grants and instead create durable, market-driven ecosystems that sustain domestic manufacturing.

- **Anchor Partnerships in Technology Adoption and Data Transparency**
  The ICP Model emphasizes two cornerstones for lasting impact: accelerating advanced manufacturing and improving visibility into the supply chain. Retrofitting idle U.S. facilities with continuous flow or digital manufacturing systems can lower costs, improve quality, and expand domestic capacity quickly. At the same time, exchanging of data ensures that all partners share accurate information on sourcing, production volumes, and vulnerabilities.

The Role of the Federal Government

The federal government plays a critical role in creating both the "top-down demand signal" and the "bottom-up confidence" necessary for partnerships like the ICP Model to thrive.

Top-Down (Federal to Industry):
The federal government can drive demand for domestically produced high-quality products by establishing procurement and reimbursement preferences for high quality, U.S.-sourced APIs and medicines. This includes:

- Creating a federal buyer's market for essential generic drugs made with U.S.-sourced APIs;
- Investing in AMT modernization through grants, tax credits, and public–private demonstration projects; and
- Streamlining regulatory pathways, such as FDA's expedited review of new manufacturing processes and facilities.

Bottom-Up (Industry, States, and Healthcare Providers):
When manufacturers and state partners see clear federal commitment and demand signals, they gain confidence to make long-term capital investments in modernization rather than short-term cost reductions. Hospitals and healthcare systems, in turn, can reinforce this market pull by prioritizing domestic and high-quality drugs in purchasing decisions. This two-way reinforcement—federal demand at the top and private confidence at the base—creates a durable economic and policy environment for reshoring critical manufacturing.

Senate Special Committee on Aging
"Bad Medicine: Closing Loopholes that Kill American Patients"
October 8, 2025
Questions for the Record
Tony Paquin

Ranking Member Kirsten Gillibrand

1) **You have written extensively about the role of middlemen in the global medical supply chain.**

   How can group purchasing organizations and other middlemen be encouraged to choose products based on quality?

The core issue is that our current supply chain architecture financially rewards GPOs and PBM-owned middlemen for prioritizing the lowest sticker price, rebate maximization, and exclusive contracting, not product quality or supply chain resilience. As long as their profits are tied to volume rebates, administrative fees, and foreign-subsidized pricing, the system will continue to drive hospitals toward the cheapest offshore option—even when those products are inferior, contaminated, or prone to shortages.

To realign GPO behavior around quality rather than rebates, five practical levers are required:

1. Reform the GPO Safe Harbor to Make Quality a Condition of Protection

The 1987 Anti-Kickback Safe Harbor gave GPOs immunity for collecting "administrative fees" from manufacturers. That carveout created the market we have today—one where GPO revenue is maximized by steering volume toward the cheapest offshore bidder, regardless of quality.

Congress can condition the Safe Harbor on:

- ◊ documented quality standards
- ◊ manufacturing transparency
- ◊ country-of-origin disclosure
- ◊ compliance with FDA inspection outcomes
- ◊ resilience scoring (redundant sites, domestic backup, reliable API sources)

If a GPO wants federal protection, then quality—not just price—must be a determining factor in contracting.

This alone would begin to shift the industry.

2. Require Quality & Resilience Metrics in Hospital Contracting Decisions

Hospitals currently make decisions based on price sheets delivered by GPOs, not validated quality scores.

Congress can mandate that GPOs include *quality, safety, and reliability indicators* in their contract bids:

- ◊ FDA warning letter history
- ◊ contamination/adulteration records
- ◊ number of inspections failed
- ◊ reliance on a single foreign API site
- ◊ domestic vs. foreign manufacturing
- ◊ historical shortage performance

Middlemen should not be allowed to hide behind opaque sourcing practices when patients are harmed by contaminated eye drops, tainted APIs, or chronic shortages.

3. Establish Federal Incentives for Choosing U.S.-Made, High-Quality Pharmaceuticals

Government purchasers—including VA, DoD, HHS, and CMS-driven providers—can lead the market by integrating incentives or preferences for:

- ◊ domestic manufacturing
- ◊ FDA-inspected U.S. or allied-nation facilities
- ◊ diversified, resilient supply chains
- ◊ companies that maintain redundant U.S. manufacturing capacity

Once the federal market signals that quality matters, GPOs will follow the money.

4. Require Transparency of GPO Revenue, Rebates & Conflicts of Interest

No GPO today wants public scrutiny of:

- ◊ rebate structures
- ◊ administrative fees
- ◊ hidden pass-through monies
- ◊ exclusive contracting clauses
- ◊ penalty clauses for buying "off contract"

When these numbers are forced into the light, middlemen will pivot toward demonstrable quality because it protects them from liability and reputational risk.

5. Establish a Standardized National Quality Score for Generics

Right now, providers have no independent metric differentiating a well-run U.S. manufacturer from a low-quality offshore factory with repeated FDA violations.

A federal Generic Drug Quality Score, similar to what consumer finance or aviation safety uses, would instantly shift purchasing behavior by:

- ◊ exposing substandard overseas manufacturers
- ◊ rewarding high-quality U.S. producers
- ◊ giving hospitals a defensible reason to choose quality even when prices are close

This also protects GPOs—from the political and legal consequences of using products from factories known to cut corners.

The Bottom Line

GPOs and middlemen behave rationally under the incentives they're given.

Right now, the system rewards cheapest imports, rebate maximization, and volume steering—not quality.

To change their behavior, Congress must change the incentive system:

- ◊ tie Safe Harbor protection to quality
- ◊ mandate transparency
- ◊ require quality metrics in contracting
- ◊ reward domestic and resilient manufacturing
- ◊ expose low-quality, high-risk overseas producers

When quality becomes profitable, GPOs will choose quality. Until then, they won't.

2) **You have extensive experience with the global medical supply chain**

How can we effectively work with global suppliers to ensure quality and resiliency while we work on developing domestic drug production?

We must be honest about the reality of America's position: we currently depend on foreign suppliers for the majority of our generic drugs, APIs, and critical medical products.

Domestic manufacturing will take years to rebuild, and during that transition, we cannot afford quality lapses, counterfeit risk, or supply shocks from overseas producers.

The question is not whether we work with global suppliers—it is how we impose transparency, accountability, and redundancy on relationships that have historically operated outside U.S. visibility.

There are five practical and enforceable approaches.

1. Impose Mandatory Transparency on Global Supply Chains

Right now, manufacturers abroad operate behind opaque procurement layers. The FDA often conducts pre-announced inspections, and buyers—including hospitals and GPOs—rarely know:

- the true source of APIs
- subcontracted production sites
- contamination/adulteration history
- whether the factory is under FDA import alert
- the level of QC testing conducted

To work effectively with foreign suppliers during the transition:

Require origin transparency for all drug products:

- API source
- finished-dosage form source
- subcontracted facilities
- FDA inspection status
- contamination/adulteration history

Make this data mandatory at the time of contracting—not optional. Transparency forces quality.

2. Enforce Unannounced & Randomized FDA Inspections Overseas

The current regime of pre-announced foreign inspections is ineffective. Global suppliers know when the FDA is coming and prepare accordingly.

Congress can strengthen oversight by directing the FDA to:

- conduct unannounced overseas inspections
- increase surveillance sampling at U.S. ports
- create real penalties for obstruction or fraud
- fast-track import alerts for repeat offenders

This approach does *not* punish responsible global suppliers—it strengthens them and weeds out those who cannot meet U.S. standards.

3. Require Redundant Sourcing & Supply Chain Diversification

Today, many foreign suppliers source their API from a single plant—often in China. If that site fails, the entire U.S. market collapses.

To ensure resiliency:

- Require dual API sources for essential medicines
- Require suppliers to maintain backup manufacturing capacity in allied nations
- Prioritize manufacturers with geographically distributed production

We have learned repeatedly that "lowest cost" cannot be the sole criterion; reliability must carry economic value.

4. Develop Strategic Partnerships with Allied-Nation Manufacturers

Not all foreign suppliers are equal.
There is a fundamental difference between working with:

- Chinese state-influenced production, vs.
- manufacturers in the EU, Japan, South Korea, Canada, Australia, or India's top-tier GMP facilities.

To maintain quality and resiliency during the domestic manufacturing build-out:

Prioritize partnerships with allied nations that have:

- ◊ strong regulatory regimes
- ◊ transparent GMP processes
- ◊ democratic accountability
- ◊ alignment with U.S. national security interests

This creates a more stable short-term ecosystem while we rebuild U.S. capacity long term.

5. Use Federal Purchasing Power to Set New Standards

Federal agencies—VA, DoD, HHS, ASPR—can dramatically influence global supplier behavior by signaling that quality and resilience matter.

They can require:

- ◊ country-of-origin disclosure
- ◊ redundancy in API supply
- ◊ clean FDA inspection history
- ◊ demonstrated quality management systems
- ◊ independent lab testing results

Once federal buyers demand these standards, global suppliers will conform to keep access to the U.S. market.

Bottom Line

Rebuilding domestic pharmaceutical manufacturing is essential—but it will take years. In the interim, we must ensure global suppliers meet the quality and resiliency benchmarks American patients deserve.

We do this by:

- ◊ forcing transparency
- ◊ strengthening FDA oversight
- ◊ diversifying sources

- ◊ partnering with allied nations
- ◊ leveraging federal purchasing standards

This balanced approach avoids supply disruptions today while accelerating the long-term goal of restoring U.S. pharmaceutical independence.

Senate Special Committee on Aging
"Bad Medicine: Closing Loopholes that Kill American Patients"
October 8, 2025
Questions for the Record
Andrew Rechenberg

Ranking Member Kirsten Gillibrand

1) **One of the pillars you discuss in your written testimony is the importance of securing U.S. biotechnology leadership. Other countries have treated investments in biotechnology as strategic infrastructure. The final report that was recently released by the National Security Commission on Emerging Biotechnology created a robust framework for policy makers on how we can support this rapidly advancing industry.**

   Can you expand upon the role the federal government should be playing in securing our global leadership in biotechnology?

   The federal government must treat biotechnology as a strategic pillar of national security, on par with semiconductors or energy. America's edge in drug discovery was built on decades of public-private research collaboration, yet that foundation has eroded as NIH funding stagnated and China launched a coordinated state-driven push under Made in China 2025. NIH funding in the United States has been essentially flat. By 2024, the NIH budget was about 7% below the 2003 funding peak when adjusted for inflation.

   To secure leadership, the United States should rebuild a biotechnology industrial base around three points: (1) research reinvestment, restoring NIH budgets in real terms and dedicating a fixed share to translational ("bench-to-bedside") research, biotech startups, and public–private production partnerships; (2) clinical and regulatory standards, requiring multi-regional trials, modern comparators, and verified data integrity before FDA approval, so that low-quality single-cohort studies abroad cannot undercut our rigorous process and encourage a race to the bottom; and (3) protection of biological assets, including a prohibition on exporting patient samples, genomic data, or proprietary cell lines to adversarial countries without traceable federal review.

   For aging populations dependent on advanced biologics, securing this leadership is essential to ensuring that future therapies are discovered, tested, and produced under U.S. standards of safety and access.

2) **You have suggested that reforms to the Centers for Medicare and Medicaid Services, such as rewarding secure sourcing and realigning reimbursement flows, can enhance domestic drug manufacturing.**

   Could you say more about what these reforms might look like?

   Current CMS reimbursement formulas unintentionally reward the cheapest global bidder because they do not account for quality, reliability, or supply-chain security. Medicare and Medicaid base payments on average sales price and acquisition cost, not on whether the product is made under FDA-equivalent standards or in a secure supply chain. This drives hospitals to buy from the lowest-cost importer—often from regions with chronic quality failures. Realigning these incentives is one of the most powerful levers the federal government possesses.

   CMS should adopt a "Secure Sourcing Bonus" for U.S.–made and FDA-equivalent generics, modeled on the 2023 domestic-N95 reimbursement adjustment. A payment margin of 20 to 30 percent within Medicare Part B, Part D, and Medicaid formularies for verified U.S.–made medicines or medicines from trusted countries meeting FDA-equivalent standards would help offset foreign cost distortions, reward reliability, and reflect the true economic and security value of safe, domestic production. Because coinsurance and acquisition-cost benchmarks automatically adjust for patients, this preference can shift federal purchasing toward resilient suppliers without increasing out-of-pocket costs.

   CMS should also integrate compliance weighting into its ASP and NADAC data—factoring FDA inspection history, transparency, and dual-sourcing capability into reimbursement formulas. In parallel, CMS should require GPOs and PBMs that serve federal programs to report supplier origin and redundancy data. Public visibility into these metrics would allow CMS to link payment bonuses to verifiable sourcing integrity.

3) **You have recommended investing in strategic production to promote U.S. drug manufacturing.**

   Could you say more about how you think the federal government should invest in strategic production to promote U.S. drug manufacturing?

   Rebuilding domestic pharmaceutical manufacturing requires targeted, weighted federal investment akin to the CHIPS Act—but focused on health security. The Producing Incentives for Lifesaving Medicines Supply (PILLS) Act framework introduced by Congresswoman Claudia Tenney (NY-24) provides that model. It combines two mechanisms: a Production Tax Credit—up to 35 percent for U.S.-made generics, APIs,

and biosimilars, plus a 20 percent bonus for high domestic-content sourcing—and a 25 percent Investment Tax Credit for new or modernized facilities, fill-finish lines, and sterile-injectable capacity.

These incentives directly offset the foreign cost advantage created by subsidies, weak labor standards, and lax oversight in China and India. Credits would be transferable and refundable to help small and mid-size firms, and sunset between 2030 and 2033 to prevent permanent dependency. Importantly, the PILLS Act benefits would be compounded by a Pharmaceutical Tariff-Rate Quota (TRQ) system under Section 232 that simultaneously caps subsidized imports and creates guaranteed domestic market space for all U.S. producers. Together, they form a classic dual-policy: tariffs defend the market; incentives rebuild supply.

A complementary initiative could expand the Strategic National Stockpile into an active investment tool—offering multi-year "anchor contracts" for drugs identified as essential by HHS and DoD. These contracts, whether through HHS, DoD, or VA procurement, would guarantee baseline demand so private firms can justify new U.S. capacity investments.

4) **You have highlighted how our current drug manufacturing system harms small to mid-sized businesses.**

   How can the federal government support small and mid-sized businesses in domestic drug manufacturing?

Small and mid-sized manufacturers are indispensable for national resilience because they provide geographic diversity, redundant capacity, local employment, and innovation. Yet they face systemic barriers: monopsonistic GPO and PBM contracts, limited financing, and razor-thin margins that favor scale over redundancy.

Federal policy should establish a universal production base through the PILLS Act—ensuring all qualified domestic producers receive access to refundable and scalable tax credits for U.S.-based manufacturing and investment. This baseline support neutralizes foreign cost advantages for every firm competing to produce in America.

The differentiating mechanism should come through federal procurement and strategic stockpile design, which should reward redundancy, supply diversity, and regional distribution in contract awards. By weighting these factors in procurement scoring and long-term Strategic API and Finished-Drug Reserve purchasing, CMS, HHS, and DoD can naturally steer volume toward a wider variety of firms instead of concentrating contracts among a few conglomerates, naturally supporting small and mid-sized businesses.

When paired with secure-sourcing incentives at CMS, these procurement preferences reinforce a competitive domestic base that spans large and small producers alike, ensuring a geographically diverse, shock-resilient supply chain.

5) In your work you recommended federal oversight over group purchasing organizations and wholesalers.

Could you provide more information on what oversight efforts the federal government should pursue?

A handful of GPOs and PBM-aligned wholesalers dominate U.S. hospital and pharmacy purchasing—three GPOs control roughly 90 percent of hospital generic contracting, while three PBM-linked wholesalers control most retail supply. This concentration creates a structural bias toward the cheapest foreign manufacturers and against domestic producers that follow higher labor, environmental, and FDA standards.

At the core of this distortion is the anti-kickback safe harbor (42 C.F.R. § 1001.952 (j)), a loophole unique to this sector that allows GPOs to collect "vendor fees" from the manufacturers whose products they award contracts to. In theory, these fees are administrative; in practice, they function as pay-to-play rebates. Large multinational suppliers in China or India can afford these payments because of state subsidies and lower production costs, while smaller U.S. manufacturers cannot compete against these non-market players. The result is a self-reinforcing cycle: GPOs secure revenue from the biggest foreign vendors, and hospitals are locked into bulk contracts that marginalize domestic firms.

Congress should narrow or repeal this loophole, requiring GPOs to fund operations transparently rather than manufacturer kickbacks. Federal agencies should also mandate disclosure of supplier origin, redundancy, and FDA compliance history for any drugs purchased with federal funds. GPO and PBM contracts should weigh these criteria alongside price, rewarding firms that maintain dual sourcing, verified domestic production, and clean regulatory records.

Finally, the FTC and DOJ should investigate monopsony power, rebate-bundling, and spread-pricing practices that allow GPOs and PBMs to artificially inflate prices while capturing the margin difference between manufacturers and providers. These opaque rebate chains distort true market prices, drive down manufacturer revenue—especially for U.S. producers with higher compliance costs—and then pass inflated costs back to hospitals, insurers, and taxpayers. CMS and HHS OIG should condition participation in federal programs on transparent, diverse-sourcing, and pass-through pricing standards to ensure that savings flow to patients and providers rather than being extracted by intermediaries.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

QUESTIONS FOR THE RECORD

Dr. Marta E. Wosińska

Ranking Member Kirsten E. Gillibrand

Question:

You have written about how federal transparency initiatives will fall short of their goals if purchasers, such as hospitals, have no economic or institutional motivation to act on such information.

How can hospitals be incentivized to consider quality and reliability over the cost of drugs?What are some of the potential downsides of transparency initiatives should they not be executed alongside other initiatives, such as reforming economic incentives?

Response:

Transparency initiatives in drug manufacturing often fail to achieve their intended goals-not because the information is wrong, but because they lack the right incentive structures to motivate action. Simply making information available is not enough; those who receive it must be both motivated and equipped to act on it in ways that align with broader economic incentives or institutional structures. Without this alignment, transparency efforts become costly nice-to-haves, and may even produce unintended consequences that worsen the very problems they were designed to solve.

To understand which transparency approaches are most likely to succeed, it is useful to first examine the main types of transparency initiatives and how they interact with underlying economic incentives-which often diverge from what serves patients best. There are three main types of transparency initiatives:

1.Government-facing initiatives
2.Patient-facing initiatives
3.Institutional buyer initiatives

Existing government-facing initiatives primarily focus on mapping supply chains to identify geopolitical exposure and with it identify which drugs require alternative sources in which production stages of supply chains. Incentives to act on this information will be driven, to a large extent, by Congress (by setting out the tools and directives as well as appropriating funds to follow through) and the administration (by identifying which existing tools they can deploy).

Patient-facing initiatives include adding to the pharmacy label either the Country of Origin or a rating of product quality. The goal of these efforts is to shift markets through patients as they begin to shop for versions that presumably are less likely to have product defects. There are two intertwined reasons, however, why such initiatives could go astray. First, without reforms for how pharmacies are reimbursed, patients have limited options in how they respond to sourcing information, other than deciding not to fill the prescription. Second, neither measure is strongly correlated with actual product quality, making potential misinterpretation by patients particularly concerning.

When it comes to institutional buyers, efforts have focused largely on creating transparency in the hospital and clinic sector, not the retail pharmacy sector (where the consumer-facing measures seem to have gotten more attention). In the hospital space, there are two main types of transparency initiatives:

- Supply chain reliability assessments and;
- Early warning systems.

The data needed to support these transparency initiatives varies depending on the goal. Supply chain reliability assessments focus on evaluating the long-term dependability of a manufacturer's supply chain over the duration of a multi-year contract, using indicators such as plant redundancy, inventory controls, raw material sourcing, risk management practices, and historical shortage records. In contrast, early warning systems aim to detect abrupt risks or disruptions in the near term-drawing on real-time signals like new shortage posts on the ASHP website, reports of product discontinuations, sudden order limits from any wholesaler, newly an-

nounced adverse FDA inspection findings, recalls, or reports of supply interruptions in global logistics. The economic incentives for these two transparency approaches diverge sharply.

Early warning systems enable hospitals to continue prioritizing low-cost procurement without regard for long-term supply reliability, only shifting tactics and rapidly increasing orders at the first hint of trouble. This dynamic offers clear advantages to well-resourced institutions equipped to act quickly, which in turn has driven commercial vendors to develop various rapid alert tools. Yet this competitive hoarding erodes the advance notice intended for regulators, limits FDA's ability to intervene, and accelerates the very shortages these transparency initiatives are supposed to help prevent.

In turn, purchasing in times of relative stability-whether through spot buys or contracts-is dominated by the strong incentive to choose the lowest-cost option. There is little to push hospitals or group purchasing organizations toward factoring in supply chain reliability or resilience, as most do not directly bear the costs when a disruption occurs. While there are tools and frameworks available to inform more resilience-focused procurement, hospitals have options but typically lack a meaningful reason to use them, absent clear financial rewards or contractual requirements.

Policymakers would be wise not to fuel early warning systems for hospitals but to support supply chain reliability efforts in two ways: by supporting the related transparency efforts and by creating economic incentives.

Policymakers can promote supply chain reliability in drug procurement by ensuring purchasers have access to meaningful, actionable information. Changes to current reporting requirements-such as requiring suppliers to specify not only who a drug is ″manufactured for″ but also who it is ″manufactured by″-would make it far easier to track products to facilities that do not have a good compliance record. Supporting FDA's Quality Management Maturity (QMM) initiative is another foundational step, as public disclosure of QMM ratings would highlight manufacturers that invest in robust quality and operational practices, allowing buyers to consider reliability and performance in addition to price during contract negotiations.

Policymakers should complement transparency efforts by pursuing payment and contracting policies that create meaningful economic incentives for hospitals and manufacturers to prioritize supply chain reliability. Current proposals-such as those from the Senate Finance Committee and HHS-would authorize financial rewards or penalties based on a buyer's or supplier's record of ensuring supply continuity, product quality, or timely response during shortages. By tying payment rates directly to reliable performance-or imposing disincentives for repeated supply failures-these initiatives aim to move the market beyond cost alone, encouraging long-term investments in resilience throughout the supply chain.

Question:

In your research you recommend a broad strategy when it comes to deciding which drug supply chain resiliency efforts to prioritize and support. More specifically, you recommend that the Administration for Strategic Preparedness and Response shift from a fixed list of essential drugs toward a longer list that stratifies drugs by how critical they are, their reach, and how vulnerable they are to disruption.

Could you say more about how this longer, stratified list would better enable the federal government to support resilience efforts?

Response:

When it comes to supporting drug supply chain resilience efforts, setting priorities is important because of the scale and complexity of the drug supply chain. There are well over 2,000 approved prescription drugs, spanning a large array of ingredients, manufacturing technologies, and production sites that collectively produced 187 billion tablets and capsules for American patients in 2024, not counting other dosage forms. The lack of economic incentives in the market coupled with the magnitude of what it would take to secure all drug supply chains requires that the government prioritizes where to engage.

Prioritization is not only needed but possible because not all drugs are equally important. For example, some drugs are lifesaving in emergencies, such as epinephrine auto-injectors for severe allergic reactions or insulin for patients with type 1 diabetes. Others, like certain chemotherapy agents or antibiotics, are critical for treating serious infections and cancers. Drugs for chronic conditions, such as antihypertensives and statins, affect large patient populations but interruptions are not generally life threatening, especially in the short term.

U.S. government prioritization began with the FDA's list, created under a 2020 Executive Order, which identified over 220 drugs and medical countermeasures most needed for immediate and life-saving medical use in hospitals. The Adminis-

tration for Strategic Preparedness and Response (ASPR) subsequently narrowed this to 86 drugs, focusing more tightly on those deemed essential for acute care. Most recently, at the direction of the administration, ASPR further narrowed the target to about 26 drugs, selecting those for strategic stockpiling initiatives.

Budget and time constraints have made this narrowing process unavoidable. With limited new funds appropriated by Congress for comprehensive supply chain resilience, the administration's current efforts are focused on building and maintaining a six-month supply of active pharmaceutical ingredients (APIs) for this small subset of drugs. If policymakers pursue costlier or more complex resilience strategies such as supporting new domestic manufacturing of API and all its inputs, not even all 26 may be covered, and prioritization within this short list would become necessary under a limited budget.

A broader, stratified list would give policymakers flexibility to adjust investments as resources change. If Congress allocates additional funds, efforts could expand without reworking the prioritization framework. Such a list would guide readiness planning, clarify what additional money could achieve, and allow for a quick response as budget realities evolve.

In practice, criticality and reach remain fairly stable for most products unless major therapeutic advances occur; vulnerability can change quickly. Initial reviews should focus on identifying drugs with the greatest health impact and reach. Detailed, regularly updated vulnerability assessments can then be reserved for a larger list of higher-priority drugs, concentrating resources where they matter most and avoiding exhaustive analysis of less critical products.

To build a practical, ranked drug framework, it is also essential to factor in resilience-building cost and capacity constraints. The main cost drivers are often tied not to the price of the drug itself, but to the logistics of production-such as the potency of the active pharmaceutical ingredient (affecting how much can be handled in existing facilities if capacity is limited) and the specialization required of manufacturing processes. These realities can force tradeoffs, requiring policymakers to choose between covering more drugs that fit within common, flexible plant capacity, or prioritizing medicines that do not demand highly specialized production setups and supply chains.

Question:

Your work highlights why drug manufacturers outsource chemical synthesis for drug manufacturing to China. Chemical synthesis can create toxic materials and could be quite harmful to the environment. You recommend that the U.S. fund chemical industrial parks as part of onshoring efforts.

Could you say more about how funding domestic industrial parks could help to reduce American reliance on chemicals synthesized in China?

Response:

Efforts to derisk pharmaceutical supply chains from China require developing alternative sources for critical chemical inputs. Diversification does not necessarily mean full onshoring; establishing production capacity in allied, cost-competitive countries can often achieve greater efficiency while mitigating geopolitical risk. However, for strategically sensitive or high-risk materials, selective onshoring can enhance national resilience.

An important part of derisking supply chains from China is at the earliest, unregulated steps: key starting materials, intermediates, and auxiliary chemicals like reagents and solvents used in synthesis. This is where U.S. drug supply chain exposure is the greatest.

The reliance is driven by Chinese firms' strong cost advantage through significant economies of scale coupled with lower labor, energy, and transportation costs. Historically, a lax regulatory framework allowed Chinese producers to operate with higher environmental and workplace risks than Western and Indian competitors, enabling their cost advantage. Following the Beijing Olympics, China began to reckon with environmental pollution and began raising standards and investing in greener manufacturing methods.

The question is then, how should the U.S. respond if it chooses to onshore chemical manufacturing. Environmental deregulation alone will not succeed in shifting production to America because China will continue to hold an insurmountable cost advantage driven by lower energy, lower labor, and deep economies of scale. In fact, a race to the bottom on environmental standards would require the U.S. to set regulations lower than even India and China are willing to accept-countries that have already rejected the dirtiest manufacturing practices as economically and socially unsustainable.

The future of chemical manufacturing lies in advanced green chemistry technologies that represent the next generation of global competitive advantage. These

approaches are more efficient, create higher value-added products, and generate more skilled, higher-paying jobs than legacy chemical processes.

Chemical industrial parks offer a more sustainable and scalable alternative to traditional one-company-at-a-time funding. By co-locating multiple manufacturers within shared infrastructure-centralized wastewater treatment, utilities, analytical testing facilities, and logistics-these parks significantly lower the per-unit overhead for each producer. This model is widely used in Europe, India, and certain U.S. states.

Parks also create resilience: if one tenant exits, another can step in using the same infrastructure, protecting the government's investment and maintaining supply continuity. For policymakers working within budget constraints, industrial parks provide a mechanism to support multiple products and processes simultaneously, rather than betting on individual companies or isolated facilities.

Centralized environmental controls-shared wastewater treatment plants equipped to handle toxic intermediates, air quality monitoring, and hazardous waste management-enable cost-efficient pollution control far more effective than individual facilities can achieve. This allows domestic chemical production to meet U.S. environmental standards without imposing prohibitive costs on each manufacturer, reversing the historical trend of exporting pollution alongside production.

Senator Raphael Warnock

Question:

Rural health providers in Georgia rely on access to affordable drugs to treat patients, including older Americans. Due to financial vulnerability, rural providers have limited capacity to build a stockpile of drugs in preparation for supply shortages.

How can Congress work to ensure rural hospitals and clinics can provide affordable and safe drugs to seniors in times of a drug shortage crisis?

What kind of policy changes would incentivize domestic drug suppliers to develop generic drugs and improve aging rural populations' access to prescription drugs?

Response:

It is indeed the case that rural providers, especially those not part of a large health system, have severely limited ability to withstand supply disruptions. This stems partly from scale: they often lack staff dedicated to supply chain management, operate on thin financial margins that leave little room for inventory investment, and cannot leverage the purchasing power of larger systems. Independent rural facilities face a particularly acute challenge: unlike small hospitals within integrated systems that can at least access their parent organization's negotiating leverage and shared contracts, truly independent rural providers must navigate procurement entirely on their own.

A 2023 STAT article illustrated this dynamic during the national shortage of carboplatin and cisplatin. Large health systems weathered the disruption easily, using their purchasing power and strong supplier relationships to stockpile supplies. Small, often rural, independent oncology clinics could not-they lacked these advantages and were sidelined by allocation systems favoring historical bulk orders. Many small clinics had to ration care, send patients to distant centers, or delay lifesaving treatment altogether, intensifying distress and risking poorer outcomes for vulnerable populations. The shortage exposed systemic flaws in drug procurement practices and underscored the urgent need for reforms to ensure more equitable access to essential drugs.

Analytics and data systems play a major role in the disparities seen during chemotherapy drug shortages because large hospital systems typically have sophisticated analytics tools that allow them to monitor drug inventory, predict shortages, and swiftly respond by stockpiling or reallocating supplies across their networks. These systems provide actionable data on usage rates, inventory levels, and shortage signals, enabling proactive strategies like early purchasing or redistribution before official shortage notifications are issued. In contrast, small independent clinics often lack access to such analytics and automation, making it difficult for them to anticipate shortages or compete for limited supply-further widening the gap in access during crises like the carboplatin and cisplatin shortage.

Expanding the use of advanced analytics with small providers has the potential to help these providers better anticipate drug shortages, optimize inventory, and negotiate more effectively with suppliers, reducing vulnerability during supply chain disruptions. However, the cost, technical complexity, and need for specialized staff pose significant obstacles. Many small clinics operate with tight budgets and limited

personnel, making it difficult to adopt and maintain sophisticated data systems even if the technology itself is available. They will always be behind the curve and therefore last in line.

For most small and rural clinics, greater resilience may come from direct preparedness strategies, such as regional stockpiling programs, collaborative purchasing efforts, and supportive policy reforms that redistribute essential drugs during crises.

One such recent effort was CMS establishing a separate payment system for small independent facilities, many of them rural, to help them create and maintain a buffer inventory of essential medicines. This authority is based on the same legal mechanism used for N95 mask stockpiling during the pandemic. The program allows qualifying hospitals to receive targeted Medicare payments specifically for the costs of purchasing and storing a reserve supply of designated drugs, with eligibility focused on hospitals most likely to face financial and logistical barriers to stockpiling.

However, this authority is limited by statutory language that restricts reimbursement to only ″reasonable costs.″ The ″reasonable costs″ constraint ties reimbursement only to Medicare's share of a hospital's business, meaning that hospitals must maintain buffer inventory sufficient to serve their entire patient population-including Medicaid, uninsured, and commercially insured patients-but can only be reimbursed for the Medicare portion of those inventory costs. Additionally, the costs of tracking, monitoring, and reporting on buffer stock inventory are not reimbursed under the program. These limitations mean that the payments offered may not fully cover the financial and operational burdens of creating and maintaining a substantial buffer stock, limiting participation.

To address these limitations, Congress should strengthen the existing CMS framework by amending the statutory authority that currently restricts reimbursement to ″reasonable costs″ tied only to Medicare's share of hospital business. Specifically, Congress should authorize CMS to provide full reimbursement for buffer stock costs regardless of payer mix, recognizing that hospitals must maintain inventory for all patients, not just Medicare beneficiaries.

Additionally, the statute should be amended to support a fixed payment model rather than the current submit-a-bill approach, which would reduce administrative burden and make participation more attractive to resource-constrained rural hospitals. The fixed payment should also cover the costs of tracking, monitoring, and reporting on buffer stock inventory-costs currently excluded from reimbursement.

Congress and CMS can also influence how wholesalers allocate scarce products during shortages. Wholesalers typically allocate based on historical purchasing patterns over a short lookback period (often 3-6 months), which systematically disadvantages small rural providers with variable ordering patterns. A rural hospital that orders 100 units of a critical drug every 12 months may receive zero allocation if the lookback period captures only the months between orders. Meanwhile, large integrated health systems have a significant advantage: they can bypass wholesalers entirely and purchase directly from manufacturers during shortages, securing supply outside the allocation system altogether-an option unavailable to small independent hospitals.

To level the playing field, CMS could mandate that wholesalers use longer, smoothed lookback periods as a condition of participation in Medicare or Medicaid programs-for example, calculating allocations based on 12-24 month rolling averages rather than recent 3-6 month snapshots. Additionally, Congress could direct FDA or CMS to establish minimum fairness standards for allocation methodologies during shortages, similar to how other federal agencies regulate allocation of scarce resources. Finally, allocation formulas should be reformed to use objective metrics tied to patient population served, licensed bed capacity, or facility size, rather than pure historical purchasing volume.

Beyond influencing allocation during shortages, Congress can also make the entire pharmaceutical supply chain more reliable by reducing the risk and frequency of supply disruptions themselves. Legislative actions may include requiring redundancy and diversification among manufacturers, strengthening federal oversight for manufacturing quality and inspections, incentivizing domestic production, and supporting proactive stockpiling at the national level. These measures would help prevent supply shocks from occurring and limit their scale, ensuring that small rural hospitals are not perpetually vulnerable to access disparities even when major disruptions occur.

Question:

Hurricane Helene shut down Baxter International's North Carolina facility and caused a nationwide intravenous (IV) fluid shortage. Hospitals across the country were forced to ration their IV fluids until the company restored its manufacturing

capability. I sent a letter to the Food and Drug Administration and the Department of Health and Human Services leadership pushing them to provide relief during this crisis.

How could Congress leverage technology like predictive analytics to strengthen the resilience of domestic drug supply chains in times of natural disasters?

Response:

Predictive analytics can be an invaluable tool for monitoring supply chains and anticipating shortages, but their use during a crisis-such as the IV fluid shortage following Hurricane Helene-can compound existing vulnerabilities. When predictive analytics signal an emerging scarcity, large health systems often respond by accelerating stockpiling or bulk purchasing, which can deplete inventory faster and outcompete smaller hospitals for limited resources. This dynamic can leave rural and independent providers even more exposed, intensifying the very shortages that technology is aiming to mitigate.

Better, real-time tracking of saline usage at both inventory and patient levels would significantly improve a hospital system's ability to allocate scarce resources during a shortage. Saline and other IV fluids are FDA-approved drugs, yet many hospitals treat them as supplies rather than medications. This classification outside the pharmacy system means administrations and usage are often not barcode-scanned or tracked like medications, making it difficult for health systems to know where the product is being used or how much.

To address this tracking problem, CMS could require health systems to reclassify and track IV fluids as FDA-approved drugs rather than allowing them to be handled outside pharmacies as untracked supplies. Enhanced analytics could identify which units or patients have the greatest clinical need, optimize distribution, and reduce waste or unnecessary stockpiling throughout the network.

While real-time tracking and robust analytics enable smarter, more equitable allocation of supplies during a shortage, hospitals also need practical and systemic strategies to prepare for major disruptions. For high-volume products like saline, maintaining a buffer inventory is particularly challenging given the heavy usage, physical volume, and cost of storage. Hospitals must adopt additional safeguards and diversify their approaches beyond stockpiling to prepare for potential shortages.

For hospitals, avoiding sole-source contracts is a key step. Reliance on a single supplier for saline or other essential fluids can dramatically widen the impact of any supply disruption, whereas maintaining relationships with multiple vendors lessens vulnerability-enabling continued provision of urgent services even during supply chain shocks. Recent shortages have exposed disparities based on with which manufacturer a hospital contracts. During the 2024 saline shortage following Hurricane Helene, hospitals contracting with Baxter received only 40-60% of normal allocations, while those using B. Braun experienced minimal disruption as B. Braun's facilities were unaffected.

Manufacturers can help by investing in more flexible or 'fungible' production systems that allow rapid pivots to different bag sizes or formulations as market demand and regulatory priorities shift. Facilities able to quickly change production lines or scale outputs for alternative product sizes improve overall supply chain resilience, reducing the risk and magnitude of shortages from specific disruptions. Encouraging manufacturers to adopt these adaptive capabilities can increase redundancy and responsiveness, ultimately protecting the entire healthcare system during crises.

Congress and the administration can play vital roles in supporting alternative hospital preparedness strategies for saline shortages-using both regulatory ″sticks″ and financial ″carrots.″ On the regulatory side, policymakers could strengthen antitrust enforcement and oversight to discourage anticompetitive practices, such as exclusive or sole-source contracts that undermine supply resilience and limit access during disruptions. On the incentive side, Congress could expand payment models or grant programs to encourage hospitals to diversify suppliers and invest in logistics for alternative sourcing.

Statements for the Record

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

STATEMENTS FOR THE RECORD

Association for Accessible Medicines Statement

Association for Accessible Medicines
Statement for the Record
United States Senate Special Committee on Aging
Hearing on "Bad Medicine: Closing Loopholes that Kill American Patients"
October 8, 2025

The Honorable Rick Scott
Chairman
Special Committee on Aging
U.S. Senate
Washington D.C. 20515

The Honorable Kirsten Gillibrand
Ranking Member
Special Committee on Aging
U.S. Senate
Washington D.C. 20515

Chairman Scott, Ranking Member Gillibrand, and Members of the Committee:

AAM represents the manufacturers of finished generic and biosimilar pharmaceutical products, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. AAM works to expand patient access to safe, quality, and effective generic and biosimilar medicines by promoting a positive regulatory, reimbursement, and policy environment and advancing education regarding the safety and effectiveness of generic and biosimilar medicines.

Generic medicines are the backbone of the U.S. prescription drug market. They supply approximately 9 out of every 10 prescriptions, but only account for 12% of total U.S. prescription drug spending.[1] To put this into additional context, in 2023 the amount America spent on just *two* branded products – Ozempic and Humira – exceeded the amount spent on *all* generics.[2]

America's patients and health care providers depend on generic medicines. However, recent hearings and legislation have highlighted Congressional concern related to the geopolitical risks of overreliance on certain countries for Active Pharmaceutical Ingredients (APIs), as

[1] AAM. "2025 U.S. Generic and Biosimilar Medicines Savings Report." (September 2025) Available here.
[2] Long, D. "US Generics & Biosimilars Trends, Issues, & Outlook," IQVIA. (February 2024

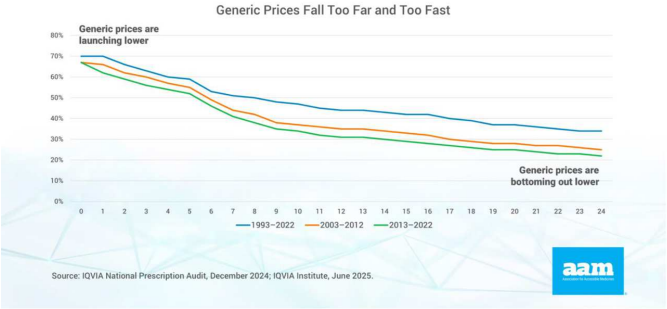
well as the vulnerabilities in our pharmaceutical supply chain. Generic drug manufacturers have been driven to offshore API and some generic drug manufacturing to other countries because manufacturing generic drugs is a highly competitive, low margin industry in the U.S. In fact, in the last five years, the total dollar value of all generics sold in the U.S., including a range of new generics, has fallen by $6.5 billion.[3]

Below, we detail the challenges faced by generic drug manufacturers, by first discussing the specific economic challenges of the market, and how Congress may help. We believe with strategic support from the U.S. government, the economic footprint of the generic drug industry in the U.S. can expand, leading to increased national security, continued access to affordable medicines for patients, a reduction of dependence on any one country for key pharmaceuticals or their components, and an expanded domestic employment base.

I. How are the Economics for Generic Drugs Difficult?

Unfortunately, little is being done to infuse sustainability into the generic marketplace. As noted below, compared to 30 years ago, generic drugs are launching at lower prices and bottoming out at lower prices. The biggest change has been increased savings through the use of generic drugs. Thirty years ago, generic prices tended to stabilize at approximately 34 percent of the brand product's list price. In the last decade, that percentage has continued to drop – to 22 percent. This type of deflation can lead to unsustainable market conditions for generic drug manufactures and dangerously impact patient care.

Deflation Puts Generic Market in Peril



[3] IQVIA Institute for Human Data Science. "The Use of Medicines in the U.S. 2023 Usage And Spending Trends And Outlook To 2027" (April 2023) Available here.

How did we get here? As a result of various government policies, consolidation among generic drug purchasers, rebate traps, and a highly competitive market, generic manufacturers are generally unable to raise prices, resulting in prices for generic drugs in the United States falling well below generic prices in other countries.

Government policies. The hypercompetitive U.S. generic marketplace puts downward pressure on generic drug prices. In addition, U.S. government policies place limits on generic drug pricing. Within both Medicare and Medicaid, generic manufacturers face penalties if they increase their prices above the rate of inflation. Strangely enough, due to the structure of the Medicaid inflationary rebate, generic manufacturers may face payment penalties, even when they do not increase their prices (e.g., through purchasing pattern fluctuations, including changes in customer base and seasonal changes in product usage).[4]

Consolidation. Price deflation has been driven by unchecked consolidation among generic drug-buying organizations. Three hospital/clinic group purchasing organizations control roughly 90 percent of all generic medicine purchasing for hospitals/clinics.[5] In the retail market, three purchasing consortiums (wholesaler/retail chain combinations) collectively control 90 percent of the retail prescription market.[6] Fewer buyers means fewer markets for the more than 200 generic drug manufacturers in the U.S., and can result in unsustainably low prices with as many as a dozen manufacturers making any given product.

Rebate traps. In the United States, brand manufacturers will often pay rebates to a health plan or a pharmacy benefit manager (PBM) to ensure that a particular drug or drug is on formulary and has little utilization management. The "gross to net" calculation examines the list price and subtracts any of those rebates. In 2024, the "gross to net" reduction for brand products totaled $356 billion.[7] These rebate payments create perverse incentives for PBMs and health plans to prefer the branded products over generics. Most, if not all, of those rebates get passed on to plan sponsors, who tend to use rebates to reduce premiums and offset overall healthcare costs, not reduce the cost of prescriptions for the patients.[8] Recent reports suggest that, rather than relying on rebates to drive compensation, PBMs are instead focused on various fees (including GPO fees) and specialty pharmacy offerings.[9]

II. What are the Challenges to Domestic Manufacturing of Generic Drugs?

Generic manufacturers, far more so than brands, face challenges to domestic production that include: (1) lack of significant, long-term U.S. government financial incentives to encourage production of domestic APIs and generic drugs, (2) challenges with U.S. reimbursement, (3)

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[4] Avalere. "The Medicaid Drug Rebate Program and Considerations for Generic Markets." (February 2025) Available here.
[5] Seeley, E. "The Impact of Pharmaceutical Wholesalers on U.S. Drug Spending." The Commonwealth Fund. (July 20, 2022) Available here.
[6] Fein, A. "The 2022-23 Economic Report On Pharmaceutical Wholesalers And Specialty Distributors." (October 2022) Drug Channels Institute. Available here.
[7] Fein, A. "Gross-to-Net Bubble Hits $356B in 2024—But Growth Slows to 10-Year Low." (July 2025) Available here.
[8] Fein, A. "Surprising Data on Employer-PBM Rebate Pass-Through Arrangements in 2023." (August 2023) Available here.
[9] Nephron Research. "Trends in Profitability and Compensation of PBMs & PBM Contracting Entities." (September 18, 2023)

labor shortages, and (4) regulatory barriers. As a result, there lies dormant significant generic drug manufacturing capacity in the United States.[10]

Congress and key agencies need to envision a decades long commitment, not only in terms of overall funding but also with respect to creating legislative and regulatory pathways to ensure a meaningful number of generic drugs are manufactured in the United States.

Lack of Significant Financial Incentives. Unlike other countries, the United States has not coalesced around a comprehensive approach to enhance the domestic manufacture or even the resiliency of the generic drug supply chain. Disappointingly, HHS has only invested $60 million in domestic manufacturing of key starting materials and API,[11] and that investment did not shore up traditional generic manufacturers or ensure a continued investment in infrastructure. Continued investment is needed.

Challenges with U.S. reimbursement. Current government payment policies lead to underpricing and cause generic, particularly generic sterile injectables, to leave the market. Medicare reimbursement policies for sterile injectables creates a race-to-the-bottom that drives prices below market equilibrium.[12] In many cases, this also harms generic adoption by rewarding providers for using higher-cost brand drugs.[13] Mandatory 340B discounts threaten the sustainability of producing low-margin, high-value generics by mandating further discounts of generics that have already been priced to unsustainably low levels. In addition, state drug takeback mandates and the Medicaid generic drug penalty also creates downward pressure and instability within the market and could potentially inhibit any federal policy to promote U.S. sourced generic drugs.

Labor shortages. A 2022 Department of Health and Human Services (HHS) -sponsored report noted that the United States faces a shortage of workers with the specialized knowledge for pharmaceutical manufacturing, with 60 percent of U.S. manufacturing jobs going unfilled.[14]

Regulatory barriers. With respect to API manufacturing, there are key barriers – permitting issues and Food and Drug Administration's (FDA's) inspection of manufacturing sites. Thus, Congress may want to consider various proposals to expedite permitting processes to aid with the construction of new facilities. To ensure compliance with the current Good Manufacturing Practices (cGMP), the assessment, or review, process for new and generic drug marketing applications include FDA's assessment of whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market. As noted in the

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[10] Center for Analytics and Budget Insights of the Olin Business School at Washington University. "US Generic Manufacturer Available Capacity Research Survey." (September 2022) Available here.
[11] European Pharmaceutical Review. "Biden Administration to support resilience of US pharma supply chain." (August 2021) Available here.
[12] Gottlieb, S. "Drug Shortages: Why they happen and what they mean." (December 2011) American Enterprise Institute. Available here.
[13] Ginsburg, P. Lieberman, S. "Medicare payment for physician-administered (Part B) drugs: The interim final rule and a better way forward." (February 2021) USC-Brookings Schaeffer On Health Policy. Available here.
[14] Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services. "Essential Medicines Supply Chain and Manufacturing Resilience Assessment" (May 2022) Available here.

2022 HHS report, the current process may be lengthy, with the average time to set up a new plant taking 5-7 years and adding a single line to an existing plant, 3-5 years.[15]

Complex generics also represent an important but under-utilized avenue of savings for U.S. patients and healthcare payors.[16] Despite recent efforts to promote the approval of complex generics, these products are still slow to be approved by the FDA. As a result of these delays, a 2021 analysis found that the delay in FDA approval results in annual lost savings of $1.3 billion (range of $600 million– $1.7 billion).[17] While the FDA has taken some steps to address these critical issues,[18] much more can be done.

III. How Can Congress Help?

AAM has previously advocated for a variety of policy proposals to boost pharmaceutical manufacturing and increase the sustainability of the generics market within the United States, including (1) guaranteed purchase of certain essential medicines, (2) increased regulatory efficiencies, (3) stopping pharmacy benefit manager (PBM) and Medicare policies from denying patients access to new generics, and (4) rolling back of harmful federal policies that actively impede generic competition.

Guaranteed Purchases. Guaranteed fixed volume and price agreements are essential to ensuring the viability of U.S.-based generic manufacturing for essential medicines and inoculating those investments against low-priced imports of the same medicine. When engaging with the industry, however, HHS, the Department of Veterans Affairs (VA), and the Department of Defense (DoD) must encourage multiple suppliers in the market. HHS should leverage fixed price and volume guaranteed contracts when expanding the Strategic National Stockpile, and the VA should utilize fixed price and volume guarantees for national contracts to supply the VA and DoD.

Increased Regulatory Efficiencies. The FDA should streamline its regulatory review and approval processes by removing duplicative actions and reducing the time for approvals across the board. The agency should expand cooperation with the manufacturer, working collaboratively to evaluate and approve the facility and the tech transfer processes concurrently, as opposed to waiting until after the facility is built and the equipment is installed or validated. The FDA also recently announced a new pilot program that prioritizes ANDAs whose applicants test for bioequivalence in the U.S. and source API and finish domestically.[19]

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[15] Ibid.
[16] A subset of generic prescription drugs, complex generics are copies of non-biologic medicines that have a complex molecular base, route of delivery, formulation, or dosage form; are a drug-device combination product; or have other particularly complex approval requirements. Complex generics, including epinephrine auto-injectors for anaphylaxis and inhalers used to manage asthma, treat chronic and serious medical conditions, such as multiple sclerosis, schizophrenia, metastatic breast cancer and diabetes.
[17] Brill, A. "Potential Savings from Accelerating US Approval of Complex Generics." (February 2021) Available here.
[18] Focus Area: Increasing Access to Complex Generic Drug Products | FDA
[19] Food and Drug Administration. "FDA Announces New ANDA Prioritization Pilot to Support U.S. Generic Drug Manufacturing and Testing." (October 3, 2025) Available here.

To accomplish these goals, the FDA should create an internal, intra-agency working group focused on helping to expedite reviews and approvals to onshore pharmaceutical manufacturing. This working group should include representatives from the Office of Inspections and Investigations; the Office of Pharmaceutical Quality; the Office of Compliance; Office of Generic Drugs, and other offices as determined by the FDA. This working group should focus on reviewing for approval the transfer of production back into either U.S.-approved facilities or newly constructed facilities at new or existing sites, including those utilizing advanced manufacturing technology. This working group should grant meetings with the company to discuss the overall transfer plans. For example:

- Inspector(s) and Office of Pharmaceutical Quality staff should make site visit(s) during the construction or validation phase.
- The mechanism should be similar to a pre-ANDA meeting – that is, a developmental phase inspection and then a pre-submission inspection.
- Quality specific disciplines [e.g., Microbiology reviewer(s)] should conduct site visits to help expedite facility compliance.
- Inspections should be expedited and completed within 60 days of request for inspection.

Stop PBMs and Medicare Policies from Denying Patients Access to New Generics. Medicare and Pharmacy Benefit Managers (PBMs) must stop prioritizing higher-priced brand-name drugs over generics. Congress and the Administration should ensure patient access to new generic medicines and reform PBM practices by encouraging PBM transparency and eliminating PBM profits from linking their fees to the drug list price (i.e., delinking). In the near term, the Centers for Medicare & Medicaid Services (CMS) should take immediate steps to better measure drug product net cost to ensure rebates and fees that drive formulary design and product placement result in a lower net cost at the unit level. As part of that process, CMS should require prescription drug plan sponsors to provide an explanation and justification when a formulary does not cover a generic drug, including whether the formulary is instead covering or preferring the reference product or an alternative product; what rebates, fees or other contractual arrangements apply; and attest that the covered or preferred reference drug or biological product is lower net cost at the unit level. Finally, CMS could modify its formulary review and approval criteria to examine Part D plan sponsor coverage of generic drugs compared to coverage rates for those products in the commercial market.

Rollback Harmful Policies. Too many federal policies actively harm generic competition, including (1) updating the Medicaid inflation penalty, (2) further addressing the 340B program, and (3) amending the Inflation Reduction Act (IRA) to provide a level playing field for generics. Congress could, for example, update the Medicaid inflation penalties on generics to align with those included in the IRA. The IRA applies the inflation penalty to single-source generics and gives HHS authority to exempt products in or at risk of shortage.[20] Applying this to the Medicaid inflation penalty would more appropriately address the unique features of the generic drug market. This proposal was recently included in the Senate

[20] Pub. L. 117–169

Finance committee bipartisan discussion draft.[21] Given that the Medicaid inflation penalty also drives the price under the 340B program, this will provide targeted relief to generic manufacturers in both programs. Congress could also further address concerns with the 340B program by eliminating the unit rebate amount of 13% for generic manufacturers so that the ceiling price is set at the average manufacturer price, less any (hopefully modified) inflationary rebates. Because generics save far more than arbitrary price controls, policymakers should ensure that the IRA price controls do not harm generic competition by addressing the timelines to allow for competition before the price controls are in effect, ending the unfounded and unclear "bona fide marketing" standard, and addressing the IRA "valley of death" (i.e., lack of coverage of a newly launched product, except in certain circumstances).[22]

Moreover, the federal government may wish to encourage states to remove barriers and amend problematic policies that run counter to the intent of great U.S. domestic supply of generic drugs, as noted above.

IV. Conclusion

Generic medicines are more than a healthcare innovation: they are a means of survival for millions of Americans. AAM shares Congress's interest in addressing longstanding concerns surrounding domestic manufacturing and the national supply chain.

The challenges to meaningfully increasing domestic pharmaceutical manufacturing are significant. The process of building new capacity, whether through new facilities or utilizing currently unused excess manufacturing capacity, takes time. It requires capital investments, acquisition of needed ingredients, validation and FDA inspection of manufacturing lines, among other requirements. Accordingly, such an effort requires not only a decades-long commitment, but the patience and endurance to see it through.

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[21] Wyden and Crapo Release Draft Legislation to Combat Prescription Drug Shortages. Available here.
[22] For more information on the "valley of death", see AAM's blog located here.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

STATEMENTS FOR THE RECORD

American Hospital Association Statement

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Advancing Health in America

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Statement

of the

American Hospital Association

for the

United States Senate

Special Committee on Aging

"Bad Medicine: Closing Loopholes that Kill American Patients"

October 8, 2025

On behalf of our nearly 5,000 member hospitals and health systems and other health care organizations, and our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — the American Hospital Association (AHA) appreciates the opportunity to submit this statement for the record to the Senate Special Committee on Aging hearing "Bad Medicine: Closing Loopholes that Kill American Patients."

Each day in America's hospitals and health systems, patients receive safe and effective care from provider teams using a wide array of pharmaceuticals and medical devices. Patients' lives depend on the ready availability of drugs and devices to respond to emergent conditions like heart attacks and infections, as well as other critical illnesses like cancer and organ failure. The medical supply chains for pharmaceutical products and medical devices are highly complex, requiring hospitals to draw on domestic and international sources. These supply chains are prone to significant disruption from a wide range of factors, including transportation interruptions, natural disasters, raw materials shortages and production breakdowns.

Despite ongoing efforts to bolster the domestic supply chain, international sources still supply a significant proportion of essential medical goods. For example, many pharmaceutical products are sourced from overseas. U.S. providers use a wide variety of imported cancer and cardiovascular medications, immunosuppressives, antibiotics and combination antibiotics. For finished pharmaceutical products, the major hubs of production are India and the U.S. For injectables, the U.S. is the largest manufacturer

with 45% of production volume. However, for solid oral dosage forms, India has 60% of production volume.[1] In addition to finished pharmaceutical products, the U.S. sources many raw ingredients internationally for pharmaceuticals. These raw ingredients are commonly known as active pharmaceutical ingredients (APIs) and are the most important components of any pharmaceutical manufacturer's supply chain. The U.S. gets nearly 30% of its APIs from China, and according to a 2023 Department of Health and Human Services estimate, over 90% of generic sterile injectable drugs — including many chemotherapy treatments and antibiotics — depend on APIs from either India or China.[2]

For many patients, even a temporary disruption in their access to these needed medications could put them at significant risk of harm, including death. Carefully planned chemotherapy treatments and antibiotic schedules are essential to giving patients the best chance of overcoming their diseases. Similarly, the provision of necessary cardiovascular medications must be continuous to preserve patients' cardiovascular health.

As of the second quarter of 2025, there are 253 drugs on the active shortage list.[3] A recent Government Accountability Office analysis found that the duration of drug shortages has increased, with nearly 60% of drug shortages lasting two or more years in 2024, compared to only one-third of shortages lasting that long in 2019.[4]

In addition to pharmaceutical products and their APIs, health care providers in the U.S. are also dependent on imported medical devices. According to one estimate nearly 70% of medical devices marketed in the U.S. are manufactured exclusively overseas.[5] In 2024 alone, the U.S. imported over $75 billion in medical devices and supplies, according to AHA analysis of Census Bureau data. These imports include many low-margin, high-use essentials for hospital settings that are necessary for patient care. Some of these devices are used only once to protect patients from infection, such as single-use blood pressure cuffs, stethoscope covers and sterile drapes. Others are small devices used ubiquitously in hospitals, such as anesthesia instruments, cautery pencils, needles, syringes and pulse oximeters. The low-margin nature of these products makes them difficult to produce within the U.S. At the same time, disruption in the availability of these devices would curtail hospitals' ability to perform life-saving surgeries and keep patients safe from contagion, as well as hinder providers' ability to effectively diagnose, monitor and treat patients.

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[1] India and the United States Manufacture Most Finished Medicines for the U.S. Market, USP, Supply Chain, February 19, 2025.
[2] https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf
[3] https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
[4] Drug Shortages: HHS Should Implement a Mechanism to Coordinate Its Activities GAO-25-107110. April 09, 2025. Publicly Released: April 09, 2025.
[5] https://www.medicaldevice-network.com/analyst-comment/trump-tariffs-us-medical-device-market/

While these statistics are an indicator of the importance of reshoring to protect America's interests and strengthen the pharmaceutical and medical device supply chains, reshoring cannot, on its own, provide the supply chain stability needed to ensure unrestricted access to necessary drugs and devices for patient care. For example, the lingering shortages of intravenous (IV) fluids stemming from the impacts of Hurricane Helene on a large North Carolina production facility in 2024 took approximately 11 months to resolve, officially ending in August 2025, with full restoration of supplies announced in May 2025.[6] Despite that facility being located on American soil, it was not impervious to supply chain disruptions.

The AHA believes it is necessary to strengthen the domestic supply chain for essential pharmaceutical and other medical products and recognizes the value of reducing reliance on international sources; the AHA also acknowledges that domestic disruptions highlight the need for a diverse supply chain that includes international sourcing. Achieving both safety and diversity will require significant time, effort and ingenuity due to the logistical complexity and resources involved in reorienting pharmaceutical and medical supply chains.

To that end, a critical step toward protecting America's pharmaceutical and medical supply chains is understanding vulnerabilities from the beginning of production to the moment a drug is administered to a patient or a device is used to deliver care. Supply chain vulnerabilities often only become apparent when the chain has been broken, as in the case of the IV fluid shortage that resulted from Hurricane Helene. Proactively mapping and assessing the pharmaceutical supply chain, as well as supply chains for other medical devices and equipment, is an important step to improving resiliency in U.S. supply chains and protecting patients' access to care.

The AHA expressed support earlier this year for S. 1784, the Mapping America's Pharmaceutical Supply (MAPS) Act. The bill would codify an executive order from the administration to secure essential medicine supply chains.[7] Additionally, it would require the Department of Health and Human Services to perform a comprehensive risk assessment of the entire U.S. pharmaceutical supply chain. The MAPS Act is an effective step toward strengthening the U.S. pharmaceutical and medical device supply chains. Additionally, the AHA is supportive of S. 2062, the Rolling Active Pharmaceutical Ingredient and Drug Reserve (RAPID Reserve) Act.[8] This legislation awards contracts to eligible generic-drug makers that would require them to maintain a six-month reserve of critical generic drugs and their active ingredients to prepare for shortages. The AHA encourages the Senate to pass these pieces of legislation and look for more opportunities to encourage both protection of and diversity in the supply chain to ensure health care resilience and strengthen U.S. national security.

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[6] IV saline solution shortage resolved, FDA reports. AAP News, August 18, 2025.
[7] https://www.rickscott.senate.gov/2025/5/sen-rick-scott-colleagues-introduce-the-maps-act-to-boost-u-s-medicine-supply-chain-curb-dependence-on-communist-china
[8] https://www.congress.gov/bill/119th-congress/senate-bill/2062/text

Strengthening supply chains for essential pharmaceutical and other medical products is necessary, and the AHA recognizes the value of reducing reliance on international sources. Achieving this goal will require significant time and resources, given the complexity of medical and pharmaceutical supply chains. Additionally, the importance of supply chain diversity as a means of protecting patient safety should not be underestimated. The AHA appreciates the committee's attention to this topic and looks forward to further collaboration in the future.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

STATEMENTS FOR THE RECORD

American Society of Health-System Pharmacists Statement

October 8, 2025

The Honorable Chairman Rick Scott
The United States Senate
Special Committee on Aging
G 16 Dirksen Senate Office Building
Washington, DC 20510-6050

The Honorable Ranking Member Kirsten Gillibrand
The United States Senate
Special Committee on Aging
G 16 Dirksen Senate Office Building
Washington, DC 20510-6050

Re: ASHP Statement on the Senate Special Committee on Aging Hearing, *Bad Medicine: Closing Loopholes that Kill American Patients*

Dear Chair Scott and Ranking Member Gillibrand:

Thank you for holding this hearing on the solutions to threats to the U.S. drug supply chain impacting America's seniors. The American Society of Health-System Pharmacists (ASHP) is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health system community pharmacies.

America's seniors rely on a secure, resilient drug supply chain, whether they are seeking life-saving care in inpatient and outpatient facilities or picking up medications at their community pharmacies. Many generic drugs, including sterile fluids used for injection or irrigation, and critical oncology drugs, such as cisplatin, carboplatin, methotrexate, and vinblastine — are frequently at risk of drug shortages and supply-chain disruptions. While these shortages may be attributed to multiple factors, the root causes can be directly linked to economic factors that erode the resilience of the supply chain. We appreciate the committee's commitment to strengthening the generic drug supply chain.

ASHP's Role in Addressing and Managing Drug Shortages: Our members manage drug shortages in health systems and pharmacies throughout our nation's supply chain. We use public submissions, in conjunction with the University of Utah Drug Information Service, to maintain a drug shortage list that tracks drug availability across the nation. Information submitted is verified with drug manufacturers before it is posted on the ASHP Drug Shortages List. Drug shortage information gathered is also shared with the Food and Drug Administration (FDA). We list every drug shortage reported on our drug shortage database as soon as it is investigated and confirmed, usually within 24-72 hours.[1] We also provide practitioner-focused resources to help the healthcare community manage shortages. Examples include information on unapproved drugs and unlabeled uses (when well-researched and reported to be safe and effective); recommendations for therapeutic alternatives; drug-to-drug comparisons and comparisons within individual drug classes; and safety recommendations.

[1] https://www.ashp.org/drug-shortages/current-shortages

Underlying Causes of Generic Drug Shortages: While spikes in demand can cause short-term drug shortages, the most severe and persistent shortages are driven by economic factors that undermine investment in manufacturing capacity, manufacturing quality,[2] and supply chain reliability. These economic challenges are driven by extreme price competition among generic manufacturers. For example, the lower profitability of generic drug manufacturing has caused companies to completely stop manufacturing certain less-profitable drugs.[3] To effectively address drug shortages, the United States needs to focus on the key drivers of generic drug shortages, including manufacturer reliability, supply chain issues, and larger healthcare marketplace trends that have placed intense economic pressure on the overall cost of generic drugs.

Recommended Solutions: To effectively address drug shortages and protect seniors' access to care, we strongly urge policymakers to focus on the key drivers of generic drug shortages: quality and supply chain issues and larger healthcare marketplace trends that have placed intense economic pressure on the overall cost of generics.

ASHP has developed the following recommendations designed to directly address the root causes of generic drug shortages which can be applied to both foreign and domestic manufacturers:

Improve Transparency into Manufacturer Quality to Enable Purchasing Based on Quality as Opposed to Cost: Healthcare providers and pharmacies currently have very little ability to select manufacturers based on the reliability of their supply chain. This lack of transparency undermines their ability to source products from the most reliable manufacturers.

- We recommend that FDA finalize, and make public, metrics of quality manufacturing maturity (QMM), so that purchasers can buy from manufacturers less likely to experience a shortage.
- In the absence of publicly reported QMM metrics, we recommend FDA make unredacted manufacturing inspection reports publicly available so that purchasers have a better understanding of supplier manufacturing challenges, and what products are made at facilities with a history of manufacturing quality and compliance problems.

Encourage New Manufacturers and New Manufacturing Sites: Entering the market to manufacture a generic drug is a multi-year process that requires investment in scientific, manufacturing, and regulatory functions. This makes it difficult for new manufacturers to enter the market and increase supply when shortages occur.

- We recommend that FDA waive drug user fees for generic drugs described in 506C(g) of the Federal Food Drug and Cosmetics Act, which says FDA may prioritize and expedite review of an abbreviated new drug application (ANDA) or related supplement to mitigate a shortage. This fee waiver should apply only to manufacturers that commit to promptly market their generic drug if it is approved.

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[2] https://news.nd.edu/news/extreme-price-competition-in-pharmaceutical-industry-may-put-patients-at-serious-health-risk-study-shows/
[3] https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages#xj4y7vzkg

Enforce Existing Shortage Prevention Requirements: Congress previously passed legislation requiring manufacturers to report information about their manufacturing and supply chains to the FDA and to develop risk management plans to help prevent disruptions to drug manufacturing. FDA has raised concerns that manufacturers have failed to provide this information for more than 4,000 manufacturing facilities — greater than half of registered facilities.[4] This disregards Congress' intent, increases the risk of manufacturing disruptions, and prevents FDA from responding to shortages.

- We recommend Congress amend section 510(j) of the Federal Food, Drug, and Cosmetics Act to include meaningful penalties for manufacturers that fail to develop risk management plans or report manufacturing and supply chain data as required by this section.

Encourage Long-Term, Guaranteed-Volume Contracts: Medicare payment policy for inpatient and provider-administered generic drugs, particularly inclusion of inpatient drug costs in diagnosis-related groups (DRGs) and the absence of a mechanism to evaluate quality, leaves healthcare providers with cost as the differentiating attribute when making purchasing decisions. This encourages healthcare providers and their group purchasing organizations (GPOs) to aggressively negotiate the price of generic drugs. To encourage greater investment in manufacturing capacity and quality, both in the United States and abroad, federal policy should provide manufacturers of critical generic drugs who make this commitment with greater certainty of their ability to recover their investment and receive purchase volume for these products. Such policy should also give healthcare providers certainty that they can rely on the manufacturer to provide a particular level of supply for the term of the contract.

- We recommend that the Centers for Medicare & Medicaid Services provide an add-on payment to providers for critical generic drugs determined by the U.S. Department of Health and Human Services (HHS) to be at risk of experiencing a shortage if those providers certify that they have entered a contract to acquire at least 50% of their historical purchase volume for those products via long-term contracts.
    - To ensure manufacturers invest in supply chain stability and quality, the contract must include a requirement that the manufacturer will maintain a six-month buffer supply of finished product, and include meaningful penalties for failure to supply contracted products, including when manufacturing disruptions result from regulatory violations or supplier disruptions.
    - To receive add-on payments, providers must ensure that they enter long-term supply contracts with manufacturers that participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.[5]
    - Providers and manufacturers could attest to meeting these requirements rather than providing proprietary contract information to HHS.
    - Providers should be free to delegate long-term supply contracting to their GPO to meet these requirements.

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[4] https://docs.house.gov/meetings/IF/IF14/20230511/115917/HMTG-118-IF14-20230511-SD006.pdf
[5] Recommendations from ASHP and other healthcare providers in 2021 called for FDA to make these metrics public. (https://www.ashp.org/News/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations)

- To minimize the administrative burden, add-on payments should be made based on the provider's total Medicare spend on the contracted drug product, rather than requiring per beneficiary accounting for medication use.

Diversify the Manufacturing Base: The federal government should use its purchasing power to ensure that at least a minimum number of manufacturers remain in the market and maintain active manufacturing capacity for critical medications. While this would not prevent any given manufacturer from experiencing a supply disruption, it would increase the likelihood that another existing manufacturer would be able to respond, in the medium term, when a shortage occurs.

- We recommend the federal government encourage greater diversity and redundancy in the supply chain by spreading purchase volume from federal agencies across at least three different manufacturers with an approved ANDA for any critical generic drug determined by HHS to be at risk of experiencing a shortage.
  - The federal government could leverage its purchasing through the Department of Veterans Affairs, the Department of Defense, the Indian Health Service, the Bureau of Prisons, and the Administration of Strategic Preparedness/the Strategic National Stockpile.
  - Federal purchasers should ensure that manufacturers under this program do not rely on the same contract manufacturers, as this would not actually diversify the manufacturing base.
  - To ensure manufacturers invest in supply chain stability and quality, the federal contracts must include a requirement that the manufacturer will maintain a six-month buffer supply of finished product, and include meaningful penalties for the failure to supply, including when manufacturing disruptions result from a regulatory violation or supplier disruption.
  - Federal agencies should give preference to manufacturers that participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.

Finance Private Sector Buffer Supplies: Encouraging healthcare providers and their distributors to maintain a buffer supply of critical medicines would reduce the impact of manufacturing disruptions on patient care.

- We recommend that the federal government provide low- or no-cost financing to encourage private sector maintenance of a buffer inventory of critical drugs.[6]
  - Providers and distributors should continue to have discretion to determine what products they stockpile.
  - Providers should continue to be free to contract with GPOs, drug distributors, or manufacturers to manage storage and rotation of drugs stockpiled on their behalf.
  - Access to financing should phase in slowly, to minimize the risk of a demand surge that could result in shortages as providers and distributors build their stockpiles.

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[6] Recommendations from ASHP and other healthcare providers in 2021 called for incentivizing the creation of private-sector reserves of essential medicines, medical devices, and supplies not adequately provided by the SNS. (https://www.ashp.org/News/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations)

ASHP thanks you for your efforts to strengthen America's health care supply chain. We look forward to continuing to work with you to ensure American seniors have access to life-saving medications. If you have questions or if ASHP can assist your office in any way, please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

Tom Kraus
American Society of Health-System Pharmacists

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

STATEMENTS FOR THE RECORD

Continuus Pharmaceuticals Statement

U.S. SENATE SPECIAL COMMITTEE ON AGING
"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"
OCTOBER 8, 2025
STATEMENTS FOR THE RECORD

CONTINUUS Pharmaceuticals Statement

Dear Chairman Scott, Ranking Member Gillibrand, and Members of the Committee, CONTINUUS Pharmaceuticals appreciates the opportunity to submit this statement on closing loopholes that kill American patients. We thank the Special Committee on Aging for its attention to this important issue. CONTINUUS Pharmaceuticals specializes in end-to-end Integrated Continuous Manufacturing (ICM), with the application of novel process technologies that enable the rapid production of pharmaceuticals at significantly reduced costs and with better quality assurance. CONTINUUS' mission is to produce high-quality drugs that can be delivered to patients more effectively and at a lower cost.

A Fragile Supply Chain Built on Foreign Dependence
Concerns over the pharmaceutical industry's dependence on foreign suppliers for key starting materials (KSMs), active pharmaceutical ingredients (APIs), and even finished drug forms (FDFs) began surfacing nearly two decades ago. As governments in emerging markets — especially China and India — invested heavily in scaling up pharmaceutical manufacturing, Western companies increasingly outsourced production to take advantage of lower labor costs and looser environmental regulations.

As a result, domestic manufacturing capacity and institutional expertise in the United States and Europe steadily declined. The global pharmaceutical supply chain became increasingly fragmented and complex, leading to a host of practical benefits, as well as vulnerability to disruption. **Today, approximately 80% of APIs and 40% of finished drug products used in the United States are sourced from overseas — with China and India being major suppliers.** From a strategic, quality, and geopolitical perspective, this concentration of sourcing poses greater risk than reliance on countries with stronger regulatory alignment and shared oversight norms, such as Switzerland. This dependency has contributed to recurring drug shortages, often triggered by quality or compliance issues at offshore facilities.

Solving this increasingly unsurmountable predicament will not be easy and will not be fast. Our competitors have spent decades building their domestic capabilities, often engaging in non-free-market tactics, such as insidious government subsidies and pricing strategies. As a result, they have effectively cornered the market for pharmaceutical manufacturing, creating the untenable stranglehold observed today. Furthermore, the answer for this complex problem will not be so easy as building typical run-of-the-mill manufacturing facilities in the United States – they will not work. US labor costs are too high to allow for the manually intensive and outdated batch production systems used in India and China, and our environmental standards will preclude such inefficient and non-eco-friendly processes.

Thus, any effective reshoring effort will need to incorporate novel technologies that are automated and more time- and cost-effective.

CONTINUUS Pharmaceuticals has a Working Solution
CONTINUUS Pharmaceuticals was founded in 2012 to address precisely this challenge. The company set out to develop a fully integrated, end-to-end continuous manufacturing platform for small molecule drugs (those most consumed by Americans, also subject to the most foreign dependence) — one capable of streamlining production, reducing costs, and accelerating time to market. Over the ensuing decade, CONTINUUS made steady progress, laying the groundwork for a solution that could reshape how drugs are made and delivered.

From the outset, CONTINUUS recognized that meaningful change would require more than automation or digital overlays to existing systems. That is why it developed the Integrated Continuous Manufacturing (ICM) platform — a ground-up redesign of small molecule drug production built for efficiency, quality, and scalability. Building such a system involves more than just engineering innovation. Every element must be designed, fabricated, tested, and validated in full compliance with current Good Manufacturing Practices (cGMP – the standard required for commercial distribution). It is a rigorous, multi-year process, but one that yields a manufacturing platform ready to support a new era of domestic pharmaceutical production.

CONTINUUS Pharmaceuticals' ICM platform represents a fundamental departure from conventional approaches to small molecule drug production. Unlike most systems that attempt to establish continuity by just physically connecting existing batch-based unit operations, the ICM platform was built from the ground up. This distinction is critical, as true continuous manufacturing is not just about running isolated steps in a nonstop fashion, it is about seamless integration. Without it, even novel technologies will still operate in a fundamentally batch-oriented paradigm, with all the inefficiencies and delays that come with it. The power of the ICM platform lies in its holistic design, which eliminates the gaps between upstream and downstream processes, enabling a fluid, uninterrupted flow from starting materials to finished drug product.

Integration unlocks the full promise of continuous manufacturing: faster production, greater efficiency, lower costs, and improved quality control. The CONTINUUS ICM platform can operate on a 24-hour basis, dramatically reducing manufacturing footprint, minimizing downtime, and enhancing process control. By combining novel technologies with a fully integrated design, CONTINUUS delivers a manufacturing paradigm that is not only faster and leaner but also more agile, scalable, sustainable, and future-ready. The following case studies demonstrate several important benefits of ICM (compared to batch):

- Case 1 – Patented anti-viral therapeutic
  - Cost of goods reduction ~37%.
  - Lead time reduction from >1 yr to ~50 hours.
  - Reduction in environmental impact ~4x.
  - Comment: This is CONTINUUS' lead product with a top-five global pharma. Final stability studies were positive, achieving a full technical proof-of-concept with a commercial product.
- Case 2 – Metformin HCl, a low-value generic
  - Cost of goods reduction ~30% (this compound has been produced in batch for decades, and as a result significantly optimized).
  - Lead time reduction from ~1 wk to ~24 hours.
  - Reduction in environmental impact ~53%.
  - Comment: Even though this project was not commercially implemented, it demonstrated two important things:
    1) With ICM, a low-value generic could be made in the US at a cost competitive with costs in India.
    2) The low value of many generics (in the case of metformin, the API sells for ~$4-5 USD/kg) makes any capital investment very unlikely from institutional/traditional investors.

In addition to the advantages described above, it is important to note that ICM represents a platform technology that: 1) can be easily reconfigured to produce different compounds (i.e., it is flexible/modular), 2) provides better quality through more rigorous second-to-second monitoring coupled with closed loop control, 3) has under gone several proof-of-concept studies that have clearly demonstrated its technical and economic advantages compared to batch, 4) can be scaled to meet the US market (vs. other technologies that operate at a much lower throughput), and 5) can be used to produce both the API and/or the final dosage forms (FDF) in the same line. Furthermore, from its inception at MIT, the US FDA has been involved with its development to ensure alignment with regulatory expectations. The FDA recently published that drug applications with continuous manufacturing components had significantly shorter review times than standard applications with batch manufacturing. This was possible through the Emerging Technologies Team (ETT) that is tasked with working with industry on innovative manufacturing solutions.

Leveling the Playing Field

For the reshoring of critical pharmaceutical manufacturing to be successful, the US Government will need to engage in nonconventional methods that it has been reluctant to pursue in the past, but are consistent with that of competing nations. Critical elements to such a plan include:

- Investment in Capex. To build the necessary infrastructure (i.e., manufacturing plants), at a scale that could support the US population, significant capital over many years will be required. As these facilities will need to compete with already depreciated plants in India and China, they will not be attractive to most institutional investors. Especially for critical drugs that are often generic and of very low value, there simply will not be a compelling reason to invest, even though these medicines are often lifesaving. Thus, involvement from the US government will be necessary.

- Reimbursement Schemes. Incentivizing companies (e.g., insurance companies) to purchase drugs made in America through various means, such as preferential reimbursement from Medicare/Medicaid, would also enable reshoring efforts.
- Offtake Contracts. For low value, but critical, drugs, offtake contracts from the US Government would encourage their manufacturing by pharmaceutical companies. Without these contracts, companies will not be able to afford the risk associated with developing manufacturing processes for them.

A Unique Opportunity
As large pharmaceutical companies are currently looking to establish manufacturing capacity in the US, as a result of recent trade/tax maneuvers by the federal government, **an opportunity exists to advance the standard of pharmaceutical manufacturing in the United States, while establishing this critical capacity**. This can be done by offering incentives for these companies to utilize advanced technologies, such as ICM, when they build their production plants in the US. In this way, American-based pharmaceutical manufacturing facilities will be utilizing the best and most cost- and time-effective technologies to compete with and win against the current frontrunners.

I have also included our recent article[1] highlighting the challenges and opportunities of reshoring domestic production which was published in Pharma's Almanac that aligns closely with the work you have been doing on this topic and I believe is relevant to the hearing today.

Sincerely,
Salvatore Mascia, Founder & CEO
CONTINUUS Pharmaceuticals

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[1] https://www.pharmasalmanac.com/articles/enabling-the-reshoring-of-pharma-manufacturing-with-integrated-continuous-manufacturing


Enabling the Reshoring of
Pharma Manufacturing with
Integrated Continuous
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A Fragile Supply Chain Built on Foreign Dependence

Concerns over the pharmaceutical industry's dependence on foreign suppliers for key starting materials (KSMs), active pharmaceutical ingredients (APIs), and even finished drug forms (FDFs) began surfacing nearly two decades ago. As governments in emerging markets — especially China and India — invested heavily in scaling up pharmaceutical manufacturing, Western companies increasingly outsourced production to take advantage of lower labor costs and looser environmental regulations.

As a result, domestic manufacturing capacity and institutional expertise in the United States and Europe steadily declined. The global pharmaceutical supply chain became increasingly fragmented and complex, leading to a host of practical benefits, as well as vulnerability to disruption. Today, approximately and used in the United States are sourced from overseas — with China and India being major suppliers. From a strategic, quality, and geopolitical perspective, this concentration of sourcing poses greater risk than reliance on countries with stronger regulatory alignment and shared oversight norms, such as Switzerland. This dependency has contributed to recurring drug shortages, often triggered by quality or compliance issues at offshore facilities.

While some industry stakeholders recognized the strategic risk this posed to both national security and public health, the issue gained sporadic attention and little traction until the COVID-19 pandemic. Suddenly, the dangers of an overextended, foreign-reliant supply chain were thrust into sharp relief. As global logistics faltered and critical medications became scarce, the conversation around reshoring pharmaceutical manufacturing gained unprecedented urgency.

CONTINUUS Pharmaceuticals was founded in 2012 to address precisely this challenge. The company set out to develop a fully integrated, end-to-end

continuous manufacturing platform for small molecule drugs — one capable of streamlining production, reducing costs, and accelerating time to market. Over the ensuing decade, CONTINUUS made steady progress, laying the groundwork for a solution that could reshape how drugs are made and delivered.

The pandemic served as a tipping point, not only underscoring the fragility of the status quo but also sparking renewed government interest in domestic manufacturing resilience. Federal investments were made to support advanced manufacturing initiatives and bolster supply chain security. However, political turnover and shifting priorities have slowed momentum, and many of the structural issues remain unresolved. While pharmaceutical companies are now being urged — or in some cases pressured — to bring manufacturing back onshore, achieving that goal will require more than relocation. It will demand a fundamental rethinking of how drugs are made.

Real Reshoring is Dependent on Innovation

The call to reshore pharmaceutical manufacturing is well-founded — but simply returning legacy processes to domestic facilities will not solve the problem. There is a reason drug production migrated overseas in the first place: dramatically lower labor costs, less stringent environmental regulations, and efficiencies that made outsourcing the default economic choice. Replicating those same batch-based processes in the United States or Europe would only reintroduce their inefficiencies — at a higher cost.

True reshoring requires reimagining how drugs are manufactured. Without innovation, bringing production back risks becoming unsustainable, economically nonviable, and environmentally burdensome. New technologies and manufacturing paradigms must be adopted to ensure that domestic drug production can be cost-competitive, scalable, resilient, and environmentally sustainable.

This shift will not happen overnight. The pharmaceutical supply chain's reliance on overseas production was the result of decades of investment in manufacturing infrastructure and government intervention and sponsorship in countries like China and India. Reversing that trend will require sustained effort — and political will — on longer timescales that extend beyond shorter-term

initiatives. Achieving a reshored, secure pharmaceutical supply chain at meaningful scale demands long-term commitment, cross-sector collaboration, and regulatory alignment.

CONTINUUS Pharmaceuticals has been pursuing this vision for over 10 years. From the outset, the company recognized that meaningful change would require more than automation or digital overlays to existing systems. That's why we developed the Integrated Continuous Manufacturing (ICM) platform — a ground-up redesign of small molecule drug production built for efficiency, quality, and scalability. Building such a system involves more than just engineering innovation. Every element must be designed, fabricated, tested, and validated in full compliance with current Good Manufacturing Practices (cGMP). It is a rigorous, multi-year process, but one that yields a manufacturing platform ready to support a new era of domestic pharmaceutical production.

A New Blueprint for Continuous Manufacturing

CONTINUUS Pharmaceuticals' ICM platform represents a fundamental departure from conventional approaches to small molecule drug production. Unlike most systems that attempt to establish continuity by simply linking existing batch-based unit operations into connected systems, the ICM platform was built from the ground up. Each unit operation was redesigned to operate seamlessly as part of a fully integrated, end-to-end continuous process.

This distinction is critical. True continuous manufacturing is not just about running isolated steps in a nonstop fashion; it's about integration. Without that, you may still be operating in a fundamentally batch-oriented paradigm, with all the inefficiencies and delays that come with it. The power of the ICM platform lies in its holistic design, which eliminates the gaps between upstream and downstream processes, enabling a fluid, uninterrupted flow from starting materials to finished drug product.

Integration unlocks the full promise of continuous manufacturing: faster production, greater efficiency, lower costs, and improved quality control. The CONTINUUS ICM platform can operate on a 24-hour basis, dramatically reducing manufacturing footprint, minimizing downtime, and enhancing process control. By combining novel technologies with a fully integrated design, CONTINUUS delivers a

manufacturing paradigm that is not only faster and leaner but also more agile, scalable, sustainable, and future-ready.

Breaking Through Resistance to Innovation

The pharmaceutical industry exists in a paradox. It is propelled by scientific innovation and discovery, yet often cautious — even resistant — when it comes to adopting new manufacturing technologies. This conservatism is rooted in a deeply ingrained commitment to patient safety and regulatory compliance. As a result, even well-proven advancements like continuous manufacturing, widely embraced in other sectors, have faced slow adoption in drug production.

Much of this hesitation stems from perception rather than reality. Novel systems like CONTINUUS Pharmaceuticals' ICM platform inevitably raise questions: about qualification, validation, cleanability, and above all, regulatory acceptance. For many companies, the perceived risk of being first to adopt an unfamiliar technology outweighs the potential benefits. Yet without early adopters, systemic change remains elusive.

Fortunately, regulatory agencies have evolved in tandem with technology. Over the past decade, the U.S. Food and Drug Administration (FDA) has become a vocal advocate for continuous processing. The FDA's Emerging Technology Team (ETT) was established specifically to support companies adopting novel manufacturing platforms, providing early guidance to ease regulatory navigation. More recently, the Advanced Manufacturing Technologies (AMT) Designation Program was introduced to formalize and accelerate approvals for drugs produced using innovative, pre-vetted platforms.

The FDA has published data showing that continuous manufacturing applications receive faster reviews on average than traditional batch processes, thanks to established frameworks like ETT. These efficiencies are underpinned by the inherent quality advantages of continuous manufacturing, including real-time monitoring, better process control, and fully contained systems that minimize contamination risk.

The challenge now is no longer technological; it's cultural. With regulatory support in place and the advantages clearly demonstrated, the next step is overcoming

industry inertia and making bold moves toward a more modern, resilient manufacturing model.

The Payoff of Integrated Continuous Manufacturing: Speed, Quality, Cost, and Sustainability

Shifting from traditional batch manufacturing to a fully integrated, end-to-end continuous process delivers transformative advantages across four critical dimensions: speed, quality, cost, and sustainability.

Continuous processes dramatically accelerate production timelines. What once took months — or even years — can now be completed in a matter of days. This acceleration is not just theoretical; it has been demonstrated across multiple stages of the drug life cycle, from development through commercial manufacturing.

Cost reductions follow naturally. The equipment and facility footprint for an ICM-based production suite is significantly smaller than that of a traditional batch operation. Fewer unit operations, higher process efficiency, and improved yields mean less starting material is required, purification steps are streamlined, and waste generation is minimized. These efficiencies translate to lower operating costs while maintaining, if not exceeding, product quality.

Quality, in fact, is where continuous manufacturing offers some of its most compelling benefits. With real-time monitoring and control at every step, continuous systems operate in a state-of-control and can immediately detect and correct deviations. This level of process control ensures greater consistency and purity, while reducing the need for post-production testing and rework.

Sustainability is an increasingly vital metric, and continuous manufacturing delivers here as well. ICM systems consume less energy and water, use solvents more efficiently (both in processing and cleaning), and produce fewer emissions. The carbon footprint of a continuous plant can be three to four times lower than a comparable batch facility, making it a powerful tool in advancing both environmental and ESG goals.

The primary barrier remains capital expenditure (CapEx). Building and installing a new ICM system requires upfront investment, which can pose a challenge, especially for generic manufacturers with narrow margins and contract development and manufacturing organizations (CDMOs). However, the longer-term payoff is compelling. For new facilities, the required CapEx for an ICM-based suite is approximately half that of a comparable batch operation. This lower cost structure, combined with faster timelines and superior performance, makes the platform especially well-suited to greenfield projects and the launch of new-to-market drugs, as well as future-proofing for the manufacture of existing products.

Even so, public investment plays an important enabling role. Government financing to offset the initial buildout can serve as a critical accelerant, helping companies reshore not just facilities, but the future of pharmaceutical manufacturing itself.

Innovation Favors the Bold—and the Well-Funded

Across the pharmaceutical industry, there is growing consensus on the benefits of continuous manufacturing. But recognizing the advantages and taking the leap are two very different things. Transitioning from an entrenched batch process to a cutting-edge continuous platform requires a significant shift: in capital investment, mindset, and operational design.

So, who is best positioned to make that move?

Generic manufacturers are often laser-focused on keeping costs low while maintaining acceptable quality. Their tight margins and follow-the-leader business model make them unlikely to be first adopters of high-CapEx innovations like ICM. This is especially true for low-margin, yet essential generic drugs that are critical to public health but lack the return on investment needed to attract sustained private-sector interest. For these indispensable but economically unattractive products, government intervention may be required to ensure continued domestic production. Without it, the market alone may not support reshoring, regardless of technological innovation.

CDMOs, while increasingly vital to the industry's global supply chain, tend to follow the priorities of their clients. Since they rarely own the regulatory filings for the products they make, CDMOs are generally not in a position to take the lead on

adopting disruptive manufacturing technologies, unless their pharma partners explicitly ask for it.

It is branded pharmaceutical companies, particularly those with deep pipelines, broad portfolios, and longer investment horizons, that are leading the charge. These companies have the resources and strategic incentive to build new facilities around continuous platforms. They also benefit most from the ability to accelerate development, secure supply chains, and reduce environmental impact — all while maintaining control over sensitive intellectual property and product quality.

As more ICM systems are installed and demonstrate measurable success, CDMOs will be next to follow, eager to support their pharma clients with faster, more cost-effective solutions. Generics will eventually join the wave, likely once off-patent products originally produced on ICM platforms require replication. But for now, the reshaping of pharma manufacturing is being spearheaded by innovators with the vision, and the capital, to make the first move.

Policy and Investment Must Match Innovation

While regulatory agencies are already proponents of continuous processing, they are continuing to take further steps to support the wider transition from batch to continuous manufacturing that is needed to galvanize significant reshoring of drug production to the United States and Europe. This active regulatory support for innovative technologies like CONTINUUS' ICM platform — supported further by evolving governmental interest outside of regulatory agencies — will help to ensure such solutions are not perceived as too risky.

Financial support for installation of ICM systems by not only big pharma, but also small and emerging companies bringing novel therapies to market, is also needed to strengthen domestic pharmaceutical manufacturing capabilities. The combination of financing and an established regulatory framework are essential to supporting measurable reshoring of drug production.

Regulatory agencies, particularly the FDA, have taken important steps to promote continuous manufacturing: programs like the FDA's ETT and the AMT Designation are helping to facilitate and promote broader adoption of novel platforms like CONTINUUS Pharmaceuticals' ICM system. This helps ensure that advanced

technologies are seen as reliable, approvable, and scalable to overcoming industry inertia.

Equally important is financial support. Even with its long-term economic advantages, the upfront CapEx required to build and validate an ICM-based facility can be a barrier, particularly for small and emerging companies developing novel therapies. Public investment, whether through direct funding or loan guarantees, can play a pivotal role in enabling these companies to invest in both domestic production and transformative technology. Supporting large pharmaceutical firms alone will not be enough to secure resilient, diversified manufacturing capacity.

To incentivize end-to-end domestic production, U.S. reimbursement models should be updated to recognize and reward manufacturers that use domestically sourced processes and components. This could include mechanisms such as pricing differentials, procurement preferences, or eligibility for federal contracts. Without aligning reimbursement incentives with supply chain resilience goals, the economic case for reshoring, particularly for high-volume, low-margin products, may remain too weak to drive widespread industry change.

Encouragingly, Congress is increasingly recognizing the urgency of strengthening domestic pharmaceutical manufacturing, not just as an economic issue but as a national security imperative. Lawmakers from both parties, including Senators Elizabeth Warren and Tom Cotton, have highlighted the risks of U.S. dependence on foreign drug and API suppliers, especially in the context of defense readiness. This bipartisan concern is beginning to translate into action, including support for innovative FDA initiatives that could accelerate reshoring. One promising example is a recently announced priority review voucher program, which, while still under development, could potentially be applied not only to full drug applications but also to CMC packages that meet specific criteria, such as bolstering domestic manufacturing capacity.

Although the operational details of the voucher program remain sparse, its early framing is encouraging. Notably, one of the criteria outlined — “increasing domestic drug manufacturing as a national security issue” — aligns directly with reshoring initiatives like the ICM platform. If properly implemented, this kind of regulatory prioritization could become a powerful lever for incentivizing investment in advanced domestic production. However, it will also demand significant

resources within the FDA and careful oversight to avoid politicization or unintended delays in other review pathways.

Reshoring drug substance (API) and drug product manufacturing is only part of the equation. A truly secure pharmaceutical supply chain must also encompass KSMs and other key ingredients. While many of these materials are technically simpler to produce than multi-step APIs, relying on overseas sources still introduces vulnerabilities, particularly when supply chains are concentrated or poorly diversified. Without meaningful domestic capacity for upstream inputs, geographic risk can persist in different parts of the value chain.

Ultimately, it will take more than innovation alone to solve the reshoring challenge. The combination of proactive regulatory alignment, strategic financial support, modernized reimbursement schemes that reward domestic production, and full-spectrum supply chain planning is necessary to restore pharmaceutical sovereignty and resilience in the West.

Reshoring Is a National Health Imperative

The continued reliance of the United States and Europe on China and India for the supply of KSMs, APIs, and FDFs has created a persistent vulnerability in global healthcare systems. Whether the next disruption comes in the form of a pandemic, geopolitical conflict, or economic leverage, the risk to patient access and public health is real — and growing.

This is not a hypothetical concern. It is a strategic failure decades in the making. Today, the consequences are clear: nearly every citizen in the United States and Europe depends, in some way, on foreign-produced medicines that may not be reliably available in a crisis.

Addressing this problem will require more than political rhetoric. It demands a sustained, coordinated, and forward-looking effort across sectors and administrations. Reshoring must be seen not just as an economic initiative or a geopolitical countermeasure but as a matter of national health security.

But it cannot be reshoring as usual. Attempting to replicate traditional manufacturing models domestically will only reproduce their inefficiencies at a higher cost. The only viable path forward is reshoring with innovation—

leveraging new technologies like ICM to create a domestic pharmaceutical infrastructure that is faster, more flexible, more sustainable, and ultimately more resilient.

The journey will be long. But the critical steps must be taken now to ensure a secure and resilient future.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

STATEMENTS FOR THE RECORD

Doctors For America Statement

Statement for the Record: Doctors for America FDA Task Force
Senate Special Committee on Aging Hearing
"Bad Medicine: Closing Loopholes that Kill American Patients"
October 8, 2025

Thank you, Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Senate Special Committee on Aging, for allowing Doctors for America's (DFA) FDA Task Force to submit comments for the record regarding ongoing drug shortages. We appreciate your consideration of this important topic at this critical time.

DFA mobilizes doctors and medical trainees to be leaders in putting patients over politics to improve the health of our patients, communities, and nation. We represent over 40,000 physicians and medical students in all 50 states, in all areas of specialization. As a medical advocacy organization, DFA's main purpose is to promote the best evidence-based, scientifically proven, compassionate medical care on an equitable basis to all Americans. Access to effective and safe pharmaceuticals is at the core of our capacity to serve, help, and treat.

As you are aware, prescription medicine shortages have been a chronic, ongoing problem noted by Congress as well as well-documented and researched. The American Society of Health-System Pharmacists (ASHP) currently lists nearly 200 drugs on its shortage list, some for as long as ten years. As physicians, we have witnessed firsthand the devastating impact widespread drug shortages have on patients, which is why we are urging lawmakers to examine the appropriate reforms to address drug shortages.

Physicians' ability to treat patients effectively and in a timely manner depends on a secure and stable supply of essential medicines. Every day, physicians are forced to make difficult decisions because of shortages of treatments ranging from antibiotics to cancer therapies, often without any reliable information about the expected nature or duration of the shortage. This constant uncertainty can jeopardize patient safety, delay treatment, and increase overall health care costs.

Congress should take decisive action to modernize and secure the domestic pharmaceutical supply chain by directing the U.S. Department of Health and Human Services (HHS) to update its Essential Medicines List and establish a database that maps the pharmaceutical supply chain, including essential medicines, ingredient sources, manufacturing locations, and associated risk factors. This information will allow HHS to better predict future supply interruptions, helping to combat drug shortages and increase resiliency and readiness.

Additionally, the FDA Task Force urges policymakers to consider supplemental legislation to expand FDA's authorities so that it can competently monitor, inspect, and intervene in the supply system for all pharmaceuticals, which after all, are often life-saving necessities.

In particular, we urge you to consider FDA's legislative proposal to require companies to provide data identifying the suppliers they use for their products, which the agency has said will help them to identify potential shortages earlier. This is something the administration has raised as well as indicated by several recent executive orders aimed at ensuring FDA and HHS have the capacity and authorities necessary to appropriately monitor essential medicines and pharmaceutical ingredients.

Progress on drug shortages cannot proceed without addressing the most common cause of shortages, manufacturing issues, both in the U.S. and abroad. As the FDA notes in its legislative proposal, unreliable data is often not detected until after marketing authorization or distribution of a non-medical product. The shortage of trained inspectors has been a chronic issue and has become increasingly severe since the end of the pandemic. Congress can make the case for an adequate number of inspectors while current PDUFA negotiations are in the early phase.

Thank you for this opportunity to submit this statement for the record. Doctors for America's FDA Task Force looks forward to continuing to work with Congress to identify ways to tackle drug shortages, protect our patients' health, and strengthen our nation's resilience and security. We also look forward to being a resource to this Committee and supporting your work to reach these urgent objectives.

U.S. SENATE SPECIAL COMMITTEE ON AGING

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OCTOBER 8, 2025

STATEMENTS FOR THE RECORD

Lupin Statement

Lupin Statement – Advancing U.S. Medicine Security and Reshoring Essential Medicines
Medicine security is National Security.

Lupin is the 3rd largest U.S. generic pharmaceutical company by prescription volume and one of the world's leading producers of affordable medicines, operating across more than 100 markets and employs thousands of professionals worldwide.

As a vertically integrated global company with headquartered in Naples, Florida, Lupin is committed to reducing America's dependence on China for critical pharmaceutical ingredients and ensuring a diversified, reliable supply chain that supports both U.S. patients and the nation's defense readiness. Lupin's U.S. presence includes advanced N.J. and Fl. R&D centers, manufacturing, and supply-chain operations focused on strengthening America's access to safe, quality, and affordable medicines.

Lupin: A Trusted Partner in Federal Medicine-Security Initiatives. Lupin has been an active participant in the federal government's medicine-security initiatives, aligning with security goals to rebuild resilience and de-risk from China. The company has engaged collaboratively through the U.S. Department of State's TRUST Initiative 1.5 discussions, filed ASPR-led national-security offer of engagement, and has collaborated with the Administration on specific reshoring proposals and concepts to advance practical pathways to drive reshoring and supply chain resilience. Lupin asserts that generic medicine reshoring must be built on strong public-private partnerships—supported by targeted incentives and accompanied by reforms to ongoing, untoward. U.S. market dynamics, particularly the distortions created by middlemen, such as GPOs and PBMs, that undermine fair generic procurement and sustainable domestic manufacturing.

Reshoring in Action: Building New Manufacturing Capacity in Florida. Lupin has been working with the State of Florida to construct a state-of-the-art inhalation manufacturing facility in Coral Springs, Florida. This facility is designed to reshore critical, essential medicines, expand U.S. manufacturing, and partner with the government to ensure that patients, families, and our armed forces have secure access to the medicines they depend on every day. It's anticipated that the *new manufacturing facility will create high wage jobs, produce 25 percent of all U.S. albuterol inhalers - a medicine on the FDA Essential Medicines List that has faced repeated shortages over the years; and manufacture 25 additional high-priority respiratory therapies essential for U.S. health and preparedness*. By expanding domestic production of critical inhalers, Lupin is working to ensure that patients—from children with asthma to U.S. soldiers in the field—have reliable access to lifesaving medicines.

Lupin is all in on America's medicine-national security mission. As a vertically integrated global manufacturer with deep U.S. roots, Lupin is investing heavily to reshore critical medicines, build advanced manufacturing capacity, and reduce dependence on China.

But success requires a true public-private partnership. Reshoring essential generic medicines cannot rely solely on individual company investments, it must be supported by federal and state incentives, procurement guarantees, and regulatory streamlining.

At the same time, sustainability demands that Congress address the **distorted U.S. market dynamics** driven by **GPOs and PBMs**, whose concentrated purchasing power has pushed prices to unsustainable levels, undermining domestic manufacturing viability and contributing to shortages.

A lasting solution should include:

- **Avoid tariffing generic medicines**, allowing companies to reinvest those funds directly into reshoring manufacturing instead of being punished with a counterproductive tax burden
- Treat essential generic medicines as **critical national-security defense asset**s
- Establish **multi-year purchasing and stockpiling commitments** to guarantee utilization and surge capacity for generics
- Provide **targeted tax incentives, cost-share grants, and tariff relief** for inputs from trusted allies and partners
- Reform U.S. generic procurement pricing structures so that companies investing in U.S. production are not penalized for doing the right thing.

Lupin is ready to partner—with Congress, the Administration, and the states —to drive policy and production, to de-risk the supply chain, and to secure America's affordable-medicine future.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

STATEMENTS FOR THE RECORD

Lupin - Coral Springs, FL Statement

Lupin Announces Plans for a New Pharmaceutical Facility to Be Constructed in Coral Springs, Advancing Florida Employment Opportunities and U.S. Medicine Security

Furthering U.S.- based pharmaceutical capacity in Coral Springs, to produce critical respiratory medicines while supporting 1,000+ construction jobs and over 200 long-term, skilled jobs.

Media Contact
Elise Titan, Director, U.S. Communications, Pharma
Email: Elisetitan@lupin.com

FOR IMMEDIATE RELEASE

CORAL SPRINGS, Fla., [October 8, 2025] - Global pharmaceutical leader Lupin today announced its plans for a new pharmaceutical manufacturing plant in Coral Springs, a significant step in safeguarding the health and safety of Florida families and the nation. With a projected cumulative investment of $250 million, including research & development, infrastructure and capital expenditures over a five-year period, the new site will have the capacity to accommodate the production of more than 25 critical respiratory medicines, including lifesaving albuterol inhalers for children with asthma and service members at home and overseas. By strengthening domestic manufacturing and enhancing supply chain diversification, this critical project will enhance medicine security and generate over 200 new long-term, skilled jobs by 2030 in Broward County.

"On behalf of FloridaCommerce, I'm excited to welcome Lupin's expansion in Coral Springs and the high-impact investment it brings to our state," said Florida Secretary of Commerce J. Alex Kelly. "Thanks to Governor DeSantis' leadership, Florida has built a strong foundation for growth—with a strong focus on research and development, nine consecutive years as the #1 state for postsecondary education and three consecutive years as the #1 state for talent development, Florida has become #2 in the nation for both pharmaceutical and medical device manufacturing. Lupin's investment will strengthen Florida's position as a leader in life sciences, boost our advanced manufacturing capabilities and enhance the state's medicine security—delivering long-term benefits to both our economy and the health of Floridians."

"Congratulations, Lupin, on your expansion in Coral Springs. This significant investment and job growth reinforces the strength of pharmaceutical manufacturing as an important targeted industry in Greater Fort Lauderdale/Broward County. Our community offers the strong talent pool life sciences companies require and the attractive quality of life skilled workers seek," said Bob Swindell, President/CEO of the Greater Fort Lauderdale Alliance.

"In Coral Springs, we're pairing innovation with American manufacturing. This new state-of-the-art facility will scale albuterol inhalers and other critical respiratory medicines and will build on our existing presence in Florida, which is home to Lupin's headquarters and our Advanced

Inhalation Research Center. As a trusted partner, it is of paramount importance to Lupin to continue to strengthen America's medicine security and ensure patients have reliable access to affordable medicines," said Christoph Funke, Chief Technical Operations Officer, Lupin.

This life-sciences project drives STEM jobs, innovation, and medicine security. The Coral Springs facility will anchor U.S. production of critical respiratory therapies, diversify the supply chain, and ensure affordable, reliable access—from routine pediatric care to pandemic-scale demand.

In recognition of its investment and job creation plans, Lupin will receive tax credits and incentives from the state of Florida. Lupin is partnering with Florida Commerce/Select Florida; City of Coral Springs; Greater Fort Lauderdale Alliance; Broward County Commission as part of this strategic project.

About Lupin
Lupin Limited (BSE:500257) (NSE: LUPIN) (REUTERS: LUPIN.BO) (BLOOMBERG: LPCIN) Lupin Limited is a global pharmaceutical leader with products in over 100 markets and a strong U.S. footprint in respiratory care and complex generics. With its U.S. headquarters in Naples, Florida the company operates 15 manufacturing sites and 7 research centers globally and employs more than 24,000 professionals.

To learn more, visit www.lupin.com or follow us on LinkedIn

U.S. SENATE SPECIAL COMMITTEE ON AGING

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OCTOBER 8, 2025

STATEMENTS FOR THE RECORD

National Taxpayers Union Statement

NATIONAL TAXPAYERS UNION

122 C Street N.W., Suite 700, Washington, DC 20001

October 8, 2025

The Honorable Rick Scott, Chairman
The Honorable Kirsten Gillibrand, Ranking Member
Special Committee on Aging
United States Senate
G16 Dirksen Senate Office Building
Washington, DC 20510

Dear Chair Scott, Ranking Member Gillibrand, and Members of the Committee:

On behalf of National Taxpayers Union (NTU), America's oldest national-level taxpayer advocacy organization, I write to offer comments for the record regarding the Committee's hearing today entitled "Bad Medicine: Closing Loopholes that Kill American Patients." Having reviewed the proceedings of a previous September Committee hearing, "Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans," NTU humbly believes that the taxpayers' perspective might prove useful in Congress's deliberations going forward.

Introduction

For most of NTU's 55-year history, our team has analyzed and provided commentary on important questions surrounding the fiscal impact of federal legislation and regulations on the health space. We have noted with great concern the decades-long cost spiral in federal health care programs, which has seemed to defy attempts at reducing or at least controlling the burden on current and future taxpayers.[1]

To NTU, it is evident that innovative approaches to reducing health care costs must continue to be explored and implemented, to reorient this unsustainable trajectory toward a more realistic and affordable direction. We believe that thoughtful deployment of prescription drugs (both branded and generic/biosimilar) in more settings, as longer-term alternatives to costlier treatments, can be a vital part of this necessary exercise.[2] For this reason, we believe the Committee should carefully deliberate the impact of public sector policies—not just private sector processes—on drug safety and patients' well-being. Accordingly, we offer the following observations.

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[1] See, for example, the Congressional Budget Office report on the growth of Medicare and Medicaid costs at: https://www.cbo.gov/publication/60127.

[2] For further analysis of how branded and generic prescription drugs can have a salutary effect on the cost trajectories of taxpayer-funded health care programs, see the lengthy NTU analysis at: How Much is Medicine Worth to the American Taxpayer? A Cost-Benefit Analysis - Publications - National Taxpayers Union.

Comments

Counterfeit medicines can and do enter the United States; government policies intended to "do something" about prices, such as drug importation and tariffs, can actually contribute to the problem and cost taxpayers significantly.

For many years, NTU has warned that proposals to allow importation of prescription drugs from abroad carry fiscal—not just health—risks because of their potential to allow counterfeit medicines into the U.S. Seven states—ranging from Colorado to Vermont—have attempted to craft regimes relying on Canadian drug importation, with Florida's program being the most prominent owing to the size of its market. The following perspective published last year from the firm of Ropes and Gray neatly summarizes the fiscal concerns today over importation policies at the federal and state levels:

> [T]here is ample skepticism that drug importation programs will ever reach the size or scope to result in meaningful savings. Further, the supply chain may have other new costs on account of any importation program – including greater administrative costs in administering a state-based program and in addressing safety risks related to counterfeit or misbranded products, as well as compliance costs associated with new regulatory requirements. Further, and significantly, drug importation could lower manufacturer revenue or otherwise have a chilling effect on incentives to pursue research and development of new or improved versions of drugs. The Congressional Budget Office estimates that reductions in revenue to manufacturers as a result of the program would lead to cuts in research and development that would cause approximately eight fewer new drugs to be introduced to the U.S. market over the next 10 years and roughly 30 fewer drugs over the following decade.[3]

For many years, NTU has also warned that the complexities of ensuring patient safety from imported medications, particularly branded drugs, mean heavy costs to taxpayers. A 2018 letter from NTU to the Utah Legislature, which was considering importation at the time, provides a more detailed explanation:

> Ensuring consumer safety likewise carries a considerable financial burden to government agencies, and therefore taxpayers. In 2004, a [U.S] Department of Health and Human Services report estimated that approximately 10 million packages entered the United States with imported prescription drug products; developing a federal regime to screen all these packages for safety would add up to nearly $3 billion—or approximately the total potential savings from an importation regime, according to the Congressional Budget Office (CBO). It would be a mistake to assume that some 15 years later, improvements in tracking, testing, and monitoring shipments have erased these costs. The significant outlays necessary to preserve the integrity of the pharmaceutical supply chain – especially due to the proliferation of counterfeit Internet pharmacies – could still easily overwhelm whatever price breaks drug importation could produce nationwide or in Utah. Policing transshipments that might be sent from Canada but actually manufactured elsewhere would remain difficult. Interestingly, not even the association representing U.S. pharmaceutical wholesalers, some of whose members would presumably benefit by the contracted portion of the proposed Utah program, has endorsed importation.
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> We would also note that the net impact of importation on consumers – and in the case of Utah's Medicaid and state employee insurance programs, taxpayers – remains uncertain, despite being

[3] For the full analysis, see: 20240227_FDA_Article.pdf.

> informed by other states' generally negative experiences. Illinois, for example, terminated its importation program in 2008 after fewer than 4,000 residents availed themselves of the services. More recently, in December 2018, importation advocates hailed a report from Vermont's Agency of Human Services (AHS) which claimed that a wholesale Canadian-oriented importation regime there could allow commercial insurers to "see savings of between $1-5 million dollars." Yet, that same report also noted that administration of such a program "would likely come at substantial cost to the state, requiring upfront investment and appropriations." . . . On the question of whether the benefits of a potential Vermont importation program would outweigh its costs, AHS demurred.[4]

We believe that, if the Committee is to honestly explore the question of risks to patients from ingredients and medications from abroad, it must first recognize federal and state governments' role in promoting policies that add to the task of policing supply chains.

Private companies and taxpaying families already pay for government drug safety functions; are they getting the value they deserve?

The safety of prescription drugs should be a paramount concern not only to patients and policymakers, but to taxpayers as well. Aside from the human suffering that results from unsafe medicines, the financial toll of remediation for those affected can be heavy. Patient injuries in government-funded health care programs make heavier the burdens taxpayers must already bear for treatments, while the salutary effects of authentic medications in driving down expensive hospital stays, surgeries, and other treatments are diminished as patients are unable or unwilling to access them.

Here again, however, NTU believes that even as the Committee looks to the private sector for answers on patient safety of medications, it should be asking hard questions of the public sector as well. As a recent example, some controversy has arisen over the safety and efficacy of Anti-Obesity Medications (AOMs), with a focus on the practices of certain compounding pharmacies. According to an analysis of FDA and other data conducted by the Partnership for Safe Medicines (a business coalition) and the former Director of the Food and Drug Administration's (FDA's) Criminal Investigations Division, 2,465 bulk foreign shipments of semaglutide or tirzepatide entered the U.S. for inspection between September 2023 and January 2025. Of these, 239 came from entities that were not registered in advance with FDA, and from that number 195 "were allowed into the U.S. despite clear legal prohibitions."[5] How did this happen, despite industry- and taxpayer-funded government safety procedures? Committee members deserve answers.

We hasten to add that, under the User Fee Agreements that prescription drug, generic drug, medical device, and other businesses conclude with the FDA, the private sector effectively pays billions to the government to be regulated, accounting for up to half of FDA's budget.[6] The value the private sector receives from these payments is diminished when activities such as import inspections or inspections in facilities abroad that export to the U.S. fall by FDA's wayside.

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[4] See the full letter at: Open-Letter-On-Importation-Legislation.pdf

[5] For further details, see: New report reveals illegal ingredients for knockoff weight loss drugs flooding into U.S. from foreign sources, endangering patient safety – Partnership for Safe Medicines.

[6] For background, see: FDA User Fees: Examining Changes in Medical Product Development and Economic Benefits - NCBI Bookshelf; and FDA Human Medical Product User Fee Programs | Congress.gov | Library of Congress.

The Generic Drug User Fee Agreements (GDUFA) were first launched in 2012 after a highly consultative process, during which, not only patient and government concerns were heard, but also those from the industry itself. While U.S. generic companies sought more predictable and expedited pathways to product approval in exchange for paying fees, they also called for resources collected from them to be expended on more facility inspections, especially abroad. The current iteration of GDUFA agreements are so detailed as to provide for education of foreign regulators on how U.S. inspections of generic manufacturing and API production facilities outside the country would occur.[7] The federal government has articulated its own specific benchmarks under GDUFA, and has regularly reported on them. NTU believes that, if patient safety problems are occurring despite these measures, FDA and other federal entities should be able to provide technical evaluations of where and how inspections can be improved.

Inspections have risen since GDUFA, now in its third round, but, as with other User Fee Agreements concluded with industry for branded prescription drugs, medical devices, and other areas, it is vital for the legislative branch to exercise its oversight function regarding the value received for the fees that are paid. Taxpayers, whose general fund contributions also provide resources for medical product regulation, deserve this level of accountability from government as well. In the case of these User Fee Agreements, such oversight should not be the sole province of one committee whose primary jurisdiction is health care or revenue. This Committee has already held two hearings on the topic of drug safety; we would urge the Committee to consider calling witnesses from the FDA and other government entities involved in supply chain safety to testify in future proceedings.

If the goal of the hearing is to discuss onshoring drug supply chains, other policy directions will need to be taken.

At its September 17 hearing, the Committee asked pointed questions of witnesses, particularly those connected with generic and biosimilar manufacturing, about whether their use of foreign Active Pharmaceutical Ingredients (APIs) caused unacceptable patient safety risks with their products. NTU would urge a wider view of the benefits that a diverse supply chain has for the United States. A report released last week from the Competitive Enterprise Institute's Jeremy Nighohossian reminds us of these benefits for pharmaceuticals and those who need them:

> While the US may offshore production and import large quantities, this has tended to allow US manufacturers to focus on producing higher-value products, creating a global trade system where the US is at the top of the value pyramid and imports the basics from less developed manufacturing economies. This is one way in which trade makes everyone better off, through distributing manufacturing efficiently.
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> While the pharmaceutical supply chain shifted to producing more generics in Asia and even many brand drugs in Europe, US employment in pharmaceutical manufacturing actually increased. It is up by about 75,000 jobs since 2011, rising three times as quickly as the US population overall. Since 1987, the employment in pharmaceutical manufacturing has risen twice as fast as the population. People often make the mistake of thinking that increased imports mean fewer jobs for Americans, but it often means just different (and better) jobs. It doesn't always mean more jobs in an industry, either, but it happens more than one would expect.[8]

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[7] For background on GDUFA, see, for example, the following sources: The generic drug user fee amendments: an economic perspective - PMC; Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA) | FDA; and Final-GDUFA-III-Commitment-Letter.pdf.

[8] See the full study at: I. Pharmaceutical - Competitive Enterprise Institute.

Thus, recent proposals to levy massive tariffs on imported medicines may backfire on the American economy and for the branded as well as generic pharmaceutical sector. As Nighohossian further explains:

> Would production shift to the United States, though? And if so, which production? Generic manufacturing is very low margin because it's commodified and simple and highly competitive. A tariff that raises the sales price would tend to put some manufacturers out of business, reduce their competitiveness, and reduce the quantities manufactured. Given the continued competition from abroad, we would expect profits to remain low, and the US would be unlikely to produce more generic products domestically. The only result of the tariffs, all other things being equal, would be increased cost to domestic consumers. How much costs go up will be hard to disentangle from the complicated nature of American health care, where insurance companies and PBMs are negotiating prices and creating delivery networks and also in light of President Trump's developing Most-Favored-Nation drug price policy.[9]

And as NTU has explained elsewhere, the Most Favored Nation pricing proposal is a grave threat to taxpayers, portending far more negative consequences than, for example, a concerted effort to negotiate a NATO-style commitment from other countries to share a greater burden of prescriptions drug spending (especially for innovator drugs) than they currently shoulder.

Overall, we believe the Committee should exercise caution over the tendency to suspect all foreign sources of pharmaceuticals, especially APIs, as a threat to America's security. For instance, generic and biosimilar providers, which are a key component to the U.S.'s unique environment that offers both access and affordability for prescription drugs, depend upon high-quality APIs to manufacture their goods. As NTU explained in comments earlier this year on its Section 232 investigation into pharmaceuticals:

> Raising the costs of certain API imports would erode this trade advantage and impose higher costs on innovator drugs that show up in Medicare, Medicaid, and other taxpayer-supported health programs. Discoveries that could occur here, thereby bending the cost curve over time, will either shift abroad or never occur in the first place. For their part, generic manufacturers already operate on extremely thin margins to remain profitable, even as their sales volumes increase. Tariffs will raise the costs of their inputs as well, perhaps leading some firms to cease operations here.[10]

The United States should avoid imposing high tariffs on prescription drugs, including generic drugs. According to a recent *New England Journal of Medicine* article, "If finalized, the application of pharmaceutical tariffs under Section 232 would upend long-standing trade conventions that have protected medicine imports from tariffs, increase costs for public health care payers, and potentially reduce the availability of important generic medicines in the United States." The report notes that most U.S. generic drug imports originate in India and Europe, and that both regions have undertaken efforts to reduce their reliance on active pharmaceutical ingredients provided by China.[11] New tariffs on generic drugs with low profit margins would increase their cost and potentially reduce the supply of generic goods available to compete with higher-priced brand name drugs.

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[9] Ibid.
[10] See the NTU comments at: Section 232 Tariffs on Pharmaceuticals Will Increase Costs and Weaken U.S. National Security - Publications - National Taxpayers Union.
[11] See the study at: The Risks of Pharmaceutical Tariffs for Generic Drug Availability | New England Journal of Medicine.

Compulsory licensing and attempts on the part of other countries to obtain Trade-Related Aspects of Intellectual Property Rights (TRIPs) waivers are yet another way that markets abroad attempt to benefit financially from U.S. discoveries. As NTU has explained before, such schemes, if U.S. leaders allow them to proliferate further, will damage America's standing as the strongest economic and health care innovator in the world.[12] *These are very real threats to our national security.*

If onshoring is to occur in an organic manner that creates a net gain for Americans, sound tax policy is the best position from which to begin. The provisions in comprehensive legislation President Trump signed into law in July are ideal in this regard, by making permanent the full and immediate expensing, research and development expensing, and 163J interest provisions permanent, as well as strengthening the Foreign-Derived Intangible Income provisions. Pharmaceutical manufacturers of all types have responded positively to these policies with tens of billions of dollars in new U.S. investment commitments. When combined with streamlined drug approval processes, new pilot programs to strengthen pharmaceutical affordability programs, and recent developments in consumer-driven drug purchase markets, these policies represent a sound approach to putting American patients and taxpayers first.[13]

Conclusion

As NTU has noted many times, no other country in the world can boast of such a successful policy environment that both encourages discoveries to reach patients (nearly 90% of newly launched drugs worldwide are available here) and controls costs (over 90% of prescriptions written in the U.S. are for generics).[14] Indeed, unbranded generics are, on average, about one-third less expensive in the United States than in other countries with significant generic markets.[15] To the extent that branded prices are higher here than abroad, a combination of foreign governments' policies are often contributing to that trend.[16]

This strategic asset of drug access and affordability should be strengthened, not undermined.

Thank you for your consideration of these comments, and, should you have any questions on this or any other fiscal or regulatory matter before USTR, we are at your service.

Sincerely and respectfully,

Pete Sepp, President
National Taxpayers Union

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[12] For further details on TRIPs waivers, see an analysis from NTU's research arm here: Instead of Waiving IP Rights on Innovation, America Should Vaccinate the World - Publications - National Taxpayers Union.
[13] See, for example, NTU's recent work at: Rebate Model Pilot Can Boost 340B's Mission, Reduce Costs - Publications - National Taxpayers Union; and Most Favored Nation Drug Pricing Model Won't Cut Costs for Americans - Publications - National Taxpayers Union/

[14] See NTU's commentary at:
https://www.ntu.org/publications/detail/hatch-waxman-drug-patent-law-meets-middle-age-and-taxpayers-can-celebrate.
[15] For further analysis, see: International Prescription Drug Price Comparisons: Estimates Using 2022 Data | RAND
[16] See, for example: https://www.linkedin.com/pulse/time-end-foreign-free-riding-fix-global-imbalance-k1huf/.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BAD MEDICINE: CLOSING LOOPHOLES THAT KILL AMERICAN PATIENTS"

OCTOBER 8, 2025

STATEMENTS FOR THE RECORD

Teva Statement

TEVA PHARMACEUTICALS

Statement for the Record
United States Senate Special Committee on Aging
Hearing on *"Bad Medicine: Closing Loopholes that Kill American Patients"*
October 8, 2025

The Honorable Rick Scott
Chairman
Special Committee on Aging
U.S. Senate
Washington D.C. 20515

The Honorable Kirsten Gillibrand
Ranking Member
Special Committee on Aging
U.S. Senate
Washington D.C. 20515

Chairman Scott, Ranking Member Gillibrand, and Members of the Committee:

For more than 120 years, Teva's commitment to better health has never wavered. Teva is a leader in generic, biosimilar, and innovative medicines with a portfolio consisting of over 3,500 products in nearly every therapeutic area. Approximately 200 million people around the world take a Teva medicine every day and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with our established presence in generics and biosimilars, we have significant innovative research and operations supporting our growing portfolio of innovative and biopharmaceutical products. **Teva Pharmaceuticals, a leader in generic medicines, stands with you in seeking ways to safeguard, protect and increase access to affordable medications for all Americans.**

TEVA IN THE UNITED STATES

In the U.S., **Teva has over 5,400 employees across seven states (Florida, Mississippi, New Jersey, Ohio, Pennsylvania, Utah, and Virginia).** Today, Teva is the second-largest supplier of medicines to the U.S. by volume. For the U.S. market, Teva manufactures more than 400 generic prescriptions in more than 2,000 dosage strengths and package sizes, including oral solid dosage forms, injectable products, inhaled products, liquids, ointments and creams.

Teva's critical role in the U.S. healthcare ecosystem complements Congress' domestic policy agenda: Teva provides American workers with good manufacturing jobs where they produce safe, effective and affordable medicines for American patients. On the strength of our extensive domestic manufacturing network in states like Florida and Ohio, **Teva produces 1 in 14 of all generic prescriptions Americans take annually. More than three-fourths of those medicines are sold for less than $20.**

MAINTAINING ROBUST MANUFACTURING CAPACITY AND A RESILIENT SUPPLY CHAIN

Over the past 30 years, the generic pharmaceutical industry has consolidated and increasingly offshored its production to countries with lower labor and manufacturing costs in response to low profit margins. Factors that put U.S.-manufactured pharmaceuticals at a competitive disadvantage include foreign government investments, lower offshore operating costs and labor rates, and dependency on offshore sources for raw materials.

In a 'race to the bottom' industry when it comes to price, generic drug manufacturers operate in a market of intense pricing pressure. Over the past few decades, sectors of the healthcare system, including hospital systems, Group Purchasing Organizations (GPOs), wholesalers, and the pharmaceutical industry, have consolidated to achieve efficiencies and increase negotiating power with suppliers and customers. Generic manufacturers have also been negatively impacted by heavy rebating strategies that limit market access opportunities. These rebating policies between the innovator brand companies and pharmacy benefit managers (PBMs) can often block lower-cost generics on public and private managed care contracts.

Teva has the largest supply chain of any pharmaceutical company and our network of about 37,000 employees and 48 global manufacturing sites work around the clock to make sure our medicines reach patients and healthcare systems across 25 countries. Teva's manufacturing facilities outside of the United States are in allied nations such as Bulgaria, Croatia, Germany, Hungary, Ireland, Israel, Lithuania, Netherlands, Poland, Spain, and the United Kingdom.

Unique in the industry, Teva has a robust manufacturing base in the United States and allied countries. **Every single day, American patients take nearly 52 million doses of a generic Teva medicine that is manufactured in the European Union (EU). In fact, Teva produces nearly 65% of the generic medicines sold in the U.S., in the EU – with the remainder of the drugs manufactured in the U.S., Israel and India.** Teva does not manufacture any medicines in China. Teva supports efforts to strengthen supply chains, and a robust pharmaceutical supply chain based in the United States and in U.S.-allied countries is the best avenue to avoid unnecessary disruption to patient care.

Like Teva's sources of finished goods, the company's active pharmaceutical ingredient (API) needs are sourced through a diversified network of suppliers around the world. More than two-thirds of Teva's API is sourced from the European Union and the United States. **Less than 5 percent of Teva's API is sourced from China.** Teva's sources of API stand in stark contrast to the broader industry which, by some estimates, relies on India and China for more than 80 percent of APIs listed in FDA Drug Master Files (50 percent from India and 32 percent from China).[1] **This mix of API sources for Teva products is therefore distinctive and is associated with less risk of the harm that the Committee is exploring related to API from China.**

A closely connected, diverse, high-quality and resilient pharmaceutical supply chain based in the United States and in U.S.-allied countries (such as Canada, Europe, Israel, and Mexico) is the best means to ensure that U.S. patients and the U.S. health care system have access to a secure and consistent supply of critical pharmaceuticals. The U.S. already plays an important role in this supply chain, with generic

[1] United States Pharmacopeia; Global manufacturing capacity for active pharmaceutical ingredients remains concentrated. November 2024. Available: https://qualitymatters.usp.org/global-manufacturing-capacity-active-pharmaceutical-ingredients-remains-concentrated

companies providing more than 52,000 jobs at nearly 150 facilities, and manufacturing more than 60 billion doses of prescription medicines annually.[2]

THE SILENT CRISIS OF THE GENERIC MEDICINE SHORTAGES

In the United States, drug shortages have become a persistent public health issue, negatively impacting patient care and outcomes. In the last decade, the frequency of these shortages has continued to rise, with 271 identified drug shortages by year-end 2024, a significant increase from 185 in 2015.[3] Shortages disproportionately impact generic drugs with generics comprising up to 84% of all ongoing shortages.[4] Of generic drugs, generic sterile injectables (GSIs), which include saline for IVs, life-saving cancer therapies, and essential antibiotics, are particularly vulnerable, with GSIs accounting for 67% of drug shortages in 2023.[5]

Generic drugs are at the core of this problem because of their low cost and because they make up 91% of all medicines prescribed.[6] Despite the high volume, generic drugs only account for 12% of total spending on prescription drugs – a percentage that has declined from 27% in 2015[7] due to a nearly 50% reduction in prices across most product segments. In other words, the volume of generic drugs is steadily rising, but generic manufacturer revenue is decreasing, with an estimated decline of $6.4 billion in revenues over the last 5 years alone.[8] This comes against a backdrop of increased competition, disrupted supply chains, inflation and the U.S. healthcare system's dependency on just three buying groups.

In the last decade, the number of generic manufacturers selling medicines into the U.S. has increased by 50%.[9] Public policy, therefore, has created competitive intensity where the average small molecule drug has around six other competitors on the market[10], but in many product categories, we see 10 to 20 companies competing for market access, making it unsustainable for anybody to earn a return on investment. While such intensity would typically indicate a healthy industry with robust competition, the supply side of this equation is concentrated like in no other Western nations; **in roughly the same period, consolidation among buyers – wholesalers and Group Purchasing Organizations (GPOs) – has concentrated more than 90% of generic drug purchasing into the hands of three principal buying groups, creating a powerful monopsony within the healthcare system.**[11]

Indeed, CVS/Red Oak, McKesson/ClarusONE and Walgreens Boots Alliance not only control the majority of all drug supplies, but they also dictate the conditions under which business must occur. The three customer groups have set up business practices that prioritize the lowest price, which make drug supplies more unstable, and move the entire inventory and supply risk to the manufacturer. They themselves operate on razor thin margins, preventing redundancies and safety stocks from being built for U.S. supplies.

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[2] **A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain. Association for Accessible Medicines. Available April 2020. https://accessiblemeds.org/resources/blog/quickest-route-us-essential-medicines-production-existing-and-idle-production-sites/ Accessed February 24, 2025.**
[3] American Society of Health-System Pharmacists. (2024). Drug shortages statistics.
[4] Senate Committee on Finance. (2024). Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs. Hearing held January 25, 2024.
[5] American Hospital Association. (2024). Drug prices and shortages jeopardize patient access to quality hospital care.
[6] Report: 2022 U.S. Generic and Biosimilar Medicines Savings Report. Association for Accessible Medicines (AAM). https://accessiblemeds.org/resources/reports/2022-savings-report. Accessed June 14, 2023.
[7] Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers. Association for Accessible Medicines (AAM). https://accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf. Accessed June 15, 2023.
[8] The Use of Medicines in the U.S. 2023. IQVIA. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us-2023. Accessed June 29, 2023.
[9] Generic Pharmaceutical Manufacturing in the US - Number of Businesses 2004–2029. IBIS World. https://www.ibisworld.com/industry-statistics/number-of-businesses/generic-pharmaceutical-manufacturing-united-states/. Accessed June 29, 2023
[10] Specialty Pharmaceuticals, Raymond James. February 2021.
[11] AAM Calls Out Threat of Consolidation Among Purchasers. Chloe Kent, Generics.pharmaintelligence.informa.com. Available March 24, 2022. https://generics.pharmaintelligence.informa.com/GB151757/AAM-Calls-Out-Threat-Of-Consolidation-Among-Purchasers. Accessed June 29, 2023.

Today, hundreds of manufacturers are trying to capture one of three contracts for any given molecule. These dynamics have created a hyper-deflationary market that has led not just to a "race to the bottom," but an absolute free fall in certain generic drug prices. As prices have fallen, manufacturers like Teva have taken reasonable steps to manage production costs: manufacturing has been consolidated from several facilities to one, eliminating excess supply capacity; production and supply chains have moved overseas to countries such as India and China which benefit from large volume facilities, low energy prices, reduced work standards and wages, and lax environmental laws. To save costs, other manufacturers have delayed maintenance or forgone necessary upgrades. Yet others have reduced quality systems to a minimum.

Meanwhile, raw materials and production costs continue to rise due to inflation and other factors. Buyer consolidation and contracting practices coupled with state and federal laws that restrict the ability to increase a medicine's sales price limit manufacturers' ability to respond to an increase in the cost of raw materials. Especially over the last three years with hyperinflation, manufacturers were banned from passing on manufacturing cost increases to their customers due to these regulations, thus pushing many product categories further into the red. **Often, manufacturers are left with few options: they can sell the drug at a loss to keep their manufacturing going until all raw materials are consumed, or they can discontinue the product entirely.** This business reality results in drugs that have fewer than three companies as suppliers, and often, these companies rely on a single drug substance supplier themselves (often from China). And when a drug goes into shortage, the industry is unable to respond quickly due to year-over-year efforts to cut costs to preserve margin. **It needs to be understood that drugs cannot be manufactured overnight when another competitor goes out of stock: the supply chains have lead times of 6 to 12 months, and no manufacturer knows if the prices in the market will cover the costs.**

POLICY RECOMMENDATIONS

This generic medicine crisis did not befall us overnight and there is no simple solution for dismantling more than a decade's worth of systemic policy and market failures. Teva wants to work with Congress on solutions that are both meaningful and achievable. If low-cost generics and biosimilars are going to continue to finance much of the U.S. healthcare system by preventing and treating conditions effectively, we must be willing to pay a sustainable price for these medicines that reflects their overall value to the system – and to patients. Our company is ready to partner with Congress to effectively maintain and expand access to critical medicines. Some policy recommendations to address these problems:

1. **Support Domestic Manufacturing for Essential Medicines**

   Without a reorientation of the U.S. market that pays a price commensurate with these medicines' value, manufacturers will continue to seek efficiencies, and lower labor costs outside of the United States will continue to drive production overseas.

   For U.S. companies that used to produce their own APIs, sourcing from China and India made sense. The emerging countries could make the ingredients for less, under looser environmental and labor standards. According to KPMG, a drug generally can be produced for 20% less in China than in India.[12] In addition to lower labor costs, manufacturers are able to source cheaper raw materials there, which can be up to two-thirds of the total production cost.[13] China has a huge

[12] KPMG, "Generic Medications and Asia-Pacific Health Systems." Available: https://assets.kpmg.com/content/dam/kpmg/sg/pdf/2021/03/Generic-Medications-and-Asia-Pacific-Health-Systems.pdf
[13] *Ibid.*

production scale advantage as well. For some APIs, Chinese companies have more than twice the capacity of their Indian counterparts.[14] The Chinese government itself has clearly understood the value of the pharmaceutical API industry. Since the 2000s – the same time as the eastward migration of API factories – the Chinese government implemented numerous laws and regulations to ensure robust domestic API production.

Teva strongly agrees with Congress that consolidation of active ingredient or finished product supply in any one country – especially China – is a vital national security issue. However, in the U.S., cost-containment measures necessary to offset competitive pressures from lower-cost countries have generated many undesirable effects, such as increased competition from heavily subsidized foreign markets, price erosion and supply constraints.

The last pandemic has made the U.S. acutely aware of the pharmaceutical supply chain's fragility and major competitive advantages by China. The question is how to adjust and guarantee supplies of vital medicines. There is still a way to build a more balanced supply chain with the right policies and incentives for pricing and investment. To safeguard the quality, safety and reliability of our API and pharmaceutical supply, Congress should consider the following recommendations consistent with reforms proposed by the think tank American Compass:

a. **Incentives such as tax credits and long-term fixed government contracts for pharmaceutical APIs essential medicines to move manufacturing back to the U.S and other strategic allies.** Congress should especially consider making direct financial support available to finance next-generation technologies that can automate processes necessary for domestic production of APIs, key starting materials (KSMs) and essential medicines. Domestic use of technologies that rely on a high degree of automation is perhaps the only way the U.S. can offset the labor cost advantages inherent to countries like India and China;

b. **Create new or expanded exclusivity incentives to increase overall generic drug industry profitability** (for example, a "Made in the USA" exclusivity period for domestically manufactured generic drug products);

c. **Diversification of API supply with a priority review voucher.** The PRV program can serve as a blueprint to strengthen the drug supply chain, and particularly the availability of APIs used in drug products that are in shortage or that are otherwise deemed essential;

d. **Apply limited tariffs or import quotas to Chinese medicines and chemical inputs;**

e. **Provide limited tariff exemption for generic and biosimilar pharmaceutical imports, and the API necessary for their production;**

f. **Reform the SAPIR.** In 2020, the Department of Health and Human Services launched the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR). SAPIR, modeled after the Strategic Petroleum Reserve, aims to provide a readily available source of APIs that can

[14] Nikkei Asia, "The Great Medicines Migration." April 25, 2022. Available: https://asia.nikkei.com/static/vdata/infographics/chinavaccine-3/

be quickly converted into finished medicines. However, this reserve is reportedly only 1% full.[15] Congress should reform this program to ensure it is operating appropriately.

2. Reform Medicaid and 340B

Market dynamics and government discounting requirements severely limit the profitability of generics. Prices are further restrained by payor reimbursement policies for generics, notably bundling of payment with the underlying procedure and payment limits such as Medicaid Federal Upper Limits and state Maximum Acquisition Costs (MACs). If these market dynamics were not enough to deter manufacturers from introducing or maintaining low-margin generics on the market, government discount requirements exacerbate the disincentive.

To have our drugs covered under Medicaid, Teva and other generic manufacturers pay a base rebate of 13% of the average manufacturer price plus a penalty rebate for price increases exceeding the rate of inflation. The inflation rebate in some cases generates a rebate that eliminates 100% of the manufacturer's revenue for units dispensed to Medicaid patients. Beginning in 2024, the sunset of the 100% statutory cap on the Medicaid unit rebate will result in rebates that exceed the price of the drug. The Medicaid inflation rebate carries over to the 340B drug pricing program, where it can result in ceiling prices as low as *one cent per unit*, with no limits on the quantity that 340B hospitals can purchase at that price.

Thus, the inflation rebate acts as a *de facto* price cap, making it difficult for generic manufacturers to recoup increases in manufacturing or intermediate component costs, or respond to increased demand.[16] The government discount requirements, added to the underlying pricing dynamics, cause manufacturers – especially those with drugs highly utilized by Medicaid and by 340B hospitals – to reduce their inventory of drugs or remove them entirely from the market, causing shortages.[17] Drug shortages disproportionately affect antineoplastic agents and other injectable generics.

At a minimum, Congress should consider the following:

a. **Align Medicaid inflation rebates with Medicare Part D inflation rebates:** In the Inflation Reduction Act (IRA), Congress established under Medicare Parts B and D an inflation rebate program, like the Medicaid inflation rebates, under which drugs with price increases greater than the rate of inflation are subject to government rebates equal to the excess price increase.

   Importantly, generics approved under an ANDA are exempt from the Part B inflation rebates, and Part D also exempts ANDA drugs except in the case of sole-source generics or when an ANDA drug has 180-day exclusivity.[18] **Implicit in the Part D exception is Congress's current recognition that, except under circumstances when a generic has market exclusivity or is the only generic on the market, market dynamics generally will restrain prices such that there is no need for, or Medicare benefit from, an inflation**

[15] Council on Strategic Risks. Available: https://councilonstrategicrisks.org/2024/03/05/the-national-security-rationale-for-stockpiling-key-pharmaceutical-ingredients/ Accessed April 24, 2025.
[16] Bates White, Penalizing Generic Drugs with the CPI Rebate will Reduce Competition and Increase the Likelihood of Drug Shortages, Sept. 12, 2017.
[17] Testimony of Ted Okon, Executive Director, Community Oncology Alliance, June 13, 2023, Hearing on "Preparing for and Responding to Future Public Health Security Threats." House of Representatives, Subcommittee on Health, Committee on Energy and Commerce ("Okon Testimony"); E.C. Jacob, Factors Involved in U.S. Generic Drug Shortages, U.S. Pharmacist, June 18, 2020.
[18] 42 U.S.C. 1395w-14b(g)(1)(C)(ii).

penalty. To reflect this recognition, the Medicaid inflation rebate for generics needs to be updated to be consistent with the Medicare Part D equivalent. Accordingly, Teva proposes that the Medicaid statute be amended to provide that the Medicaid inflation rebate will not apply to ANDA drugs, except in the non-competitive situations described under Medicare Part D.

b. **Exempt antineoplastic drugs from Federal Upper Limits:** Federal Upper Limits should be lifted for antineoplastic generic drugs. The disproportionate number of injectable cancer drugs in shortage is causing a crisis of rationing and needless suffering and death for patients who cannot obtain inexpensive yet essential chemotherapy drugs. Federal Upper Limits on Medicaid payment, which apply to drugs with at least three therapeutic equivalents on the market, act as a disincentive to market entry or continuation on the market for generic cancer drugs. Removing these limits would be one way to attract more manufacturers to invest in the production and marketing of these drugs.

c. **Exempt drugs on FDA's drug shortage list from Federal Upper Limits:** Federal Upper Limits should also be lifted for generic drugs on FDA's shortage list. For these drugs, it is important to reduce disincentives to the entry of new manufacturers to alleviate the shortage. The average drug shortage lasts about 1.5 years but can be much longer, and more than 15 critical drug products have been in shortage for over a decade. While the delay for a manufacturer who must obtain approval of a new ANDA can be substantial, in other cases manufacturers, though not currently marketing a drug, may already have ANDAs in place that they can use themselves or license to other manufacturers. Therefore, at the time a generic drug first appears on the shortage list, it is not too late to encourage new market entrants.

3. **Ensure generics and biosimilars can enter the market quickly**

Sustaining an environment that encourages innovation and protects intellectual property while also fostering off-patent competition has never been more important The Hatch-Waxman Act, enacted by Congress more than four decades ago, was specifically designed to strike this balance, including through one critical mechanism known as "skinny labeling." Skinny labeling enables generic drug manufacturers to gain FDA approval for uses not covered by brand patents without challenging or infringing on those patents. This provision, which allows timely generic market entry, is the very reason why so many patients can access essential medications.

True to its promise, the Hatch-Waxman Act has successfully increased competition, improved access to medicines, and generated billions of dollars in annual savings for patients and the American healthcare system. From 2015 to 2020 alone, just 15 skinny labels led to an extraordinary $14.6 billion in Medicare savings. In scenarios where a branded medication has multiple approved indications but does not hold exclusivity across all of them, skinny labels facilitate generic entry for approximately 50% of those indications.

Despite the remarkable patient access and health system savings benefits of skinny labeling, legal challenges have escalated between generic and brand manufacturers – adding additional layers of complexity to the already burdensome processes for generic drug approvals and patent enforcement. In recent years, brand-name drug manufacturers have sued generic manufacturers for patent infringement despite the generic's adherence to FDA guidelines for a skinny label.

These legal challenges set a dangerous precedent that prevent more affordable generic alternatives from entering the market. Congress should recognize that generics with lawful skinny labels do not currently or historically stifle innovation. In fact, this system has worked harmoniously for the past 40 years.

Thus, Congress should:

a. **Consider S. 43, The Skinny Labels, Big Savings Act as "must-pass" before end-of-year.** This bipartisan bill led by Senators John Hickenlooper (D-CO), Tom Cotton (R-AR), Peter Welch (D-VT), and Susan Collins (R-ME) would preserve the skinny labeling pathway available under Hatch-Waxman and FDA guidance. It would also save billions of dollars by ensuring generics and biosimilars get to market after patents expire and become a lower cost option for patients.

CONCLUSION

The crises related to the pharmaceutical supply chain did not befall us overnight and there is no simple solution readily at hand. I encourage your Committee – and Congress as a whole – to orient yourselves to solutions that are both meaningful and achievable. If we are going to continue to finance much of the U.S. healthcare system on the back of America's critical generic and biosimilars industries, we must be willing to pay a sustainable price for these medicines that reflects their overall value to the system. Teva believes any effort to address this crisis must address this fundamental value imbalance; in short, the system needs to pay more for generic medicines.

Sincerely,

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