

FOREIGN DEPENDENCE: HOW CHINA CAPTURED AMERICA'S DRUG SUPPLY

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Wednesday, March 11, 2026

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

The Committee met, pursuant to notice, at 3:32 p.m., Room 216, Hart Senate Office Building, Hon. Rick Scott, Chairman of the Committee, presiding.

Present: Senator Scott, Tuberville, Moody, Gillibrand, and Alsobrooks.

OPENING STATEMENT OF SENATOR RICK SCOTT, CHAIRMAN

The CHAIRMAN. The Special Committee on Aging will now come to order.

What if I told you that Communist China, an adversary of the United States, and they made that decision, has sole control of the building blocks of many of the medicines seniors Americans rely on, completely dependent on. I am not just talking about a few medicines, I am talking about our antibiotics, our diabetes drugs, our blood pressure medications, essential life-saving medicines found in every hospital, every pharmacy, and every medicine cabinet in this country.

This isn't speculation, it is a reality. Xi Jinping and his thugs in the CCP have decided to be our enemies, and they are controlling the very medications our families rely on to live happy, healthy lives. Today's hearing is about getting to the bottom of why this is the case.

I want to be very clear. It didn't happen because Communist China was clever or lucky, this happened because Washington was negligent. Lobbyists are powerful and politicians in both parties chose cheap over safe. For years, we watched Communist China's Government and its leaders execute a deliberate, documented, publicly stated plan to capture the global drug supply chain.

They weren't trying to hide it, the signs were obvious and our government did absolutely nothing to stop it. As a matter of fact, politicians created regulatory barriers and enacted policies that pushed manufacturing overseas and right into the CCP's hands. This Committee has spent the last six months exposing this threat and building this case piece by piece, hearing by hearing.

In September, we exposed how our dependence on foreign generics is threatening drug safety and availability for American patients. In October, we brought in experts to examine solutions

and discuss ideas like procurement reform and supply chain transparency. In November, we had American manufacturers testify what a rebuilt domestic industry could actually look like.

In January, along with Ranking Member Gillibrand, and several members of this Committee, introduced the CLEAR LABELS Act to inject transparency into our drug supply chain, because the American people have a right to know where their drugs, and the medicines keeping their mothers, fathers, and children alive, come from.

We have written to the FDA and the Secretary of HHS, we have written to drug distributors, and group purchasing organizations demanding answers about their foreign sourcing. We have written to Secretary Hegseth about what dependence on Communist China means for the health and readiness of our troops. We even published an investigative report that documents in plain terms what decades of offshoring has done to the American drug manufacturing industry.

Over the last 24 years, domestic production has collapsed, dropping from 84 percent of the U.S. market in 2002, 84 percent, to just 37 percent today. 80 percent of APIs used in these essential medicines have no U.S. source whatsoever. Think about that, 80 percent.

During COVID-19 the Chinese Government nationalized its own medical supply production, turned off the exports, turned off the exports, and decided which countries got life-saving drugs based on politics, 37 Chinese factories that made ingredients for American drugs shut down during the pandemic.

U.S. hospitals and healthcare workers fighting to keep Americans alive ran out of sedatives, antibiotics, and cancer drugs. That was a taste what it looks like when you let an adversary control your supply of essential medicines. It should serve as a warning to all of us, if we just sit here, hold this hearing, thank our witnesses, and go home without acting, it will happen again, but worse.

We didn't come here today to preside over another Washington exercise when all we do—where all we do is identify a problem, and then pat ourselves on the back for a nice hearing. This Committee has been working since day one to sound the alarm, talk to experts, and present real solutions to fix the problem. I hope today will be a moment that alarm becomes impossible to ignore.

To all the members of this Committee and all congressional colleagues, let us continue to work together to fix this problem. Let us find a path forward that will protect American patients and American lives, the lives of our constituents.

I would like to recognize Ranking Member Gillibrand for her opening statement.

**OPENING STATEMENT OF SENATOR
KIRSTEN E. GILLIBRAND, RANKING MEMBER**

Senator GILLIBRAND. Thank you, Chairman Scott and thank you to our witnesses, being here today.

As this Committee continues to investigate the generic drug supply chain, its safety, its quality, there is one refrain that is repeated at each hearing, and that is that the United States has become reliant on China and India for key ingredients to manufac-

ture generic drugs, active pharmaceutical ingredients, and key starting materials.

A combination of factors has led to China's dominance in this space. Subsidies provided by the Chinese Government lacks environmental regulations and lower costs of labor but China is not the sole reason that the United States is reliant on foreign manufacturers for these critical chemicals. Underlying market factors in the United States have led to a race to the bottom where incentives for manufacturers are solely based on cost and not quality, while amongst all of the generic drugs that Americans take are—sorry—while almost all of the generic drugs that America takes is safe, Congress must empower the FDA to conduct rigorous oversight to make sure foreign manufacturers comply with our safety standards.

Congress must also work with industry to move away from cost being the only factor for purchasing. We must also incentivize manufacturers and purchasers to consider quality when they are sourcing active pharmaceutical ingredients and final dose form medicines. While the United States has unfortunately ceded much territory regarding the generic drug supply chain, there are still steps we can take to reshore or friendshore for sourcing.

However, the United States must keep our global leadership in biopharmaceutical innovation. China has rapidly scaled up their innovation for these novel medicines and therapies. They have reformed their clinical trial system, invested Government funding into development, and improved coordination between early research and commercial scale manufacturing. While the United States does not need to replicate the steps that the Chinese Government has taken exactly, we have to realize that China is moving at a much faster pace than we are.

The United States has been the standard bearer for clinical innovation for decades. It would be a detriment to our global leadership if we let China surpass us in innovation. I look forward to working with my fellow Members of Congress to ensure that emerging biotechnology and innovation is supported in a way that incentivizes these companies to stay in the United States.

I also urge my colleagues in Congress to adopt recommendations laid out by the National Security Commission on emerging biotechnology. Congress has the roadmap to continue our global leadership in biopharmaceutical innovation and we must recognize this sector for the asset that it is.

I look forward to continuing this robust conversation today, and I look forward to collaborating with my colleagues across the aisle on this incredibly important issue.

The CHAIRMAN. Thank you, Ranking Member Gillibrand.

Next, I would like to welcome our witnesses. They are experts on Communist China and supply chains and they can explain how we got here and what we can do to address our reliance on the CCP.

First, I would like to welcome a fellow Floridian, Congressman Ted Yoho. Served in Congress for eight years, formerly chairing the House Foreign Affairs Subcommittee on Asia and the Pacific. Thank you for coming and I look forward to hearing your testimony.

**STATEMENT OF HON. TED YOHO, FORMER
CONGRESSMAN (FL-3), SENIOR ADVISOR,
KYLE HOUSE GROUP, WELAKA, FLORIDA**

Dr. YOHO. Chairman Scott, and Ranking Member Gillibrand, thank you for the opportunity to address your committee on this important and timely topic.

The integrity of pharmaceuticals consumed by Americans, especially our seniors, must be of the highest standards in quality, purity, and effectiveness and free of adulteration from toxins and cancer-causing substances that cause illness or death. The responsibility lies with the pharmaceutical companies and U.S. Government agencies like the Food and Drug Administration and the offices—or the Office of the United States Trade Representative.

The medical community including drug retail outlets, insurance companies, hospitals, and doctors all share the responsibility of ensuring medications are of the highest standards. China took advantage of the U.S. self-inflicted wounds which was caused by overly burdensome regulations, tax policies imposed by the U.S. Government, as well as by corporations seeking higher profits to appease boardrooms and investors.

China enticed U.S. manufacturers to their shores with the lure of low taxes, lacks regulations, cheap labor and a 1.4-billion-person market.

However, the cost to drug makers, the danger to the U.S. consumers, and the vulnerability to U.S. national security were missed. Drug makers soon realized they were subject to Chinese rules, laws, patent agreements. They were required to have Chinese Communist Party Members on their boards, and relinquish up to 51 percent of their companies to state-owned enterprises.

Corporations must give up their drug formula for approval. If not surrendered freely, they are stolen. Chinese companies then spring up, creating the exact same drug and selling it below cost. As a result, U.S. manufacturers cannot compete and are forced to leave the market. The result is that China controls the world market, price, and supply chain. This is a national security risk and a health risk to our country.

As detrimental as that is, it gets worse. China does not adhere to or practice the good manufacturing practices set by the FDA. Nor do they follow the standards set by U.S. Pharmacopeia, a 200-year-old U.S. organization that establishes requirements for pharmaceutical manufacturers to ensure the purity, quality, and effectiveness of the medicines U.S. consumers take.

This results in adulterated products entering our markets that have been documented to contain toxins, cancer-causing-agents like nitrosodimethylamine, melamine, tainted heparin, or ineffective medications causing treatment failures or death. These and many other examples are well covered in Rosemary Gibson's book, *China Rx*, printed in 2016.

Pharmaceuticals are made from key starting materials and active pharmaceutical ingredients that create the final dose form. China controls 30 to 60 percent on many of these components and up to 100 percent on others. With this control over the raw ingredients in our drugs, it is easy to see how China has positioned themselves to control much of the U.S. and the world's drug market.

The solution, change U.S. policies. First, we must require all manufacturers and countries wishing to sell or import drugs into the U.S. market to meet the same FDA inspections as U.S. manufacturers. That means an unannounced 24/7 inspection. This is non-negotiable. Congress must create laws requiring all nations producing pharmaceuticals for sale in the U.S. to meet U.S. FDA inspections.

Second, we must encourage U.S. manufacturers to move back to the U.S. with a combination of investment, tax incentives, trade policies, and tariffs. President Trump's four executive orders have already brought back millions of dollars of pharmaceutical manufacturing investment to our shores.

Third, we must require quality and purity inspections that adhere to USP Inc.'s gold standard for drug manufactured in or entering the U.S.

Fourth, we must forbid the FDA from relaxing regulations when drug shortages occur. Permitting this willingly allows inferior products to be sold to and consumed by U.S. military and citizen populations.

Last, we must require all medicines for our military to be 100 percent U.S.-made from the KSM, to APIs, to the final dose stage. The role of the pharmacy benefit managers needs to be reevaluated. Failure to address the Nation's pharmaceutical dependency on China, or any other nation, jeopardizes our national security and our citizens' health security, and it cannot be accepted.

I yield back and look forward to your questions.

The CHAIRMAN. Thank you, Congressman.

I now would like to welcome Mr. Gordon Chang, who has decades of experience as an author and commentator on the CCP. Mr. Chang has briefed our Nation's top leaders and written extensively about the CCP. Thank you for being here, and thank you for your wife being here, Lydia.

**STATEMENT OF GORDON G. CHANG, AUTHOR,
PLAN RED: CHINA'S PROJECT TO DESTROY
AMERICA, BEDMINSTER, NEW JERSEY**

Mr. CHANG. Chairman Scott, Ranking Member Gillibrand, and distinguished Members of the Committee. I am honored to be here and thank you so much for the opportunity to appear today.

China, as we just heard, has monopolies over many of our pharmaceuticals and the question is, what is at stake? The reason why this is so important is because China could deny these medications to us. This statement needs context.

China's regime believes it is at war with us. In May 2019, People's Daily, the most authoritative publication in China, in a landmark editorial, declared a "people's war" on us. March 2023 PLA Daily, the official publication of the Chinese military, defined people's war as "total war," and China to win this war, and they are serious, China to win this war has a doctrine of unrestricted warfare.

In 1999 two Chinese air force colonels wrote a book by that title, and they argued that China could adopt any tactic to take down the United States, so unrestricted means unrestricted. China, we know, has weaponized its near monopoly over rare earths in the

trade discussions, but it has not weaponized its 100 percent monopoly, 100 percent monopoly, on the production of pharmaceuticals.

This is not just a theoretical threat because in March 2020 during the COVID epidemic, the Chinese regime threatened to throw the United States into, what it called, "a mighty sea of coronavirus" by cutting off pharmaceuticals and other items that were needed during the epidemic.

China, we know, has a monopoly on many of these, so for instance, a hundred of America's most used antibiotics pharmaceuticals, they require ingredients that are made in only one Chinese factory, 100 pharmaceuticals only one Chinese factory. India the other heavyweight production center for generics, they get 80 percent of their active pharmaceutical ingredients from China and with regard to the key starting materials, 45 percent of them are produced only in China.

Generics are especially important because 91 percent of all U.S. prescriptions are filled with them. The generics, they are produced in China as well. Eighty-three percent of the top generics are produced only in China. China is the supplier of at least one of the key starting materials for 679 of the active pharmaceutical ingredients.

The Defense Department in 2023 issued a report that showed that 27 percent of the medications it used were 100 percent dependent on China and antibiotics, as we just heard, is a particular American vulnerability, so for instance, the most widely used antibiotic in America is made from four separate key starting materials that are produced almost entirely in China and America gets 45 percent of its penicillin from China as well.

FDA officials told us that they did not enforce America's standards on the importation of foreign-made pharmaceuticals, because they said if they did that it would cause severe shortages here.

We know how we got into this predicament, it was China's predatory trade policies, but it was also on America, an America that thought manufacturing was no longer important, and also thought that the nature of regimes was no longer important.

We know that in emergencies foreign countries, even our friends, will hoard medications and that happened in the 2009 swine flu epidemic for instance, so of course, we need to onshore our production and to do that, we need to impose Section 232 tariffs, invoke the Defense Production Act, enhance the investment tax credit for the production of medications, require the Federal Government to buy American-made pharmaceuticals, and authorize federally backed loans for pharmaceutical production.

Senators, we do not have a moment to lose. Thank you.

The CHAIRMAN. Thank you, Mr. Chang.

Our next witness is a leading author and expert on Communist China and the drug—and drug quality issues. Rosemary Gibson is the author of *China Rx*, a book that outlines our dependence on Communist China for drugs and ingredients. She has been recognized for her work, including receiving the highest honor for the American Medical Writers Association.

Ms. Gibson, thank you for being here. Please begin your testimony.

**STATEMENT OF ROSEMARY GIBSON, AUTHOR, CHINA RX:
EXPOSING THE RISKS OF AMERICA'S DEPENDENCE
ON CHINA FOR MEDICINE, MCLEAN, VIRGINIA**

Ms. GIBSON. Thank you, Chairman Scott, and thank you Ranking Member Gillibrand.

China Rx was the first to expose how dependent the United States is on a single country, and it also exposed that other countries like India are highly dependent on China also, so all roads lead to the same source. My comments today are on generic medicines because they are so prominent in our supply chain. The centralization of the global supply in a single country is so open to catastrophic failure, an export ban would turn our health care system into chaos.

An export ban is not hypothetical. In June 2025, last year, a statement came out of China, this was during the trade negotiations, and it was said that, "If China chose to restrict pharmaceutical raw materials from the United States, the situation in the U.S. would be much worse than it is for critical minerals". We have been warned and we have no time to waste.

Today, I am very pleased to share with you the findings of the Department of War first Generic Drug Testing program which highlights quality concerns in our medicine supply. For the first time we have data on how well our generic drugs are made and whether they meet our standards. The Department of War's work started in 2019 when I was invited to the DLA and I asked them a question: Do you test your medicines?

The Department of War's work followed on the heels of Kaiser Health Plan, which started testing generic drugs right beforehand. Here are some of the highlights of the testing program to date, so far, 13 different generic drugs have been tested, all the different manufacturers and repackagers. Fifteen percent of what has been tested fail basic quality standards. In any industry products with 15 percent manufacturing defects, it would be shut down.

Here are some of the test findings: For people who are recipients of organ transplants, their lives depend on taking a drug to prevent organ rejection. Some of those products were not manufactured right. They don't work right, and very reputable physicians believe patients have died as a result. Testing has found toxins including thallium which is known as the poisoner's poison in some products, and then arsenic, lead, and carcinogens.

Thirty years ago, when we used to make generic drugs here, for the most part, people would go to prison for this. The testing team led by the independent laboratory, Valisure, we would welcome the opportunity to brief members of the Committee on the full details of all these 13 generic drugs.

What do we do? I have three recommendations. The first, as alluded to, it is absolutely essential that a country that is a super-power have the capacity to make its own antibiotics. China Rx was the first to expose that we have no capacity to make antibiotics end to end here. We have no sovereignty and our survival is at risk. Let us do what we have done with critical minerals and bring that manufacturing back home now and not only for antibiotics, but the most essential generics that are essential to sustain life and there

are a lot of good people in this country waiting on the sidelines to help do that.

Second, the federal departments of HHS, the VA, and Department of War should be directed to use the quality data in their procurement decisions. When they do that, that quality is correlated with location that will automatically, if we use the quality data, drive out substandard generics that are typically made in Asia and it would support U.S. manufacturers who would be able to enter and supply quality medicines to our military and veterans.

Finally, we have to go right to the tip of the spear and where the root cause of this is. There is a handful of U.S. companies that source all the generics that are distributed in this country and they scour the earth looking for the cheapest. Now, going forward, it is imperative that they are held accountable for quality and not just cost.

The narrative that all generics are the same today, what this data shows, it is not true. Once again, we welcome the opportunity to brief the Full Committee on these findings which we believe are game-changing. A total of 42 drugs will be tested, and we look forward to the opportunity for this to really transform our drug supply system. Thank you.

The CHAIRMAN. Thank you, Ms. Gibson. Now, I would like to recognize Ranking Member Gillibrand to introduce the next witness.

Senator GILLIBRAND. Thank you, Mr. Chairman. I want to move to introduce our next witness, Dr. Chan Harjivan. Dr. Harjivan is visiting fellow with the Duke Margolis Institute for Health Policy. Previously, he was a special assistant to the White House where he reported directly to President Biden, working to strengthen the Nation's readiness for biological threats. He was a key architect of Operation Warp Speed, the historic federal initiative to develop the COVID-19 vaccine.

You may begin.

**STATEMENT OF CHAN HARJIVAN, VISITING
FELLOW, DUKE MARGOLIS INSTITUTE FOR
HEALTH POLICY, WASHINGTON, D.C.**

Mr. HARJIVAN. Chairman Scott, Ranking Member Gillibrand, and Members of the Committee, thank you for this opportunity to testify.

Much of the discussion around pharmaceutical supply chains have focused on admiring the problem as Chairman Scott has mentioned, foreign dependence, shortages, and market failure. Now, sound policy changes are being proposed but today I would like to focus on an integrated solution set. America still has the world's largest pharmaceutical market, flexible allocation capital, and the strongest research system with unparalleled talent.

What we need is alignment between policy, markets, and resilience. In my view, America and its democratic allies should pursue what I call an allied life-sciences platform, a strategy built around five mutually reinforcing pillars:

First, know the chain. We cannot manage risk in a supply chain that we cannot see. Congress should require auditable end-to-end supply chain mapping. This is not about burdensome reporting, much of this information already exists and it aligns with other industries and other country standards. What we need are common

data frameworks and enforcement mechanisms that allow Government and industry to identify vulnerabilities before they become shortages or dependencies. Transparency is the foundation of flexibility.

Second, buy resilience. The second pillar is about providing predictability to makers of drugs. Federal purchasers including the DoD, the VA, and CMS reimbursement systems shape a significant share of the pharmaceutical demand. They should reward supply redundancy, quality manufacturing, surge capacity, and geographic diversification and in fact, predictable contracts can lower the price for medications, not increase them.

In general, I have always been struck by how these buyers seem not to understand how stable and reliable demand signals are valuable to their suppliers and enable them to build more efficient processes. Analysis by Rios Partners highlights the significant opportunity to strengthen procurement efficiency within the VA as hospitals often purchase identical products at widely varying prices, often exceeding those paid by private-sector providers. This is costing taxpayers hundreds of millions a year while not securing the supply chain or serving patients optimally. If the DoD and the VHA don't value security of medical supply chain for the war fighter or veterans, who will?

Third, build capacity at home and with allies. The goal should not be complete reshoring of global pharmaceutical production or creating trade barriers. That would be unrealistic and unnecessary. Instead, the United States should maintain domestic manufacturing capacity for a few essential medicines while building a trusted supply network. Powerhouses such as India, South Africa, Canada, Europe, and Japan already play critical roles in the global pharmaceutical system. Let us work with them to eliminate choke points at the same time lower costs.

Fourth, win the biotech stack. The fourth pillar looks forward. Competition in life sciences increasingly spans the entire innovation pipeline, from AI-enabled discovery, to clinical trials, to advanced manufacturing. When I started consulting in 2000 the cost to develop a drug was \$500 million, in 2010 it was one billion, it is now two billion. We are not efficiently developing or harnessing technological innovation in drug development. The United States should invest in and enforce standards that catalyze technologies. The country that defines the architecture and set standards will own the AI biology industrial revolution. We don't want to win the generic supply chain battle and lose the global war in life sciences.

Fifth, mobilize long-duration capital, the final pillar. We must address the capital gap between scientific discovery industrial and industrial scale in the U.S. The implication is stark. A Chinese biotech asset is profitable at 200 million. An American equivalent is considered a failure unless it hits one billion. This imbalance transformed the entire calculus of capital allocation. One idea to address this is the creation of strategic research investment vehicles. Mission oriented, professionally governed investment vehicles designed to deploy existing long-term institutional capital into critical biotechnology platforms and manufacturing capacity. These entities would complement private venture markets by financing the

hard middle between laboratory discovery and industrial scaleup without taxpayer funding.

Let me close with three imperatives. First, if we improve supply chain visibility and reward resilience economically, the private sector will deliver. This is easy. Second, the United States does not need to produce every medicine domestically, but together with trusted allies, we can eliminate systemic vulnerabilities. This is common sense and the third, the largest strategic competition is not simply about today's drug supply chains, it is about who leads the life sciences platform for the 21st century. This is existential.

For the past hundred years, the United States and its allies built that platform. With the right strategy, we can continue to lead it.

Thank you, and I look forward to your questions.

The CHAIRMAN. Thank you, Ranking Member Gillibrand. Mr. Harjivan, we appreciate you joining us today.

Let us go to questions. Let me start with Senator Tuberville.

Senator TUBERVILLE. Thank you, Mr. Chairman. Thank you for this hearing. It can't get any more important than this.

Ms. Gibson, it is becoming common knowledge that, for whatever reason, China is often able to circumvent the FDA when producing generic medications so worldwide. That means Americans are often taking drugs that, if produced in the United States, would meet higher standards. How can we move that leverage that China has over our people making drugs?

Ms. GIBSON. You are correct, Senator, that China has outmaneuvered the FDA. The former FDA Commissioner, Dr. Robert Califf, told the House Appropriations Committee in 2023 that China quote, "Is a problem. It is not transparent. The FDA cannot get information from them to perform its regulatory functions" and he said we cannot be allowed to depend on China and as you may know in 2023 they started an anti-espionage law where regulators don't want to travel there.

I believe the way to get around this regulatory issue is, we are importing, in my mind, de facto unregulated products and the quality data demonstrate that in countries that don't respect our regulations then we should not be buying from them. If we use the quality data from the DoD testing program that will turn out and take out manufacturers in countries who do not respect our laws and we will be able to use U.S. manufacturers, so let us use the quality data to really cleanup the system. I think it is sending a market signal rather than a regulatory signal.

Senator TUBERVILLE. Thank you. In your book, the China Rx, you reveal that China controls approximately 90 percent of key starting materials to make APIs and generics. How do you think the U.S. would be affected if China were to cease those exports today?

Ms. GIBSON. A lot of people would die in this country. We would not be able—our health care systems would cease to function and you know—

Senator TUBERVILLE. We have—yes.

Ms. GIBSON [continuing]. if China wanted to spread infectious disease, we would not have the tools to be able to treat people.

Senator TUBERVILLE. Mr. Chang, you said in your testimony that China has a pharma death grip on America. How do we work to change that at the federal level?

Mr. CHANG. The most important thing is on an emergency basis, we need to bring back production here and the reason is, China has been able to outmaneuver the FDA, as you just talked about, because they do have such a big monopoly on all parts of the chain and the only way to do that is to break that monopoly, and unfortunately this is going to take some time but it does—it is possible. China developed this monopoly, we can take it back, but we have got to know that within two or three years there is a period of extreme vulnerability.

Senator TUBERVILLE. Can we use tariffs to help us out with China?

Mr. CHANG. Section 232 tariffs I think are very important in that regard. Other tariffs are also possible. The Supreme Court in the Learning Resources decision struck down the 1977 Act tariffs, but Section 301 tariffs and 232s could very well create the conditions where, if we had an enhanced investment tax credit, and if the President were to invoke the Defense Production Act, these are things that could stimulate domestic production immediately.

Senator TUBERVILLE. Thank you. Last November, we had a young man that came from my State in Birmingham, Oxford Pharmaceuticals, to testify the importance of onshore drug manufacturing. Mr. Chang, what can we do to encourage pharmaceutical companies to acquire APIs domestically instead of sourcing them from places like China or India? Is that possible?

Mr. CHANG. It is possible but the first thing I think we need to do is get the Federal Government to require the purchase of American-made pharmaceuticals, or pharmaceuticals that are friendshored if they are not available in the U.S. It is an all-of-the-above approach because, as I mentioned, China is able to get around all of our rules because they know that if they cutoff production then, as Rosemary Gibson just told us, Americans are going to die.

It is an all-the-above approach on an emergency basis. I know that is not a satisfactory answer, but unfortunately, I think it is close to where we have to be and if we don't do this, the problems are just going to get worse because China is becoming more predatory.

Senator TUBERVILLE. Yes. Congressman, you served on the House Foreign Affairs Committee, you understand the risk. What is at stake if we do not gain control of what is going on here?

Dr. YOHO. National security. I mean, we would be beholden to another country, i.e. China. This is something, it is imperative that we get this right. We get it done now. The Defense Production Act, as President Trump used in his first term to create those products here, you know, the PPEs, is something we could do now.

The other thing is the ABCs of manufacturing anywhere but China, friendshore, nearshore, onshore. Use the tools we have to bring that stuff home now. We know where China is going. We know what their end intent is, and we need to do it now.

Senator TUBERVILLE. Yes. This CLEAR LABELS Act that the Chairman has—of putting absolutely what is in the drugs that we take. How important is that?

Dr. YOHO. It is real important. I like it. I think it is something that needs—but for it to be effective people have to read it.

Senator TUBERVILLE. Yes.

Dr. YOHO. We tried that on the Ag Committee with the COOL Amendment. I think legislation like that is strong and I think we need to do it but I think we need to put more force on the FDA to regulate drugs or inspect them the same way they do here and tell those countries, you are going to do it our way or don't sell here. It is your choice.

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

The CHAIRMAN. Senator Moody.

Senator MOODY. Thank you. Thank you for being here. It seems like yesterday that our country was reeling when we received a rude awakening from the COVID-19 pandemic and the millions of Americans that needed medical care so quickly and in that moment of national vulnerability, we began to realize just how heavily our country depends on China for medical supplies, including pharmaceuticals. Since their entry into the World Trade Organization in 2001, China has concentrated its efforts to circumvent international trade norms, committing economic espionage by stealing our IP, and disrupting our economy and this is one of the many ways I think our Chairman and Ranking Member have been great about holding hearings to show how vulnerable we are to this dependence on China for our drugs, and specifically how it can be a national security threat.

I am grateful, Chairman, that you are willing to commit the time today to hold this hearing. I think it is one of the most important things we can be doing on this Committee since so many of our citizens in Florida, our seniors, and otherwise, dependent on recurring daily medications. This is so very important.

Many of the shortages that Americans have had to face are not because of natural market dynamics but because of the coordinated Chinese engineered multi-decade effort to subvert our economy, and really much of the west. In the past decade, from what I can see, we have seen a decrease of 61 percent in our domestic API manufacturing facilities, which are essential for our drug production.

One of the things that we heard from in the opening statements was something that concerns me, which is that they are—the Chinese notoriously ignore quality and safety standards, manipulate prices and utilize dubious labor standards. FDA import alerts routinely cite carcinogenic impurities, falsified batch records, and non-sterile conditions from manufacturers in China, with roughly one-third of all FDA import alerting on Chinese facilities.

I am grateful for the administration. They are trying to fix this problem. At least they are focusing on it. They are aware of it. In the course of the last year, the administration announced multiple hundred-billion-dollar investments being made in the American economy and of these investments, the White House announced in December that 150 billion will be invested into American pharma-

ceutical manufacturing, reducing our reliance on foreign industries, in places like China.

We know not only will this secure up our supply market and make sure that we can trust the ingredients in our pharmaceuticals, but that we have ready access to them in times of vulnerability. Also hopefully brings back American jobs in that industry.

Mr. Yoho, again, thank you for being—former Congressman Yoho, I would like to say, as you know, I have been very strong in pushing back on the way China has meant to infiltrate the strength of this country, or undermine the strength of this country. I am the lead sponsor of a bill to halt visas for Chinese nationals and students when their laws require them to cooperate with the CCP. I am fighting hard to keep illegal Chinese vapes from coming in. They keep dumping them over and over, and we have no idea what is in them, and our kids are being affected.

This is another way, I think, that we can focus on ways to protect Americans. Are there any ways that you can tell us today that we can take quick concrete action here in the Senate that would—what is the most effective thing we can do right now as senators in terms of legislation, or otherwise, to make sure that we are re-shoring domestic manufacturing of drugs?

Dr. YOHO. Awareness. I think the biggest thing is fill this room up with people, the news people, American people knowing what is going into their pharmaceuticals. Second thing is get on the FDA through legislation that you all can introduce to require, and this is not directing the FDA, but you are saying any country producing pharmaceuticals for the United States will meet FDA standards anytime, anywhere, 24/7. If not, it is your choice not to sell into my market, and you need to enforce that.

I was with an FDA inspector last week who was the one doing the inspections in China when we beefed it up so they could go in there, but it was kind of like the IAEA with Iran. They would let you go where they wanted you to go and you couldn't ask too many questions or they would shut it down, so China saying they are more tolerant and are going to abide by the rules, it is a joke. We need to put the pressure on them and stop that and the other thing is bring that production here using any tool we have, whether it is the DFC, using the Defense Production Act, or any other tool like that but we don't have time to play around with this. This is imperative that we get this done within the next year and a half, two years, period.

Senator MOODY. Well, I want to thank the people that showed up today because we almost filled this room. That was a great recommendation. Thank you, Chairman.

The CHAIRMAN. Thank you, Senator Moody.

Senator GILLIBRAND. Thank you, Mr. Chairman. I really appreciate this testimony that you have all given. You have highlighted for us why this is such an urgent crisis and I could hear from each of your testimonies how concerned you are. It is something the Chairman and I are very focused on and we hope to have meaningful legislation to move us in the right direction in this Congress.

For Dr. Harjivan, the United States holds a key advantage over India and China in the biomedical and biotechnological space with its strong support for universities that produce world-renowned sci-

entific research. Historically, we have been able to recruit the top talent from nearly anywhere including China and India.

One of the pillars that you talked about in your written testimony was the importance of securing U.S. biotech leadership. China has treated investments in biotech as strategic infrastructure. The final report that was recently released by the National Security Commission on Emerging Biotech created robust framework for policymakers about what we can do to rapidly support this advancing industry.

Can you expand upon the role the Federal Government should play in securing our global leadership in biotech and how important is it for the United States to set the global standard for biotech research and development? What are the national security risks of the U.S. losing its leadership to China in this space?

Mr. HARJIVAN. I mean, the threat is real about losing leadership. I think my analogy would be, and we are all of that age where we remember the internet, how it was developed. With the early days of the internet, it was a bit of chaos, right. We put structure around it, we put standards around it, we put HTTP and then HTTPS, because of that industry could coalesce around that. We had Facebook, we had Meta, we had Uber, we had Netflix, these are all American companies, so we control the internet through innovation, but we set the standards for the internet.

As we enter the age of AI and biology we also need to be setting the standards. NIST, the FDA, need to work really hard so we set global standards. The world trusts U.S. standards, not Chinese standards. Once we set that, I trust industry to coalesce around that develop innovation. We don't know where these innovations are going to go, for the next 50 years these innovations will be transformative in our society. We need to own that.

Our allies will also trust our standards as well. We need to work with them, but we need to work at pace. I feel we are not working fast enough in developing innovations in standards. We use AI now to develop drugs, but the FDA still uses the same time lines to approve those drugs. We need to accelerate that, so we need to develop new metrology. We need to work with NIST, with FDA, to work with industry partners to develop standards that we can work against.

Senator GILLIBRAND. Okay. Would anybody else like to answer that question?

Mr. CHANG. China has certainly made the development of biotechnology a priority. If you go back to the Made in China 2025 Initiative, that is one big World Trade Organization violation but nonetheless, the regime continued to do that and that is one of the reasons why China has become innovative in biotech, where before it was just making drugs for other countries, especially us.

Rosemary Gibson has mentioned that we need to be as determined in this area as China has been. That doesn't mean that we have to violate norms and guidelines on trade, but it does need—but it does mean that we need to put the resources there and that is of course going to be a partnership but the Federal Government does need to lead and to make it clear to industry that this is a critical national security threat, and it is a something that must be done as we have just heard.

Senator GILLIBRAND. Thank you. In some of your testimony, you talked about how federal procurement reform through HHS, the VA, and the DoD is a way to incentivize quality manufacturing for generic drugs. Can you each talk about that a little more? Dr. Chan Harjivan, you have talked about it, and Ms. Gibson, you mentioned it as well in your testimony.

Ms. GIBSON. Yes, I will start. I think a way to do this expeditiously is to have the Department of Veterans Affairs, HHS, and the Department of War to use the data that Department of War paid for to guide procurement decisions. If we buy based on quality, you are more—they will be more likely buying products made in the United States and other countries that actually care about the quality of the drugs that they produce, so automatically deal with some of these issues and bring in some of the companies that you had in the hearing back in November.

I think it is important to even go further upstream. China, and India, and other countries that don't respect our laws, their products cannot be sold here unless they have a buyer, unless they have those who source them, so who is sourcing them? There is a handful of companies, about six of them, that source all the generics and they go on the basis of the cheapest product.

I know from talking with CEOs of ethical U.S. companies say, we can't compete if they are going to be buying and sourcing from companies that have a litany of FDA recalls, warning letters, and 483s, so we have to go to the tip of the spear, the root cause and this might be tough to do politically, but I think the CEOs of these companies should be convened, and to indicate that we can no longer—they should no longer be sourcing vital medicines only on the basis of cost. They have to include quality and we have the testing data to begin to do that and that will affect everything else that is distributed around the country.

Senator GILLIBRAND. Thank you.

Mr. HARJIVAN. I would add that it does not need to be costly either. We can—with longer term contracts, with visibility into supply chain, we can actually have lower term contracts because they will have predictability of demand. Visibility into that is very important. When I go buy a car, I can see where it is made. They will tell me which parts come from which country. When I put a drug into my mouth, I have no idea about the quality, nor do I know where it is made.

We also need diversity. When we buy—you know my restaurant, my favorite restaurant chain gets its tomatoes from three different sources, California, Mexico, and Texas maybe, right. When I buy a drug, it is often a single-source supplier. I actually don't worry whether it comes from Idaho, India, or Ireland, or China, but I don't want it to come from only India or China, or Ireland, shortages often come up in the United States as well because we have single-source suppliers.

It is transparent supply chain and diversity of supply but with long-term contracts and building in these quality measures I think will lower the cost and I have talked to generic manufacturers who agree with me as well. We could actually lower the cost of generics by having this process in place.

Ms. GIBSON. If I may add just one further point? The Generic Drug Testing Program has found that we are actually paying more for poor quality generics, and some of the cheaper ones are the better quality ones.

Mr. CHANG. One of the issues is going to be FDA rules and regulations that restrict innovation. Obviously, this is the competing considerations here because we do want drugs to be effective, we do want them to be safe, but we also want to encourage innovation here and really the alternative to innovation here is innovation in countries that consider us to be an enemy.

When we think about FDA regulation, I think that we should believe—it should look at what the alternative is. We don't want to have drugs manufactured in China, so we need to encourage them here, and that very well may mean a real change in the way the FDA looks at new drugs.

Senator GILLIBRAND. Congressman, would you like to add anything.

Dr. YOHO. Yes. In addition to what I have said about the FDA changing the regulations with the power of Congress doing that, I think holding CEOs at drug companies and pharmaceuticals, if they know they—if they brought something in and it didn't meet the correct standards, hold them accountable. You know, somebody has got to be held accountable because they put those drugs on the market that goes to our consumers, and the seniors, you know, unfortunately I am one—I am happy to be one of those now. We take more medication than when I was in my youth.

They are more dependent on that and we have got to make sure of that. Just something of interest here on, when you look at pharmacy—or the antibiotics virtually all that is in China. When you look at the fermentation and the fluorination process, India relies on that but they have closed down their fermentation and fluorination processes, so 100 percent of that comes from China. That is a national security and health risk that needs to be addressed now and I think those are things that we need to put the money in our NIH and the research used properly.

I was at a meeting last week and they said: Too many of our scientists and researchers are going to Africa or being courted by China to go over there, so five years from now the brain drain, we are going to lose that cutting edge, and it is hard to get back to first place when you are falling behind. We need to entice people to stay here to do the research and support that.

The CHAIRMAN. Mr. Harjivan, why is it so difficult for the Federal Government to buy American drugs? I mean, we have got Department of War, we have the VA, we have, you know, prison system, we have all these groups, why is it so hard?

Mr. HARJIVAN. I mean, they are not the largest part of purchasing, but they are significant part of purchasing. I think it is a few things, I think—I will be honest, I worked at the White House and had a lot of discussions with the VA and the DoD, I think there is a bit of lethargy there. I think there are also entrenched incumbents who supply them a lot of the people who do the contracting for them as well.

I think that they need a bit of a nudge, right and I think they need to understand the value of this as well. I think if you look at

the cost of quality, if you look at the cost of contracts, and the cost of switching, we have been—literally, the DoD and the VA having helped enable Chinese to come in when there is spot pricing and they come in with these spot—to spot lower prices.

I think we can resolve this as we look at other supply chains as well, and mimic them as well, so this is not—this my point is, this is not hard to do. There is just a little bit of a nudge they need to understand the value to the warfighter, to veterans by doing this. I think they need a better understanding of procurement as well. They often default to a lot of these organizations that was referred to earlier but I think by having better procurement practices they can make better educated buyers and that is the whole chain.

I am going to add one more thing though. It is not just buying the end product, if we pay more for a generic, we could see, it is about economic rents along the way, right, so if you look at maybe a KSM supplier, they make three-to five-percent profitability. Maybe an API, three-to five-percent profitability. Distributors make what, one or two percent? Then all of a sudden it is a big leap when you look at the PBMs, GPOS, et cetera.

What we don't want is to raise the price and they simply capture the economic rents. We have to understand that when we pay more, it has got to flow back down, so we can have onshoring, friendshoring of some of these capabilities as well. The other part of it is the complexity of the supply chains.

It is not just KSMs and APIs, it is excipients, it is solvents, et cetera, as well, so we need transparency as part of that of purchasing and paying for a little bit more for these products to understand the visibility of all the choke points as well. As was mentioned, China is really good identifying the choke points. It is not just owning the market. It is the choke points that they are owning. We need to understand those choke points.

We also need to own some of those choke points ourselves and that has happened in other—in our Operation Warp Speed we saw lots of choke points that we owned we can use as countermeasures as well. We need to make sure we continue to have those.

The CHAIRMAN. Yes. Every successful business person figures out where their leverage point is, where people need to do business with them, and we have got to do the exact same thing. China has done it, yes?

Mr. HARJIVAN. Actually, these companies are doing what their shareholders want them to do, right, maximize profitability but we just need to change the metrics a little bit so that the patients actually benefit more as well.

The CHAIRMAN. Yes. Now, I when I was in business, I always tried to figure out how to make sure that I was indispensable. You got paid better when you were indispensable. Shocking.

Mr. HARJIVAN. You want to be—I am a pharmacist, but you want to have a monopoly, right and that is what these companies are doing but we are allowing them to have monopolies, the role of the government and policy is to not have monopolies in many industries, including this one.

The CHAIRMAN. Congressman Yoho, you have been vocal about Communist China's use of economic coercion as a foreign policy tool. How does leverage of drugs and APIs compare to what we

have seen with rare earth, or semiconductors in terms of the speed and severity with which Beijing could deploy it against us?

Dr. YOHO. I think you are going to see pharmaceuticals play in there a lot more. I had to wonder when Secretary of State Rubio said they were going to revoke the student visas for 267,000 Chinese students, and about a week or two later, President Trump says: No, we are going to have 600,000. I wonder if there was a backdoor meeting where Xi puts his arm around the President and said: Donald, let us talk about this. You know, we control the drugs here.

Those are the kind of things that could happen. I am not saying it happened, but I don't want to be in that situation. We need to have what is best for America at heart, and we need to be prepared for that and it needs to start five, six years ago but you can't start fast enough and so I think that kind of leverage is something you are going to see. We have already seen them do with the rare earth minerals. They have done it to Japan. They have done it to us and it is only going to ramp up as things escalate.

The CHAIRMAN. There are companies and lobbying interests that benefit from keeping Chinese drug supply chains intact, and resist reshoring efforts as we heard, right? Congressman, you have never been shy about naming those names. Who are the players most invested in maintaining or enforcing the status quo, and how should Congress think about their influence as it considers legislation?

Dr. YOHO. Well, I think your big pharma companies that have the lobbyists that come up here. You know, again, I think those companies ought to be held accountable. If you bring in a tainted drug, I mean, when I was practicing as a veterinarian, melamine was being put into the dog food, killed thousands of dogs, does kidney damage, but there was over 300,000 people in China that was fed to their—in their baby formula and you know, there were a handful of people died, but what about the long-term health risk? You know, chronic—kidney disease and things like that.

I think you need to call people out and say, if you are going to sell this drug into my market, if it is tainted, it goes back to you, and you are going to be 100 percent reliable—or liable for this. It is hard ball, but I think this is time to play hard ball.

I guarantee you if you go to those manufacturers and the CEOs of those c companies and you tell them that these are the new rules, and I think we need to do—really put the pressure on the FDA, but it is going to require legislation so that another administration doesn't waive those FDA rules, if Congress mandates that, and says, this is how these drugs will come into this country, I feel better—I will feel better in the future.

The CHAIRMAN. Ms. Gibson, how has the lack of accountability for foreign manufacturers allowed subpar drugs to enter our market?

Ms. GIBSON. Because they can, and we are buying only on the basis of cost irrespective of quality and if I may, Senator, your question about why is it so hard for the DoD to do the right thing? In 2019, as a private citizen, I had this idea that since so much of our manufacturing base was decimated, I came up with a core of an idea for an executive order, and it is very simple, that is what

China does and that was the DoD, the VA, and HHS should give priority to U.S.-made generics in their procurement process.

Turns out that got into an executive order signed in August 2020. The same day that that executive order came out, there was a press release from the Pharamtrade group, and this was during a pandemic when we were rationing drugs, and the comment was that that—and just for essential drugs—that this would cause chaos, and it would destabilize the global supply chain.

That same year the Generic Trade Association came out with almost the same wording: It would cause instability and two days after that statement came out, the Chinese President at a G20 meeting said, “We have to ensure that global supply chains remain stable.” Is that coincidence or is it coordination? You know, I have been thinking about the speech that former U.S. Attorney General Bill Barr gave in Grand Rapids, Michigan, in 2020, and he explained what goes on. He says that, as you alluded to, that U.S. executives with businesses in China, they are expected by the Chinese Government to lobby for them here in Washington if they want their businesses in China to go smoothly, and if they don’t, it will go the other way.

We have companies here that are lobbying on behalf of China and against the American interests and so that executive order is still active but nothing has been done, and we just need to say this is the directive and it shall be done, and to help them, the different departments actually execute on those executive orders.

The CHAIRMAN. Mr. Chang, you have argued for years that the Chinese Communist Party pursues comprehensive national power through means that Western policymakers consistently underestimate. In that framework, how deliberate and how dangerous is Communist China’s dominance of the global pharmaceutical supply chain?

Mr. CHANG. Mr. Chairman, we know what the Chinese have done with rare earths, and there they don’t even have 100 percent monopolies, so given that their maliciousness, then clearly this is the next item to be concerned—for them to actually weaponize and we can go back and look at the Communist Party’s policies toward the United States. We can see what they say, we can see what they have done and it is malicious and we as Americans have refused to acknowledge that because we have wanted to integrate the Chinese into the international system, we have wanted to get along, and because we are a democracy, we are slow to recognize threats, so that is where we are and so to answer some of the previous questions, as the Congressman has said, we just need to acknowledge the aims of the Chinese regime and deal with it with the determination and vigor that is necessary and one of those things you mentioned where you are talking about accountability, why don’t we make drug makers strictly liable for the damages caused by pharmaceuticals that are manufactured abroad and imported into the United States?

That is not an unreasonable thing to do because we had about 150 Americans die in 2008–2009 because of adulterated heparin that was made in China. We had another problem in 2019 with Zantac and other heartburn medications, so this is a problem that continues, and because we know that the Chinese will weaponize

every point of contact with our society, it is something that we need to do.

If we do this, I think that drug manufacturers are going to shy away from importing from China and they will rush to make in the United States or in jurisdictions where they have confidence, so that is one of the things that we can do too onshore as quickly as possible.

As I mentioned, with regard to Senator Tuberville, there is going to be a period of vulnerability because the Chinese do have this 100 percent monopoly on perhaps 800 pharmaceuticals, and we can't ignore that but we can do all we possibly can in the interim, and that means we have got to move fast.

The CHAIRMAN. Ms. Gibson, when you first began research in China Rx, what was the reaction from the drug industry, from government officials, and from the medical community?

Ms. GIBSON. Denial.

The CHAIRMAN. They weren't accepting, they weren't saying, a good job?

Ms. GIBSON. No there was all this clamoring about: Oh, no, the numbers are wrong. It is not that high and there was a lot of manipulation of that but China Rx was very well researched, and I got the information from the actual manufacturers, the people in the manufacturing plants. They know what is going on. They know where product comes from. They know where they have to get their key starting materials and antibiotics. It doesn't come from the lobby groups and the researchers, so it was absolutely sound.

In fact, right before the pandemic hit home here in early 2020, I was with a group of pharmaceutical engineers, great people with 150 years' experience. I went around the table and said: Okay, so what percentage of our key starting materials for the drugs we need to treat all these people who are going to get sick and be hospitalized? They all said: 90 percent, 95 percent, 90 percent, so that is it.

There was—but you know, what I am really pleased at, Senator, is that now everybody in Washington knows about APIs, and they know that APIs don't fall from the sky, that they are made of key starting materials and where our dependence is, so I consider that partial success but we have such a long way to go.

If I may say something about this product liability issue. You know, if you have to go buy tires for your car and you go to a retailer, and there is 15 percent of those products could blow out while you are going 60 miles an hour on the beltway, the market fixes that. It fixes it through reputational risk, and also product liability and I believe we need to start move, not just from a regulatory point of view, but from a market signaling point of view that this is not acceptable, that you are putting products on that are harming people and we have—you know, arsenic is arsenic, thallium is thallium, you can't debate that, and there was secondary testing to verify these findings for the DoD, so I think we need to send this market signal that this is not acceptable and begin to use those tools.

The CHAIRMAN. Mr. Harjivan, is Communist China moving up the drug chain from generics to brands, and what risk does this pose to our national security and patient access to medications and

I think what you will say is, they are even—they are going further than that. They are the main—they are the main—they own the drug—the brand now too?

Mr. HARJIVAN. Yes. In fact, I would say, you know, the generic industry, it is kind of fungible, right, so it is not like rare earths or semiconductors, you don't need a billion-dollar fab, you don't need to dig up, you know, the earth to get this material. The KSMs and APIs could move pretty quickly if we have the right incentives over here. It is not a supply chain issue, it is a demand issue.

Now, for them moving up the value chain in life sciences, to me, that is an existential threat because they are moving very fast in this area. If you look at the number of, you know, different publications that they have, if you look at their work on gene therapy, look at advanced manufacturing, it is tremendous how quickly they are moving.

What they are doing though, is they are putting the right incentives for those technologies to move ahead at a rapid pace. They are putting in very quick regulatory standards. Sometimes they are not that great, but often it is because they are putting in innovative regulatory standards that actually are of high quality, not poor quality, but they are using innovation around the regulatory standards, which we should adopt.

Around quality, I think there is actual innovation there that can occur as well. When I worked on Operation Warp Speed, we were able to remotely look at manufacturing quality. We didn't have to do inspections necessarily. We could remotely monitor quality. That has advanced a lot in the last five years and so we can reduce the cost and have real-time monitoring of quality.

The big CDMOs do that already. We can require that of China and by the way, India is a big problem here too, we could do that of India as well and so I think there is cheaper solutions. Again, innovation is the key and I am telling you right now that the next 50 years is going to be all about the biology revolution, and if we don't invest right now, it is going to be really important.

I think the other part is, they invest but they are sclerotic, they invest top down, and we have got wonderful flexible capital market here, but we are not leveraging it. We need to leverage it much more efficiently in creating demand mechanisms for these products, for innovation, and then standards. Again, I think we can do it, but we are not focused on that right now, and that is a big problem.

The CHAIRMAN. Ranking Member?

Senator GILLIBRAND. It is okay.

The CHAIRMAN. All right. I want to thank everybody for being here. I think this is—I think this is an unbelievable important issue. I want to thank the Ranking Member for being a partner in this. I am actually optimistic, I actually believe that the American public is getting more informed. I think the Congress is clearly getting more informed, and I think we are going to get something done.

If you take a pill every morning for a chronic condition, there is a very good chance that pill was made using key ingredients from Communist China. There is also a good chance that you, your doctor, your pharmacist, and even the FDA have no way of knowing for certain where the pill ingredients come from, because we don't

require disclosure and by the way, if anybody feels comfortable putting something in their mouth from China, I think they are a fool. The standards in China are despicable whether you—if you are buying food from China, I think it is unsanitary. The conditions where things are produced is horrible.

Unfortunately, Congress has failed to demand transparency, and for 30 years lawmakers have prioritized the lowest possible price over everything else and I think what Mr. Chang said, I think a lot of us—a lot of people thought: Oh, we are going to bring China into the fold and all that stuff. It never happened.

COVID-19 showed us what happens when we do that, and the system breaks. Thirty-seven factories that made ingredients for American medicines shut down and the shortages hit within weeks. The Chinese Government is despicable. They nationalize its own medical supply production and decide who got what based on politics, not need. That was a warning, we didn't take the hint. This hearing is meant to change that.

Our incredible witnesses today made a clear, documented evidence-based case that what we are dealing with is not market inefficiency. It is a national security vulnerability that has been intentionally engineered by an enemy nation, not the People of China, the Government of China, enabled and supported by our own policy failures.

The solutions aren't a mystery, my and Ranking Member Gillibrand's CLEAR LABELS Act is a first step. Soon we will have legislation on closing loopholes in our system and finding ways to support additional domestic manufacturing focused on federal procurement. The seniors of our country didn't create this problem, but they are the ones paying the price and this Committee is committed to fighting for them and for solutions.

If any senators have 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 everybody for being here.

[Whereupon, at 4:40 p.m., the hearing was adjourned.]

APPENDIX

Prepared Witness Statements

U.S. Senate Special Committee on Aging:
Foreign Dependency: How China Captured America's Drug Supply
Chairman Rick Scott, Ranking Member Kristin Gillibrand
G33 Dirksen Senate Office Building
Washington, DC 20510.

Submitted by: Dr. Ted Yoho

March 11, 2026

Foreign Dependence: How China Captured America's Drug Supply, on March 11, 2026, at 3:30 P.M., 216 Hart Senate Office Building.

Thank you, Chairman Scott, and Ranking Member Gillibrand, for this opportunity to address your committee on this extremely important and timely topic. The US population especially seniors should expect the highest quality, effectiveness, and purity in the medicines they consume whether over the counter (OTC) or prescription. The pharmaceutical industry today has many manufacturers and suppliers of OTC drugs in the final dose form (FDF) consumers purchase and consume. Many of these manufacturers for both OTC and prescription drugs are in foreign countries for a variety of reasons making America dependent on another nation. The question is why?

The US Government created a situation over the past decades that drove companies offshore with high taxes, trade policies, and burdensome regulations, along with industry high labor costs. Companies sought an alternative to these factors directed by board rooms seeking higher profits. China acting astutely took advantage of a self-inflicted wound from a combination of overburdensome government policies and the drive for more corporate profits.

China enticed our manufacturers to enter the 1.4-billion-person market with the lure of cheaper taxes and labor costs, less stringent regulations, less oversight in manufacturing from governing agencies, less quality control inspection, and less enforcement of bad actors. But at what cost did these companies pay seeking increased profits? More importantly what cost did the US government and we the consumers pay?

For manufacturers, the cost was high. To do business in China a company must agree to several things. A percentage of your business must be given to a Chinese state owned enterprise (SOE). There are reports of up to 51% ownership, a controlling interest in many cases. A member(s) of the Chinese Communist Party (CCP) must be on the company board to report back to Beijing. The formula for the pharmaceutical product must be revealed if not done willingly China operatives steal it. The company must submit to Chinese regulations, patent, and labor laws. Typically, China copies the product, manufactures it,

and sells it at a price that is non-competitive to American manufacturer's break-even cost thus driving them out of business. The result is China takes control of the supply side of a pharmaceutical and pricing on the world market. This scenario is well documented in Rosemary Gibson's book, "China Rx" (2016). This is bad but not the worse.

To understand the seriousness of having a country controlling a commodity like pharmaceuticals requires knowledge of how a drug is made. The FDF of a drug is composed of key starting materials, (KSM's) and active pharmaceutical ingredients, (API's). USP, Inc. a US company founded over 200 years ago has become the gold standard in setting the standards for pharmaceuticals regarding strength, purity, and effectiveness of a manufactured drug. The manufacturing process is regulated and monitored by the US's Food and Drug Agency, (FDA), in all countries that manufacture drugs for the US market including our military to ensure the products consumers take are pure and unadulterated. The FDA has the authority to show up unannounced 24/7, (hours/days), to inspect a US manufacturing facility and the manufacture must comply or be shutdown.

In China as in the US, the FDA sets good manufacturing practice standards (GMP). Until recently the FDA would go to the foreign country set the standard and allow that country to self-inspect and monitor manufacturing with occasional pre-announced follow up inspections. This is synonymous with the fox watching the hen house resulting in many drugs' US consumers take being inferior in quality and often adulterated with unapproved reagents, solvents, and other ingredients known to be harmful causing illness, cancers, and death for both human and animals.

These toxic products are well documented. I personally experienced this in 2007 when practicing as a veterinarian. Chinese manufacturers were adding melamine to dog foods to increase the protein content of the product. Melamine is an industrial chemical used in production of plastics, fertilizers, and flame retardants, is inexpensive, and has a high nitrogen content. By itself it's not overly toxic but when mixed with cyanuric acid it is extremely toxic to the kidneys. It forms urinary crystals in the tubules of the kidneys leading to irreversible kidney damage. Thousands of pets died around the country. Testing methods to measure nitrogen content which equates to protein content does not pick this adulteration up.

There are many cases of adulterated products affecting people. In 2008 powdered milk was found to contain melamine causing kidney stones in over 300,000 infants. This powdered milk was also found in Chinese produced candies, along with Nestle's, Cadbury's and Unilever products as well. This is done solely for profit, i.e., higher protein content equals higher profits.

China's lack of following GMP and oversight extends beyond foods it extends heavily to exported medicines that are sold in the US. Many cases of toxic and cancer-causing ingredients are found in medications are well documented and poses a significant national health risk. Products tainted with N- Dimethyl nitrosamine (NDMA) a component of rocket fuel, have shown up frequently in sartan's a class of drugs that regulates blood pressure like valsartan, losartan, and ibesartan and statins drugs used to lower cholesterol. Both classes of adulterated drugs are taken by millions of Americans daily. Nitrazine, a synthetic opioid many times more potent and addictive the fentanyl is produce by unregulated Chinese chemical shops, shipped to the US killing thousands of Americans yearly. In addition, China has shown a willingness to short a product to drive up costs or limit supplies for the own use. This was clear during the covid pandemic where they supplied their population first with critical medicines needed to treat sick patients. This leaves the US and other countries vulnerable to communist China's control of the worlds pharmaceutical manufacturing, pricing, and supply. Many more examples of tainted drugs can be given and will continue until we change policies toward imported pharmaceuticals.

Solutions:

The US should use tariffs on foreign produced pharmaceuticals inciting manufacturers to produce drugs in the US including KSM's, API's and FDF at all stages. Congress needs to pass legislation that requires any country wanting to sell pharmaceuticals to the US market to abide by the FDA's 24 hour/7days unannounced inspections and testing of drugs. Foreign manufactures must follow USP, Inc. good standard for quality, purity, and effectiveness. There can be no exceptions. All medicines used by our military domestically or abroad must be US produced or meet FDA standards. The FDA must stop relaxing standards when drugs are shorted. By relaxing standards is knowingly allowing substandard products to be consumed by Americans which will have more impact on our seniors because that population generally consumes more medications than the general population. Would anyone of us knowingly give a product that was toxic to our child or grandparent? So why would we tolerate this for any American?

Conclusion:

Our nation cannot be secure with another nation controlling our pharmaceutical supply chain that is willing to leverage that against the United States. China has control of 30-100% of the FDF or ingredients that produce KSM's and API's. China controls 80% of the drugs the US military is reliant upon. A nation cannot be healthy if the very products they consume are adulterated with toxic, inferior quality components or not clinically effective. China controls the vitamins and mineral supplements that people consume and goes into our livestock feed. It is imperative for the security and health of the US and its citizens that we rebuild a domestic pharmaceutical, food, vitamin, and mineral supply chain.

Thank you,

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Testimony of Gordon G. Chang
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Presented before the
United States Senate Special Committee on Aging
Hearing on
“Foreign Dependence: How China Captured America’s Drug Supply”
March 11, 2026
SH-216

Healthcare is best left to the market, but as China weaponizes trade—and continually threatens war—it’s clear that Washington has to temporarily implement non-market solutions to ensure that Americans have access to the medicines they need. In short, America has to quickly onshore production.

The challenge for the U.S. will be, in this rapidly deteriorating global environment, finding the correct combination of coercive state action, public subsidies, and free-market incentives.

China at the moment has monopolies and near monopolies on many pharmaceuticals. There are, for instance, about 100 drugs that require ingredients only made in one Chinese factory.¹

India, “the other heavyweight generic drug producer,” gets about 80% of its APIs—active pharmaceutical ingredients, the building blocks for pharmaceuticals—from Chinese factories. Approximately 45% of key starting materials or KSMs, the building blocks for APIs, are made only in China.²

For brand-name pharmaceuticals, the U.S. makes 15% of its APIs. For generics, the figure is far less. Overall, the U.S. produces just 12% of its own APIs.³

Generics are especially important: They account for about 91% of all prescriptions filled in the U.S. More than 40% of generic drugs prescribed in America have just one manufacturer. Some 83% of the top 100 generic drugs consumed by Americans have no U.S.-manufactured APIs.⁴

An October 2025 report issued by United States Pharmacopeia, an industry standards body, reveals that China is the only supplier of at least one KSM for 679 APIs.⁵

The Defense Department in 2023 learned that up to 27% of all drugs the U.S. military purchased were “100% dependent” on Chinese APIs.⁶

Antibiotics are a particular U.S. vulnerability. Amoxicillin, the most widely used of them in America, is made from four separate KSMs that are produced almost entirely in China.⁷ America gets about 45% of its imported penicillin from Chinese factories.⁸ Around 90% of the APIs for antibiotics used worldwide come from that country.⁹

FDA officials have admitted that the agency has allowed into the United States drugs from non-compliant facilities in foreign countries because the enforcement of standards would result in shortages of needed pharmaceuticals.¹⁰

America's vulnerability is dangerous. "If you're the Chinese and you want to really just destroy us, just stop sending us antibiotics," said Gary Cohn, director of the National Economic Council in the first Trump administration.¹¹ "There's a dereliction of duty," Maria Bartiromo, the Fox Business Network anchor, said on air in October. She urged President Trump to "start putting a fire under corporate America's butt" and "to say 'get your supply chains to America, this is a national security issue.'"¹²

As Ben Noon, an American national security analyst, recently wrote, China has a "pharma death grip" on America.¹³

Some argue that China believes it cannot, as a practical matter, shut down the pharmaceutical supply to America. Yanzhong Huang of the Council on Foreign Relations, although admitting there is a "real possibility" of China employing this weapon, nonetheless points out that Beijing is deterred by the prospect of retaliation, for instance, America denying the Chinese advanced cancer treatments. Moreover, Beijing, he notes, would be cutting off an important revenue stream.¹⁴

Yet there are reasons why China just might employ the "nuclear option," as Melanie Hart, a Biden State Department official now at the Atlantic Council's Global China Hub, told Bloomberg.¹⁵

For one thing, China has already tried something similar. China placed export restrictions on rare earth elements over trade negotiations before, so they might do the same thing for pharmaceuticals.¹⁶

In September 2010, for instance, China's regime imposed a rare earth export ban on Japan following an incident in the East China Sea, where Beijing and Tokyo have competing territorial claims. In October 2025, China's Ministry of Commerce announced substantially tightened rare-earth restrictions on the U.S. in the middle of a "tariff war," imposing "the strictest rare earth and permanent magnet export controls to date."¹⁷

Moreover, Beijing has started employing export restrictions that affect the medical field, Bloomberg reported. China, for example, in April of last year put in place curbs on seven metals needed for magnets for MRI scanners and then in October hit thulium, erbium, and three other elements used in medical lasers.¹⁸

And China has already shown the world that it is perfectly capable of cutting off health-care supplies. In March 2020, Beijing threatened to throw America into a “mighty sea of coronavirus.”¹⁹ “China put export restrictions on those masks and then nationalized an American factory that produces them there,” Peter Navarro, Trump’s director of Trade and Manufacturing Policy, reported in February 2020, referring to the then-coveted N95 masks.²⁰

“I was on the phone with leaders from several hospitals in New York, and they told me that they had contracts with Chinese companies where they were waiting on things like plastic gloves, masks, all of this stuff where they were on the ships on their way to the U.S. and the Chinese government said ‘no, no, no, no, turn around, we need this stuff,’” Maria Bartiromo said on air in February of that year. “They’re not keeping up with any of the contracts that they had in place because there are massive shortages in China. They want all of these things, even if they have these contracts with players in the United States. How is anybody going to trust China in terms of keeping up their end of the bargain again in business?”²¹

The risk of China stopping the flow of prescription medicines to Americans, therefore, is not theoretical, and the consequences could be grave. “If China shut the door on exports of medicines and their key ingredients and raw material, U.S. hospitals and military hospitals and clinics would cease to function within months, if not days,” said Rosemary Gibson, co-author of *China Rx: Exposing the Risks of America’s Dependence on China for Medicine*, to NBC News.²²

A deliberate cut-off is not the only risk. “They can sell us medicines without any medicine in them,” Gibson pointed out, referring to the Chinese. “They can sell medicines that have lethal contaminants in it.”²³ Perhaps as many as 150 Americans died from contaminated blood thinner Heparin, made in China, at the end of the first decade of this century. In 2019, the FDA warned that Zantac and other over-the counter heartburn medications as well as prescribed drugs contained N-nitrosodimethylamine, a carcinogen, in quantities above those deemed safe by federal officials. The chemical, commonly known as NDMA, was manufactured in China.²⁴

So what does the United States do to reshore the production of pharmaceuticals?

There are a number of technical fixes. The U.S., for example, should establish a “federal buyer’s market” and prioritize American-made products for, among others, the Pentagon, the Veterans Administration, and Medicare. If American-made medicines are not available, the government should try to buy those produced in friendly countries. Congress should require sellers to disclose country of origin, and it’s necessary to close loopholes that now allow foreign-made products to be labeled “Made in America.” It’s time to eliminate the FDA’s red tape, which unnecessarily delays approvals and increases costs.

Congress must also ban the importation of medicines that are either uninspected or inadequately inspected. Moreover, it is way past time for presidents to enforce Section 307 of the Tariff Act of 1930, which prohibits the importation of goods made with forced labor. Both of these actions will help eliminate China's unfair cost advantages.

Ultimately, cost is the name of the game. "Beijing suffocates foreign competitors with low prices by flooding markets with an artificially high supply," reports Noon.²⁵ As Gibson told the U.S.-China Economic and Security Review Commission, "Chinese companies formed a cartel, colluded to sell product on the global market at below market price, and drove all U.S., European, and Indian producers out of business." Then, as she reported, Chinese producers raised prices.²⁶

That Chinese policy was extraordinarily successful, but Washington can retaliate by restarting domestic production with incentives, such as low-cost loans—the first Trump administration experimented with this approach with a proposed \$765 million loan to Eastman Kodak in 2020 to make APIs²⁷—and, more important, an enhanced investment tax credit.

These incentives will work best behind a temporary tariff wall. Even after the historic decision in *Learning Resources, Inc. v. Trump*, which invalidated the President's tariffs under the International Emergency Economic Powers Act of 1977, Trump still has ample authority to impose tariffs to protect domestic pharma manufacturers, especially Section 301 of the Trade Act of 1974 and Section 232 of the Trade Expansion Act of 1962.

The U.S. Department of Commerce on April 1, 2025 announced the initiation of an investigation, pursuant to Section 232, to determine whether imports of pharmaceuticals and pharmaceutical ingredients threatened national security. Trump announced 100% tariffs in September on branded and patented drugs,²⁸ but no tariffs have yet been imposed. There are reports that the White House is using the threat of these measures to get producers to, among other things, onshore production.²⁹

Tariffs in general carry disadvantages. "Tariffs create supply chain disruptions, increase costs, and adversely impact patient access," wrote four academics and researchers in the *Journal of Managed Care & Specialty Pharmacy* last May. "Uncertainty in the capital markets would negatively affect future investments in new treatments. Patients may experience increased costs through higher prices, insurance premiums, and taxes."

"Collaborative international policies, rather than punitive tariffs, may better serve US interests and lead to a more secure and consistent domestic supply of medicines," these authors write.³⁰ Yet obtaining that collaboration will be hard. The pharma industry is still outsourcing to China, evident from the January announcement that AstraZeneca has committed \$15 billion to that country "to expand medicines manufacturing and R&D."³¹

U.S. manufacturers would feel confident of moving production to American soil if they felt sure that Washington was fully committed to protecting them from vicious Chinese price tactics.

Rosemary Gibson believes that Washington, to reshore the pharma industry, must be as determined as China has been throughout the decades to make medicines on its own soil.³² Unfortunately, this means the Trump administration will have to rely, at least in the short term, on coercive measures, especially tariffs.

Chairman Scott has urged the Commerce Department to consider “the immediate application of Section 232 tariffs on foreign generic medicines,” including their ingredients. In the alternative, he has urged Commerce to make “at a minimum, a public commitment to a phased-in tariff regime that places generics on the same tariff footing as other imported pharmaceuticals within 12 months.”³³

The trick will be removing tariffs and other government-distorting elements quickly, so that the pharma industry does not become a permanent ward of the state. Reshoring will inevitably increase costs, which may be bearable given the situation but which is an ill-effect that must be remedied longer term. In the long run, there is no doubt that market incentives are the best solutions.

In any event, the best way to protect the free trade architecture—in other words, the best way to keep popular support for the general concept—is to ensure that predatory traders, such as China, are not allowed to permanently game the system. Unfortunately, unilateral coercive measures are the only thing that Beijing understands at this moment, especially when the World Trade Organization’s dispute-resolution system has proven, over the course of decades, to be incapable of enforcing the organization’s rules. Coercive measures impose the costs that defend that now-fragile system.

In the meantime, Americans are at risk. “It is UNACCEPTABLE that the most advanced country in the world can’t ensure a steady, safe supply of basic medicines for its own citizens,” Chairman Scott said last November.³⁴

It is unacceptable in peacetime, and it’s especially unacceptable as the world now heads toward more troubled times.

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Testimony of Rosemary Gibson
Author, China Rx: Exposing the Risks of America's Dependence
on China for Medicine
Before the United States Senate Special Committee on Aging
Hearing on Foreign Dependence: How China Captured America's Drug Supply
March 11, 2026

Introduction

Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee, thank you for the opportunity to testify on a matter that affects health of all Americans and our national security.

My name is Rosemary Gibson, author of China Rx, the first publication to expose U.S. dependence on China for medicines and the critical inputs to make them. As in China Rx, my remarks today focus on generic medicines which are 90 percent of drugs dispensed and the workhorse in the U.S. health care system.

U.S. Dependence on China for Medicines Has Increased

China controls approximately 90 percent of the *global* supply of key starting materials (KSMs) to make active pharmaceutical ingredients (API) in generic drugs. This highly centralized system is perfectly designed for catastrophic failure.

If China banned exports, within months the U.S. health care system would cease to function.

China's aim is to disrupt, dominate and displace U.S. advanced industries including pharmaceuticals to maximize U.S. dependence and achieve maximum economic and political leverage to dictate U.S. policy.

A June 2025 statement from within China noted, "If China really decides to take restrictive measures in the field of pharmaceutical raw material, the impact on the U.S. will be much more serious than rare earth controls."

Even as China's intention is crystal clear, U.S. dependence on China continues to rise. Here are two examples. In 2018, China Rx exposed that the U.S. has virtually no domestic production to make antibiotics end-to-end from raw material to pills. Eight years later, China's share of key starting materials to make amoxicillin and ampicillin jumped from 60% to 80% from 2018 to 2024. More recently, China reduced its price of the key starting material by nearly 40% in early 2025 with the likely aim of undercutting other global producers.

The Veterans Administration (VA) has become more dependent on China. It had been procuring medicines according to the Trade Agreements Act (TAA) which requires the VA to source drugs from TAA-compliant countries. China and India are non-compliant countries. In a sudden shift in April 2016, the VA announced that drugs made in China and India would be procured. There appeared to be no mention of Congress amending the law. An internet search uncovered a 2013 strategy paper that was prepared by a Washington, D.C. law firm apparently with offices in

China as part of a coalition of companies including brand-name and generic pharmaceutical firms that sell products to the federal government. The strategy identified tactics that appeared to be aimed at undermining the intent of Congress and to make the case for the VA to buy generics from China and India. The strategy worked and America's veterans were thrown under the bus.

How China Captured the U.S. Drug Supply -- and How the U.S. Gave It Away

While the subject of today's hearing is how China captured the U.S. drug supply, it is useful to consider how the U.S. government and industry allowed China to take it. The answer is this: they gave it away. We gave away production capacity built by the ingenuity of brilliant American pharmaceutical chemists and engineers so, as a country, we could take care of each other when we got sick. It is the duty of government to ensure this.

Having worked in the health care sector for several decades, and while writing *China Rx*, it made no sense that we were dismantling the U.S. industrial base to make life-saving antibiotics and other basic medicines.

In the interest of rebuilding this capacity, as a private citizen in 2019, without any affiliations with special interests, I drafted an idea for an executive order. It would require the federal government to give priority in procurement to domestic manufacturers. This is what China does. It buys from its own companies. I had no political connections but the idea gained attention in the middle of a pandemic and became a core of an Executive Order signed on August 6, 2020.

That same day, the pharma lobby group came out against the Executive Order saying it would "create chaos" and put the "stability of the pharmaceutical supply chain at risk." Common sense would suggest that *more* domestic production capacity would bring greater stability in the middle of a pandemic when medicines were being rationed.

Similarly that year, the U.S. generic drug lobby circulated a draft letter for the White House saying U.S. production of generics would "destabilize the medicines supply chain." Coincidentally, shortly after that during a virtual G20 meeting, the president of China reportedly used a similar talking point, saying global supply chains need to "remain stable."

The truth is that the only stability that might be mildly impacted, if at all, is China's grip on the U.S. medicine supply. After all, it is clear that China's aim is to make the U.S. dependent and keep it that way.

On July 17, 2020, then-U.S. Attorney General Bill Barr gave a speech in Grand Rapids, Michigan that may explain why so little progress has been made to return antibiotic and other essential drug manufacturing to the U.S.

"The Justice Department has seen more and more PRC officials and their proxies reaching out to corporate leaders and ...their pitch is generally the same: the businessperson has economic interests in China, and there is a suggestion that things will go better (or worse) for them depending on their response to the PRC's request. Privately pressuring or courting American corporate leaders to promote policies (favorable to China) presents a significant threat because hiding behind American voices allows the

Chinese government to elevate its influence campaigns and put a “friendly face” on pro-regime policies.”

In sum, special interests in Washington lobby for China’s interests rather than the interests of Americans so they can have a smoother ride for their businesses in China.

The consequences extend way beyond supply chains and adversely affect the quality of generic medicines and the health and well-being of Americans.

Generic Drug Quality Test Results

China Rx predicted that the FDA’s ability to perform its regulatory functions in China would diminish. This prediction has come true.

Because of growing concerns about the FDA’s ability to assure the quality of generic drugs, the Department of War launched a generic drug testing program to test 42 drugs. The aim is to use the data to make procurement decisions. To date, 13 medicines have been tested, and secondary testing has been conducted by multiple labs to validate findings. For each medicine, products from all manufacturers and repackagers are tested.

Fifteen percent of the generics tested have serious manufacturing defects. Table 1 shows results for a subset of the generics tested to date (Source: Valisure).

Table 1: Department of War Generic Drug Testing Program: Sample Results

Drug	Disease Treated	Green	Yellow	Red	Primary Reason for “Reds”
Vancomycin	Infection (antibiotic)	20	0	1	Toxin: Arsenic
Tacrolimus	Organ transplant	4	4	4	Fast Dissolution
Potassium chloride	Hypokalemia	15	3	4	Toxins: Lead, Thallium
Metformin	Type II diabetes	20	7	3	Carcinogen: DMF
Metoprolol	High blood pressure, heart failure	11	5	2	Slow Dissolution

Key findings include:

- thallium, known as the poisoner’s poison, was found in potassium chloride
- tacrolimus, a drug to prevent organ rejection after heart, kidney and other transplants, failed dissolution testing and dissolved too quickly, leaving little therapeutic benefit in

the latter part of the dosage period. Respected cardiologists believe that patients have died because of poorly manufactured generics

- a drug for heart failure and chest pain, metoprolol, was found to dissolve too slowly which can trigger repeated hospital admissions
- high levels of arsenic were found in a common blood pressure medicine
- high levels of carcinogens were found in a diabetes drug, metformin

FDA faces resistance from countries and manufacturers that choose to not comply with U.S. law designed to ensure the quality of the nation's medicine supply.

In testimony before the House Appropriations Committee on the FDA budget in March 2023, then-FDA Commissioner, Dr. Robert Califf, said the following when asked about "red flags" regarding China:

"Relying on China is a problem because it's opaque. Even if we do periodic inspections it is not enough because China is not transparent, it's not the same. I am very concerned about it. We have a lack of access to information from China. We have to be independent. We cannot allow ourselves to be dependent on China -- for all commodities including food."

Further hindering FDA's ability to protect the public is China's anti-espionage law which became effective in 2023. Foreigners can be detained for unspecified national security reasons. Pharmaceutical company executives have been detained. In Germany, where the trade press is more transparent than in the U.S., drug regulators admitted they are very concerned about sending inspectors to China due to the law. This prevents German regulators from performing their functions to assure the quality of the medicine supply.

The message is clear. Now that China's grip on the U.S. medicine supply is so substantial, it has the leverage to tell the U.S. that it doesn't need to follow its law. This portends an increase in the number of substandard generics flooding into the U.S. and increased harm to Americans.

Country-of-Origin Labeling

For decades, the pharmaceutical industry has tried to hide where generics are made because Americans tend to trust drugs made in the U.S. and are wary of medicines made in China and some other countries.

In 2008, a country-of-origin labeling bill was introduced in Congress to provide the public with information on where each active and inactive ingredient was made. The bill disappeared quickly. An industry insider quoted in China Rx said, "They (industry) realized what a firestorm it would create. If I'm a pharma company, I'm thinking it isn't good for my business for people to know."

The federal appeals court decision in 2020, Acetris Health vs. United States, cemented the industry's attempt to blackout the truth. The court ruled that drugs previously labeled "made in China" with 100% foreign content can now be labeled "made in the U.S." if the final tablet making occurs here.

Notably, the law firm representing the generic drug company in the Acetris case has the same name as the firm that prepared the 2013 strategy paper that led to the VA suddenly announcing it would buy generics from previously TAA non-compliant countries, China and India. The

strategy paper further noted that “the ideal solution is for Customs to reconsider its view regarding the transformation of bulk pharmaceutical chemicals into FDA approved products.” Seven years later, in the middle of a pandemic and lockdowns, Customs law was discarded by a federal court.

Recommendations

In 1962, President John F. Kennedy signed into law provisions that gave the FDA more authority to ensure the quality of drug manufacturing. At that time, most drugs were manufactured in the U.S. and other western countries. Now, with global supply chains, it is necessary to strengthen protections to ensure domestic production of the most essential drugs and that all drugs are manufactured according to U.S. standards.

Federal government departments including the Department of Health and Human Services, the VA, and Department of War should be directed to give priority to procuring the most essential generic medicines from domestic producers of finished drugs and their critical inputs using quality and national security criteria as well as cost.

Federal government procurement of generic drugs is typically a race-to-the-bottom on price irrespective of quality. Ethical manufacturers with a track record of uncompromising quality are too often bypassed in favor of companies with a history of recalls, warning letters, and manufacturing defects because price is the sole metric. The marginal difference in cost can be as little as 25 cents more for a 30-day dose. Marginal cost increases would be offset in part by additional federal tax revenues from more working Americans in U.S. manufacturing plants who would pay federal income tax (the multiplier effect).

Invest in antibiotic infrastructure to reshore end-to-end antibiotic manufacturing.

Targeted investments, awards, and partnerships similar to those used to reshore critical minerals are essential to fix a vulnerability of epic proportion: the absence of domestic end-to-end antibiotic production to enable self-sufficiency to treat infectious disease and be prepared for a widespread infectious disease outbreak caused by nature or an adversary.

Expand generic drug quality testing to inform federal government procurement decisions and strengthen health security and national security.

Generic drug test results can guide procurement decisions and will, for the first time, send a signal to the marketplace that taxpayer dollars will not be used to buy medicines that don't work and contain toxins. With regard to national security, medicines produced by an adversary can be weaponized. They can be made with lethal contaminants or sold without any real medicine in them, rendering them ineffective.

Hold U.S. companies that source generics accountable for quality.

A handful of U.S. companies source generics by scouring the world to find the cheapest products irrespective of quality. Generic drug quality testing can be used to inform decision making upstream in the procurement process and hold companies accountable for sourcing toxic and harmful drugs.

The country-of-origin of a drug and its API is essential information for consumers, HHS, VA, and the military to make informed purchasing decisions.

The Clear Labels Act brings welcome transparency on where a drug and its API are manufactured. If API transparency is dropped from the bill due to industry opposition, labeling only the finished drug would codify the Acetris decision into law. As a result, a drug with 100% foreign content that was once labeled “Made in China” would be labeled “Made in the U.S.” This would be deceptive labeling.

Conclusion

Chairman Scott, Ranking Member Gillibrand, and members of the Committee, thank you for your leadership in addressing a threat to our health and way of life. The generic drug testing team would welcome the opportunity to brief Committee members on the results for all 13 generics, testing methods, and next steps.

Foreign Dependence: How China Captured America’s Drug Supply — and How the U.S. and Democratic Allies Can Lead the Next 50 Years of Life Sciences

Submitted by: Dr. Chan Harjivan

Written testimony submitted by the author for the hearing record of the U.S. Senate Special Committee on Aging[1].

Chairman Rick Scott[2], Ranking Member Kirsten Gillibrand[3], and Members of the Committee: thank you for the opportunity to submit testimony for the record on the strategic risks created by America’s dependence on foreign life-sciences supply chains—especially those tied to the People’s Republic of China[4]—and on the policy architecture needed for the United States and democratic allies to lead the next half-century of life sciences. [5]

This testimony is written in the style of a final, standalone document. Where precise, product-level sourcing or cost data are not publicly available (a recurring problem in this domain), I explicitly note the data gap and provide bounded ranges with clear assumptions. [6]

Executive Summary

America’s drug-supply vulnerability is not a single statistic; it is a systems outcome. Over decades, market design (especially in mature generics), procurement practices that reward the lowest price, and a global regulatory architecture that often lacks true inspection parity pushed manufacturing offshore—first upstream (chemical precursors, key starting materials, and active pharmaceutical ingredients), and then downstream into finished dosages. This produced a supply chain that can look “diversified” at the final label and still be dangerously concentrated at the upstream layers that actually determine resilience. [7]

Three hard facts should anchor the hearing record.

First, generic drugs dominate U.S. use (91% of prescriptions), but the U.S. has allowed the industrial base behind generics to erode sharply. The Committee’s bipartisan staff report states that since 2002, pharmaceuticals manufactured in the U.S. dropped by 46 percent, and that in 2024 the U.S. manufactured 37% of the pharmaceuticals it consumed (down from 83% in 2002). [8]

Second, exposure is greatest where the public has the least visibility: upstream. The Food and Drug Administration[9] testified that as of August 2019 only 28% of API-manufacturing facilities supplying the U.S. market were in the U.S.; 72% were overseas and 13% were in China. [10] The Committee’s report further highlights that the U.S. government has limited information about key starting material (KSM) supply chains because of confidentiality

practices, and that over 40% of generic drugs sold in the U.S. have a single manufacturer—two features that convert normal disruptions into acute shortages. [11]

Third, the national-security dimension is no longer theoretical. The Department of Defense[12]’s FY2023 pharmaceutical supply chain assessment analyzed 1,744 drug families (12,917 NDCs) and found that 22% had unknown API origin; 54% of the DoD pharmaceutical supply chain was rated high or very high risk due to reliance on non-Trade Agreements Act sources (including China and India) or unknown sourcing. [13]

The policy conclusion is straightforward: the U.S. needs a “resilience-by-design” life-sciences strategy that simultaneously (1) hardens essential-drug supply chains and (2) positions the U.S. and democratic allies to win the next 50 years of life sciences—where clinical trial speed, biomanufacturing scale, AI-enabled discovery, and trusted data governance will determine strategic advantage. [14]

This strategy should be built around seven mutually reinforcing pillars:

A federal buyer and payer architecture that rewards reliability and trusted sourcing (not just the lowest price), using defense procurement as a pilot and Medicare as a scale lever. [15]

Full-stack transparency: finished dose, API, and KSM origin disclosure at lot-level (or the closest feasible proxy), with secure but actionable access for government risk analytics. [16]

Targeted reshoring for the most brittle upstream nodes (including fermentation-based antibiotics and selected sterile injectables), complemented by friend-shoring with democratic allies rather than unattainable autarky. [17]

Strategic stockpiles designed for the upstream reality (APIs and—where feasible—KSMs), aligned with the federal government’s new Strategic Active Pharmaceutical Ingredients Reserve (SAPIR) direction and paired with advanced manufacturing capacity to “replenish, not just store.” [18]

Regulatory modernization: inspection parity tools, risk-based testing, and accelerated pathways for domestically (or trusted-ally) manufactured generics and essential medicines—while maintaining quality floors and avoiding “speed over safety.” [19]

A democratic-life-sciences alliance agenda: harmonized standards, coordinated essential-medicine lists, shared surge manufacturing, and joint investment in the critical inputs (chemicals, reagents, single-use bioprocessing components) that underpin both drugs and the broader bioeconomy. [20]

A 50-year innovation posture: trusted biomedical data ecosystems, competitive clinical trial infrastructure, workforce, and commercialization pathways that prevent technology and manufacturing leadership from migrating to China’s increasingly integrated life-sciences stack. [21]

Purpose and Scope

The Committee’s hearing title—“Foreign Dependence: How China Captured America’s Drug Supply”—is accurate but incomplete. China did not merely “capture” finished drugs; the deeper capture is upstream (KSMs, intermediates, APIs, chemical ecosystems), and the broader strategic contest is life sciences as an integrated national capability—including discovery, clinical trials, advanced manufacturing, and data-intensive biology. [22]

Accordingly, this testimony covers two connected domains.

Domain one: essential medicines (especially mature generics and hospital-administered injectables), where supply disruptions harm seniors disproportionately and where procurement dynamics drive fragility. [23]

Domain two: “life sciences overall”—biopharmaceutical innovation, biologics and advanced therapies manufacturing, diagnostics, and the enabling infrastructure (AI, genomics, biosecurity, and capital formation) that will shape prosperity and security for decades. China’s current trajectory suggests it is rapidly closing gaps in clinical development and scaling “bioeconomy” capabilities as a strategic priority. [24]

A key methodological note: There is no single authoritative public dataset that maps drug supply chains from KSM to API to finished dosage for all products sold in the U.S. The DoD report, the Committee’s staff report, FDA facility counts, and selected industry analyses provide partial slices; they do not fully resolve volume shares at each tier. This “data opacity” is not incidental. It is itself one of the vulnerabilities policy must fix. [25]

Timeline of Dependence and Today’s Exposure

The most important timeline is not a list of scandals; it is the cumulative policy and market structure that created incentives to offshore.

In 1984, the Hatch–Waxman Act accelerated generic entry and drove large consumer savings, but it also intensified price competition in mature markets. Over time, many products became “race to the bottom” commodities where reliability and quality investments are poorly rewarded. The Food and Drug Administration[9]’s Drug Shortages Task Force report (2019) identifies core drivers consistent with this: weak incentives to produce low-margin products, limited market recognition of mature quality systems, and regulatory/logistical challenges in recovering after disruption. [26]

In the 1990s and 2000s, upstream chemical synthesis and fermentation migrated toward lower-cost and cluster-based production in Asia. By August 2019, FDA testified that only 28% of API manufacturing facilities supplying the U.S. market were domestic; 72% were overseas and 13% were in China. [10]

By the 2010s, the growth signal is visible in regulatory “plumbing”: Drug Master File (DMF) activity for active API shifted heavily toward India and China. The Committee’s report cites

that by 2021, India and China together represented 85% of active API DMF filings (India 62%, China 23%), while the U.S. and Europe declined to 4% and 7% respectively. A Duke analysis similarly notes that in 2021, 62% of new API DMFs were submitted from India and 23% from China, and notes that DMFs are a proxy and do not capture production volume. [27]

The COVID-19 period stress-tested the system and revealed that “finished dose” diversification can mask upstream concentration. In 2025, the White House issued an Executive Order directing Administration for Strategic Preparedness and Response[28] to fill the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR) with a six-month supply of APIs for roughly 26 “critical drugs,” and to update and develop a plan for a broader list of essential medicines. [29]

Parallel policy tools began to converge:

Defense procurement: The FY2025 Senate NDAA bill text includes Section 887 creating 10 U.S.C. § 4865, restricting DoD procurement of listed generic drugs unless they are manufactured in the U.S. and use U.S. or Trade Agreements Act–designated-country APIs and KSMs, with an availability waiver and a requirement to develop a “defense-relevant generic drug list.” [30]

Medicare incentives: In January 2026, [Entity] organization, "Centers for Medicare & Medicaid Services", "u.s. medicare agency"] Issued an ANPRM seeking public input on a “Secure American Medical Supplies” designation and possible payment approaches to offset the added costs of domestic procurement for PPE and “essential medicines,” defining “essential medicines” as the 86 medicines prioritized in the 2022 ASPR resilience assessment. [31]

Trade: In April 2025, the U.S. Department of Commerce[32] initiated a Section 232 national security investigation on imports of pharmaceuticals and pharmaceutical ingredients, including finished drugs, medical countermeasures, APIs, KSMs, and derivative products. [33]

The result is a policy moment in which procurement, payment, and trade tools can be aligned—if Congress and the executive branch choose coherence over single-lever fixes. [34]

Timeline chart

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timeline
    title Key milestones in U.S. drug and life-sciences dependence (selected)
    1984 : Hatch-Waxman accelerates generics and price competition
    2008 : Heparin contamination crisis highlights upstream opacity and quality risk
    2010-2019 : API facilities supplying U.S. market shift overseas; China share rises
    2019 : FDA Drug Shortages Task Force identifies structural shortage drivers
    2023 : DoD analyzes 1,744 drug families; reveals high risk and unknown API
  
```

origins

2025 : EO 14293 targets regulatory relief for domestic critical medicines manufacturing

2025 : EO 14336 directs filling SAPIR and building 6-month API reserves

2025 : Section 232 investigation initiated on pharmaceuticals and

ingredients

2026 : CMS ANPRM explores Medicare incentives for domestic essential-medicine procurement

The heparin crisis is documented by both peer-reviewed epidemiological investigation and FDA safety communications; DoD's supply-chain analysis and the executive and Medicare actions are official U.S. government documents. [35]

Vulnerabilities and Risks

Supply-chain vulnerability is best understood as a set of compounding fragilities. Several are worth elevating into the hearing record because they are actionable.

Single-source and geographic concentration: When a product has one qualified manufacturer, or when multiple manufacturers are clustered in a single region, even minor disruptions can cascade. The Committee report notes that over 40% of generic drugs sold in the U.S. have only one manufacturer. [11]

Opacity at the KSM layer: The Committee report states the U.S. government has limited information about KSM supply chains due to confidentiality practices, making upstream risk hard to assess and mitigate. The DoD report goes further and recommends compelling manufacturers to provide the FDA definitive information on finished drug production location and the sources (and percentages) of APIs and key ingredients, and then storing that data in a repository available to federal stakeholders. [36]

Quality, inspection parity, and regulatory gaps: A globalized supply chain is not inherently unsafe, but it is harder to oversee. The Government Accountability Office[37] has repeatedly highlighted persistent challenges in FDA's foreign inspection program, including issues that recur in inspection workforce capacity and the practical obstacles of foreign inspections. [38] The policy risk is not only "bad actors"; it is a system where purchasers often cannot observe quality differences, so low price dominates. The Committee report explicitly connects purchasers' limited quality information to a market that favors the lowest price, creating incentives to underinvest in mature quality management. [39]

Public health harm from quality variation: A peer-reviewed 2025 empirical analysis (cited by the Committee report) finds substantially higher rates of serious adverse events for generic drugs manufactured in India compared with equivalent U.S.-manufactured generics, with "serious" defined as hospitalization, disability, or death. This does not mean all Indian manufacturing is unsafe; it means manufacturing location can correlate with observable quality outcomes in mature, low-margin products and that policy should reflect that reality with better measurement and incentives. [40]

Systemic shock and coercion risk: Even if China never intentionally “weaponizes” medicines, the combination of geopolitical conflict risk and upstream concentration creates a plausible national emergency scenario. The DoD report emphasizes that DoD uses a just-in-time ordering concept and does not store additional finished drug products; it follows that disruptions from “adversarial actions” or other events can cause shortages affecting operations. [13]

This is why the Executive Order establishing SAPIR emphasizes APIs’ longer shelf lives and lower cost relative to finished drugs and directs building six-month API reserves. It also states that only about 10% of APIs by volume used for finished drug products in the U.S. are made domestically, underscoring the upstream exposure. [41]

Two supply-concentration charts

pie title Active API DMF shares (2021, proxy indicator)

```
"India" : 62
"China" : 23
"United States" : 4
"Europe" : 7
"Other" : 4
```

The DMF shares above are reported in the Committee staff report and in a Duke analysis that explicitly notes DMFs are a proxy and do not measure production volumes. [27]

pie title DoD analyzed essential-medicine APIs by origin (share of NDCs)

```
"U.S. domestic" : 25
"Canada & Mexico" : 3
"TAA-compliant (outside N. America)" : 18
"India" : 26
"China" : 5
"Other non-TAA" : 1
"Unknown" : 22
```

The DoD figures are from the FY2023 DoD pharmaceutical supply chain assessment (based on 12,917 NDCs linked to 1,744 drug families). [13]

Data gaps that matter

In the public debate, estimates of “China’s share of U.S. APIs” vary widely because they often measure different things (facility counts, DMFs, import records, or indirect exposure through third countries), and because KSM and intermediate sourcing is often not visible. A 2025 analysis argues that policy implications differ depending on whether the exposure is at the API stage or deeper upstream in precursors and specialized reagents and notes that some widely repeated “80–90% of all APIs” claims are not well specified. This uncertainty is not a reason to delay action; it is a reason to prioritize supply chain mapping and standardized measurement as the first step. [42]

China's Strategy and the Life-Sciences Frontier

China's capture of upstream pharmaceutical manufacturing must be understood as part of a broader state-enabled strategy to climb the entire life sciences value chain—from basic research to clinical trials to advanced manufacturing and commercialization. The question for U.S. policy is no longer “How do we avoid dependence?” but “How do we build a democratic innovation-and-production system that outcompetes China while remaining aligned with open-market principles and public health?” [43]

Industrial policy tools and tactics

China's strategy is explicit in industrial planning documents and in the consistent use of reinforcing “policy loops”: state guidance, subsidies and credit, industrial clusters, procurement preferences, and regulatory modernization.

Made in China 2025: The (translated) State Council-level plan is widely understood as a foundational industrial policy framed around upgrading manufacturing capability and reducing reliance on foreign goods in strategic sectors, including biopharma and high-tech medical devices. [44]

Bioeconomy planning: Scholarly analysis of China's “14th Five-Year Plan for Bioeconomy Development” describes biomedicine, bio-manufacturing, and biosecurity as core pillars of a national bioeconomy agenda—again, not as a narrow sector policy but as an integrated strategic posture. [45]

Regulatory acceleration as a competitiveness tool: China's regulator has publicly emphasized mechanisms that speed clinical trial approvals (including implicit approval frameworks), which can change sponsor behavior and compress development timelines—one of the most durable competitive advantages in life sciences. [46]

Trade and export control leverage: China has modernized export control authorities in ways that can be used across sectors. Even without specific “pharma export bans,” the strategic logic is recognizable: if a country can impose coercive leverage through supply chains (critical minerals, key chemicals, or APIs), it gains bargaining power. The U.S. response must assume that risk exists. [47]

Evidence of China's life-sciences ascent

Clinical development share: An IQVIA analysis shows trial starts from China-headquartered companies rising sharply, reaching roughly 30% of Phase I–III trial starts by headquarters location in 2008–2024 data presented in 2025. A separate Nature reporting piece (citing IQVIA) similarly describes a rapid rise over roughly a decade-plus. [48]

Scientific output: The National Science Board[49] reports that in 2022 China produced 27% of global science and engineering publications while the U.S. produced 14% (Scopus-based, fractional counting), underscoring the scale of China's research engine. [50]

AI and IP intensity: The Stanford AI Index reports that as of 2023, China led in total AI patents, accounting for 69.7% of grants. In life sciences—where AI increasingly touches discovery, biomarker development, trial design, and manufacturing optimization—this patent intensity is strategically relevant even when frontier model leadership remains contested. [51]

Capital formation mechanisms: Hong Kong Exchanges and Clearing Limited[52] notes that since the 2018 launch of listing reforms enabling pre-revenue biotech listings (Chapter 18A), 80 such companies had listed via that route as of end-November 2025—illustrating a state-adjacent capital channel for scaling high-risk biotech. [53]

What this means for U.S. strategy

The U.S. cannot treat “drug supply chain resilience” and “life sciences leadership” as separate issues. The same ecosystems that produce upstream dominance (chemicals, manufacturing clusters, workforce, supplier density) also enable rapid scale-up in biologics, vaccines, diagnostics, and advanced therapies. If upstream dependence persists, it will increasingly intersect with high-value innovation domains—especially as biologics manufacturing inputs (single-use systems, specialty resins, media components) become strategic chokepoints. [54]

Democratic Allies: Comparative Map

A U.S. strategy that aims for 100% domestic production of all drugs and inputs would be slow, costly, and—most importantly—unnecessary to achieve resilience. The goal should be “trusted capacity at scale,” built across the U.S. and allied democracies, with clear rules for transparency, quality, and surge response. Several ally strategies already point in this direction, creating an opening for coordinated action.

The European Union[55]: The European Commission has advanced a “Critical Medicines Act” agenda explicitly aimed at tackling shortages and boosting resilience, including strategic projects, procurement reforms that incorporate resilience, collaborative procurement, and international partnerships with like-minded countries to reduce single-supplier dependencies. [56]

The Council of the European Union[57] describes the Critical Medicines Act as addressing shortages and improving EU resilience in health crises, indicating that European policy is converging on many of the same tools under discussion in the U.S. (procurement criteria beyond price, strategic project facilitation, and partnerships). [58]

Japan[59]: Japan’s economic security framework includes supply chain resilience tools designed for “important items and raw materials,” and Japan provides an official English translation of the relevant economic security legislation, emphasizing integrated economic measures for national security. This is directly relevant to pharmaceutical and life-sciences inputs. [60]

Canada[61]: Canada’s Biomanufacturing and Life Sciences Strategy is explicitly framed as strengthening domestic life-sciences capability and long-term pandemic resilience; Canada also publicly reports significant investments (over \$2.5B across dozens of projects) in biomanufacturing, vaccines, and therapeutics ecosystem capacity. [62]

Australia[63]: Australia operates large, long-horizon public funding instruments for medical research (MRFF), offers targeted industrial strategy work in emerging areas like RNA, and has established national financing vehicles like the National Reconstruction Fund aimed at high-value industry transformation—tools that could be integrated into an allied life-sciences manufacturing and trial ecosystem. [64]

India[65]: India is indispensable in global generics and vaccine manufacturing, making it a crucial partner for “friend-shoring.” But India’s upstream dependence on China is a structural risk that policy must confront honestly. India’s Department of Pharmaceuticals created a Production Linked Incentive (PLI) scheme explicitly to promote domestic manufacturing of critical KSMs, intermediates, and APIs—an acknowledgement that upstream dependence is a strategic weakness. [66]

Comparative table

Ally / Region	Distinct strengths for a democratic life-sciences base	Key weaknesses / risks	Practical “fit” in a U.S.-led resilience architecture
European Union	Emerging Critical Medicines Act toolkit: strategic projects, procurement reform, collaborative procurement, partnerships. [67]	Fragmented procurement authority across member states; cost pressure in generics can still undercut resilience goals. [68]	High: align critical-medicine lists; joint procurement pilots; co-invest in antibiotics and sterile injectables; regulatory harmonization pathways.
Japan	Economic security law framework for stable supply of critical materials and integrated measures; high manufacturing quality culture. [69]	Demographic constraints; may prioritize domestic security use-cases first. [60]	High: trusted upstream and advanced manufacturing nodes; shared standards; joint surge manufacturing planning.
Canada	National BLS strategy + large project investments; proximity to U.S.; integrated innovation ecosystem. [62]	Scale constraints; may need stronger industrial-policy alignment for “full-stack” leadership. [70]	Very high: integrate as key “near-shore” node for biologics, vaccines, and critical inputs; shared workforce and regulatory science.
Australia	MRFF long-horizon	Geographic distance	Medium-high: clinical trial

Ally / Region	Distinct strengths for a democratic life-sciences base	Key weaknesses / risks	Practical “fit” in a U.S.-led resilience architecture
	funding; RNA blueprint; national finance tools for industrial transformation. [64]	from U.S. demand centers; scale limits in manufacturing. [71]	hub potential; specialized biomanufacturing and RNA pilot lines; redundancy and surge capacity.
India	Massive formulation capacity; increasingly explicit industrial policy for upstream API/KSM via PLI and bulk drug parks. [72]	Upstream dependence on China remains large; quality variance signals need strong measurement and incentives. [73]	High but conditional: partner for FDF and vaccines while jointly reducing upstream China exposure; require transparency and quality metrics as entry conditions.

This table is a synthesis of official and published policy documents and the Committee’s and DoD’s findings; it is not a claim that any one partner can solve U.S. resilience alone. [74]

Policy Options, Cost Ranges, and a Roadmap

The policy design challenge is to avoid two failure modes:

The “tariffs-only” trap: trade restrictions without a credible industrial ramp create price spikes and shortages.

The “subsidies-only” trap: grants without durable demand signals create pilot projects that cannot sustain operations.

The recommended approach is a sequenced strategy that uses procurement and payment to create stable demand, invests in targeted domestic and allied capacity, and builds the measurement infrastructure that makes progress auditable.

Core statutory and administrative building blocks already on the table

Defense procurement as the pilot: Section 887 of the FY2025 Senate NDAA bill text creates a ready-made template: a defined list (“defense-relevant generic drugs”), domestic manufacture requirements, API/KSM trusted sourcing rules, a waiver for availability at U.S. market prices, and congressional notification. As written, it operationalizes “trusted sourcing” in a way that can be audited. [30]

Medicare as the scaling lever: CMS’s January 2026 ANPRM is a pivotal signal because it recognizes that hospitals incur higher marginal costs for domestically manufactured PPE and essential medicines and asks how Medicare might offset those costs through designations and payment adjustments. In other words: it contemplates shifting the U.S.

health-financing system from “cheapest wins” toward “secure and reliable wins,” at least for defined categories. [31]

Stockpiles that match the upstream reality: EO 14336 directs ASPR to fill SAPIR with APIs for a defined set of critical drugs and to plan for broader six-month API reserves for an updated essential medicines list. This is an upstream-centric approach that can stabilize the supply chain if paired with replenishment capacity and rotation protocols. [29]

Transparency mandates: both the Committee report and the DoD report converge on a first-order requirement: map supply chains and require disclosure of finished dose, API, and KSM origins (and, ideally, proportions by source). This is the data infrastructure without which both industrial policy and emergency response will remain guesswork. [75]

Policy options table

The table below provides ranges, not point estimates. Facility costs, time-to-build, and operating costs vary by modality (synthetic API vs fermentation, oral solid vs sterile injectable, biologics vs cell therapy), environmental permitting, and the need for qualified workforce. Where public cost data are sparse, I provide “engineering-style” bounds and label them as assumptions rather than verified figures.

Policy lever	What it does	Benefits	Key risks / unintended consequences	Timeline	Cost range (rough order-of-magnitude)
Federal buyer’s market (DoD pilot → VA/other purchasers) using NDAA-style list + waivers	Creates durable demand for U.S./trusted-origin generics, including API/KSM rules and waivers for availability	Auditable, rapid to pilot; uses existing federal procurement power; can create investment-grade demand	If phase-in is too fast, risk of shortages; if waivers too broad, policy becomes symbolic	Pilot in 12–24 months; scale 3–6 years	Administrative + price premiums; incremental annual cost depends on list size and price differential; should be budgeted as “resilience insurance”
Medicare incentives (CMS SAMS-style designation/payment)	Aligns hospital purchasing with resilience, offsets higher	Scales beyond federal procurement; addresses	Poorly designed measures can be gamed; complexity	Design 1–2 years; scale 3–5 years	Annual payments depend on domestic premium and percent

Policy lever	What it does	Benefits	Key risks / unintended consequences	Timeline	Cost range (rough order-of-magnitude)
	costs of domestic/trusted supply	the biggest market design failure: procurement rewards price over reliability	burdens hospitals; risk of cost-shifting if not well targeted		thresholds; can be bounded by focusing on the 86-medicine (or updated) list [76]
Full-stack transparency mandate (FDF/API/KSM disclosure; secure federal repository)	Makes upstream reliance measurable and enforceable; enables predictive risk analytics	Essential for prioritizing investments and preventing shortages; reduces “unknown origin” exposure cited by DoD	Industry pushback; confidentiality concerns; requires cyber-secure infrastructure	18–36 months to stand up; continuous thereafter	IT + compliance costs; moderate federal investment relative to manufacturing subsidies; high ROI in avoided crises
Targeted reshoring of brittle nodes (fermentation antibiotics, select sterile injectables, key chemical intermediates)	Builds domestic capacity where strategic risk is highest and substitutes are limited	Reduces “single-region” risk; improves surge capability; aligns with national security	Environmental permits; higher operating costs; risk of stranded assets if procurement incentives vanish	3–10 years (new build); 1–2 years for repurposing existing capacity where feasible [77]	Capital-intensive; “hundreds of millions to low billions” depending on modality (assumption)
Friend-shoring + allied “strategic projects”	Builds trusted capacity across allies; reduces China dependence	Faster than full reshoring; diversifies geographic	Requires harmonized standards and mutual recognition;	2–6 years for meaningful capacity	Public co-investment + policy alignment; cost shared

Policy lever	What it does	Benefits	Key risks / unintended consequences	Timeline	Cost range (rough order-of-magnitude)
	without excessive domestic cost	risk	politics of “who gets what”	expansion	among partners
Strategic stockpiles (API-first; limited KSM where feasible) + rotation	Creates buffers against shock and coercion; API stockpiles have longer shelf life than finished drugs	Stabilizes near-term resilience	Stockpiles without replenishment can degrade/expire; can distort markets if mishandled	SAPIR actions already directed; expand 1–3 years; maintain indefinitely [78]	Cost depends on number of APIs and six-month volume; should be treated as a portfolio with rotation; EO directs ASPR to develop cost estimates [41]
Advanced manufacturing adoption (continuous, modular, flexible lines)	Improves responsiveness and reduces changeover time; can make domestic production more competitive	Enables “replenish, not just store”; strengthen surge	Requires skilled workforce and regulatory familiarity	2–7 years for scale	Mixed public-private; best treated as “capability investment” rather than per-drug subsidy

The policy rationale for pairing procurement/payment levers with targeted industrial investments is supported by FDA’s drug shortage analysis (market incentives) and the Committee’s and DoD’s findings (opacity and risk). [79]

A prioritized action matrix

This matrix intentionally focuses on actions that (1) reduce near-term risk to seniors and national security and (2) create compounding advantages for long-run life-sciences leadership.

Priority	Action	Why it matters	Lead actors	“Proof” metric within 24 months
Highest	Mandate FDF/API/KSM origin disclosure + federal repository (secure access)	Without data, everything else is guesswork; addresses “unknown origin” risk	Congress + FDA + HHS/ASPR + DoD	Share of essential-medicine NDCs with complete origin disclosure rises sharply (target: >80% of the defined list) [16]
Highest	Implement NDAA-style defense-relevant list procurement rules with phased compliance + waivers	Creates investment-grade demand; produces auditable proof of concept	DoD + Congress	First list published; procurement contracts incorporate API/KSM requirements; waiver rate publicly reported [30]
High	Finalize Medicare “SAMS” design and payment approach targeting essential medicines	Scales market reform beyond defense; aligns incentives for reliability	CMS + Congress (if needed)	Pilot cohort of hospitals; domestic/trusted share rising for defined categories [31]
High	Build SAPIR as API-first stockpile + rotation protocols	Near-term buffer that buys time for manufacturing scale-up	ASPR + OMB + FDA	SAPIR repository operational; first API tranches stored; rotation plan published [78]
High	Launch “Resilient Antibiotics” initiative (domestic + allied fermentation)	Antibiotics and upstream fermentation are recurrent chokepoints	HHS/ASPR + DoD + allies	At least two non-China sources for priority antibiotic APIs/KSMs under contract
Medium	Inspection parity modernization and inspection workforce stabilization	Reduces quality and shortage risks; improves trust in allied supply	FDA + appropriators	Reduced inspection backlog; metrics for foreign inspections improve [80]
Medium	Democratic life-sciences alliance: aligned lists, joint procurement, standards	Converts fragmented efforts into scale; counters China’s integrated model	U.S. + allies	First joint critical-medicine list alignment and joint procurement pilot launched [81]

Implementation flowchart

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flowchart TD
    A["Define 'Essential & Strategic Medicines' lists\n(health + national security)"] --> B["Mandate transparency\nFDF/API/KSM origin + secure repository"]
    B --> C["Risk scoring & prioritization\nsingle-source, geography, quality signals"]
    C --> D["Demand signals\nDoD procurement rules + Medicare incentives"]
    D --> E["Capacity build\nreshore + friend-shore + advanced manufacturing"]
    E --> F["Strategic stockpiles\nAPI-first + rotation + replenishment contracts"]
    F --> G["Measure & enforce\nshortage reduction, audit compliance, inspection parity"]
    G --> C
  
```

This “closed loop” is directly motivated by: (a) the DoD finding of unknown origins and high-risk reliance; (b) the Committee report’s emphasis on mapping and disclosure; and (c) CMS’s recognition that payment systems can offset domestic procurement cost differentials. [\[82\]](#)

Roadmap milestones for 5, 10, 25, 50 years

Within five years: The United States should be able to demonstrate that for every medicine on the essential list (as updated), there is no single point of failure at the API layer across non-adversary jurisdictions, and that the federal government can see upstream provenance in near-real time for those products. This is achievable because both DoD and the Committee report describe existing capacity that could be repurposed within 1–2 years in some cases, even while new facilities may take longer. [\[83\]](#)

Within ten years: The U.S. and allies should have scaled at least several strategically vital “ecosystem nodes” (antibiotics fermentation, sterile injectables redundancy, and selected chemical intermediates) so that adversary supply disruption becomes a manageable shock rather than a national emergency. The Committee report notes estimates that building new manufacturing facilities can take 5–10 years, which is consistent with a decade-scale target for new capacity. [\[77\]](#)

Within twenty-five years: The objective should shift from “repair” to “dominance”: the democratic alliance should lead in advanced biomanufacturing, secure supply chains for both small molecules and biologics, and the clinical and regulatory infrastructure that makes innovation fast and trustworthy.

Within fifty years: The metric is not only manufacturing share; it is strategic leadership in life sciences as a national capability: the ability to discover, trial, manufacture, and distribute new therapies rapidly under trusted governance. China’s rising share of trial starts and its scale in scientific output and AI patents suggest that absent deliberate strategy, leadership could tilt away from democracies. [\[14\]](#)

Metrics to measure success

A resilience strategy must be measurable. I recommend Congress require an annual “Life Sciences Resilience Scorecard” built on auditable metrics:

Supply diversity: For each essential medicine, number of independent manufacturing “families” at API and FDF, and geographic distribution (target: at least three independent suppliers across trusted jurisdictions for high-criticality products).

Upstream visibility: Percent of essential-medicine volume with fully disclosed FDF/API/KSM origin; percent with “unknown” origin (target: approach zero on the essential list). [16]

Shortage performance: Number of ongoing shortages and average shortage duration; FDA and related analyses show multi-year average shortage durations and identify market incentives as a driver, making this a key output metric. [84]

Quality signals: Inspection outcomes, import alerts, and independent testing metrics; the Committee report specifically highlights the need for quality-rewarding procurement and notes evidence linking quality issues to outcomes. [85]

Surge readiness: Time to scale production for a defined set of “critical drugs” under national emergency scenarios; SAPIR fill status and rotation compliance. [86]

Innovation leadership: Share of global phase I–III trial starts by sponsor location; biomedical publication output; and indicators of AI-enabled capability relevant to life sciences. [14]

Legal, Diplomatic, and Unintended Consequences

A strategy this large must anticipate legal friction and second-order effects.

Procurement law and “rules of origin”: Section 887’s text shows Congress can define procurement rules that focus on manufacturing location and upstream API/KSM sourcing, with waivers that preserve availability. That design reduces legal ambiguity by specifying what counts and by imposing reporting requirements when waivers are used. [87]

Trade law and retaliation: The Section 232 investigation shows one pathway to tariffs or other restrictions. But trade restrictions can trigger retaliation and can backfire if allies are not aligned or if domestic/allied capacity cannot ramp in time. For that reason, “trade” should be used as backstop and leverage—not as the primary engine of resilience. [33]

Diplomatic considerations: Because Europe, Japan, Canada, Australia, and India each have distinct policy tools and domestic constraints, the U.S. should propose a compact with clear mutual benefits: shared surge capacity, shared standards, and shared market access for trusted products. European and Japanese moves toward “economic security” supply chain tools suggest a receptive environment, but coordination is not automatic; it must be negotiated. [81]

Unintended consequence: higher prices without better outcomes. If domestic/trusted sourcing raises prices but does not measurably improve reliability and quality, the policy will lose legitimacy. CMS explicitly acknowledges that domestically manufactured products will generally be more expensive because of higher labor costs, which is why payment design must be tied to measurable reliability and quality metrics. [88]

Unintended consequence: accelerated consolidation. A poorly designed “domestic preference” could inadvertently advantage a small number of incumbents, creating new single points of failure. Mitigation: require multi-supplier contracting, create on-ramps for new entrants (including advanced manufacturing), and require redundancy as a condition of incentives. The Committee report’s emphasis on single-manufacturer prevalence underscores why redundancy must be a performance requirement, not merely an aspiration. [39]

Unintended consequence: environmental externalities. Reshoring upstream chemicals and fermentation can increase local environmental burdens. Mitigation: pair reshoring incentives with clean manufacturing requirements and permitting acceleration that does not reduce environmental standards—using the same “smart speed” approach now used in other strategic sectors.

Unintended consequence: shifting dependence rather than reducing it. “Friend-shoring” to India without upstream diversification can still leave the U.S. exposed to China through India’s inputs. This is why allied strategy must explicitly include KSM and intermediate diversification, not just finished dose relocation. [89]

Finally, oversight should treat life sciences as both an economic engine and a strategic domain. China’s rapid expansion in trials, publications, and AI patents is a warning that the next 50 years will be shaped by nations that can integrate discovery, development, manufacturing, and data governance at scale. The United States and democratic allies can still lead—but only with a coherent, measurable strategy that treats supply chain resilience and innovation leadership as one national project. [90]

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Questions for the Record

U.S. SENATE SPECIAL COMMITTEE ON AGING

"FOREIGN DEPENDENCE: HOW CHINA CAPTURED AMERICA'S DRUG SUPPLY"

MARCH 11, 2026

QUESTIONS FOR THE RECORD

Hon. Ted Yoho**Senator Elizabeth Warren****Question:**

What short and long-term actions should the Administration and Congress take to protect the U.S. pharmaceutical supply chain from disruptions, including during periods of international conflict or against foreign adversaries' retaliation?

Response:

Short Term: United States Government (USG) should continue with tariffs and tax incentives to entice pharmaceutical companies to move back to the US. These should not be give ways, but strong motivations to relocate back to the US. If not done, regardless of a conflict or not, the country that controls the pharmaceutical supplies can/will dictate the terms. Up to 80% of the US Military's pharmaceuticals are controlled by China or India with the majority of the key starting materials, KSMs coming from China. The likelihood of China providing essential medicines during a conflict between the US and China is nil.

Question:

How would increase domestic manufacturing of pharmaceuticals help achieve this goal?

Response:

Increasing the domestic manufacturing will do several things to secure national security. Assurance that FDA quality control is in place with the production of KSMs, APIs and FDF in the manufacturing process. Currently our FDA cannot conduct unannounced inspections in China as they do with US domestic manufacturers. This results in substandard or adulterated products entering the consumer/medical supply chain. This leads to failed treatments, iatrogenic illness and death. This is well documented in Rosemary Gibson's book, China Rx.

Domestic production will secure the pharmaceutical supply chain eliminating another country from using that control to leverage or force compliance from the US to their demands. It would help reduce the FDA shortlisted medications from being on frequent backorders that disrupts treatments for human and animal patients.

Question:

How would the U.S. population benefit from government-owned, government-operated or government-owned, contractor-operated pharmaceutical manufacturing facilities?

Response:

It is doubtful the US population would realize an appreciable benefits from government involvement in pharmaceutical production for the following reasons.

- This would limit the free market from the equation reducing competition, limit selection and be subject to stopped productions with government shutdowns and layoffs.

- It would disincentivize private research and discovery of new medications and treatments.

- It would create a situation where the government assigns winners and losers in drug manufacturing and decrease the choice of medicines.

- It would have little affect at reducing and may increase counterfeit, unregulated and unsafe pharmaceutical products entering the US market and jeopardizing US citizen health.

Domestic production would have a positive impact if KSMs, APIs, and FDF were all produced adhering to FDA inspections and meeting USP, Inc (US Pharmacopeia, Inc) standards. However, this can be accomplished in the private sector with out increasing government employment and the added expense to the American taxpayer.

Question:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in direct additional health care expenditure?

Response:

Direct costs increase when pharmaceuticals are not manufactured with the proper ingredients or follow USP, Inc. standards. When ineffective or adulterated drugs are produced it increases the duration of treatment, can lead to other illnesses or organ failure. Death have been reported that are associated with adulterated drugs entering the US market from both domestic and foreign produced drugs. When treatments are ineffective due to inferior pharmaceuticals it increases ER, (emergency room) visits and lengthier hospital stay ultimately adding more costs for the US healthcare system.

Question:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in indirect costs resulting from higher rates of illness?

Response:

The indirect costs are longer treatment durations for an illness which increases cost. A decreased quality of life for the patient, family members, and caregivers is a consequence of the adulterated/ineffective medicines. Inferior medicines can cause protracted debilitating disease, add to income stress, has forced people into bankruptcy. Adulterated/inferior drugs have caused cancers, driven people into bankruptcy and either directly caused deaths from those drugs or from suicide linked to the drug or the depression associated with their health condition or financial situation.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"FOREIGN DEPENDENCE: HOW CHINA CAPTURED AMERICA'S DRUG SUPPLY"

MARCH 11, 2026

QUESTIONS FOR THE RECORD

Gordon G. Chang**Senator Elizabeth Warren****Question 1:**

New reporting indicates that the closure of the Strait of Hormuz due to the Trump Administration's war in Iran threatens the United States' supply of generic drugs. Around half of the country's generic prescriptions originate in India - a country that "relies on the Strait of Hormuz for the arrival of key inputs in drug manufacturing including petroleum-based materials," according to reporting by CNBC.

a. What supply chain disruptions could the war trigger, and how would these disruptions affect Americans' ability to access their prescriptions?

b. Which pharmaceuticals would be most seriously compromised by the war?

c. How much would any such disruptions cost to the U.S. health care system, patients, or taxpayers?

d. What would these supply chain disruptions mean for national security and military readiness?

e. If the Strait of Hormuz remains closed, how long would it be before Americans experience the effects of significant pharmaceutical supply chain disruptions, including drug shortages?

Question 2:

If the war against Iran causes serious pharmaceutical supply chain disruptions, how long would it take for the United States to address vulnerabilities in its supply chain and resolve subsequent drug shortages?

a. What actions could the United States take to remedy these disruptions, and how much would these actions cost?

Question 3:

China is one of the biggest buyers of oil from Iran, buying more than 80 percent of Iran's shipped oil. How much does China's ability to manufacture finished drug products, active pharmaceutical ingredients, and key starting materials rely on this supply of oil, and how would disruptions to Iran's oil supply due to the war between the United States and Iran affect China's supply of pharmaceuticals?

a. How would these disruptions to China's manufacturing capacity of pharmaceuticals in turn disrupt the United States' pharmaceutical supply chain?

Question 4:

The United States has seen China ban or threaten to ban its export of critical minerals in response to the Trump Administration's trade agenda, jeopardizing national security. Given the Trump Administration's war against Iran and its intervention in Venezuela - and the impact this could have on China's oil imports - what is the likelihood of China retaliating against the United States's actions by restricting or banning the export of pharmaceuticals, including final dosage forms, active pharmaceutical ingredients, and key starting materials, to the United States?

a. What would a ban on pharmaceuticals exports from China mean for Americans' ability to access their prescriptions?

b. How soon after a ban on pharmaceutical exports from China would the United States experience disruptions in its pharmaceutical supply chain, including drug shortages?

c. How many pharmaceuticals on the Food and Drug Administration's essential medicine list would be impacted by a ban on pharmaceutical exports from China?

d. What would be the impact of such a ban on national security?

e. What would be the impact of such a ban on the ability for the department of defense to keep service members healthy and maintain military readiness?

Question 5:

What short- and long-term actions should the Administration and Congress take to protect the U.S. pharmaceutical supply chain from disruptions, including during periods of international conflict or against foreign adversaries' retaliation?

a. How would increased domestic manufacturing of pharmaceuticals help achieve this goal?

b. How would the U.S. population benefit from government-owned, government-operated or government-owned, contractor-operated pharmaceutical manufacturing facilities?

Question 6:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in direct additional health care expenditure?

Question 7:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in indirect costs resulting from higher rates of illness?

Question 8:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in higher rates of illness and increased medical complications?

Response to Question 1:

The ongoing Iran war can radically reshape the world in different directions.

If America prevails, the war can lead to decades of peace.

On the other hand, the war, given the current fragility of the current situation, could spread. In the late 1930s, separate conflicts merged into what we now call World War II. If that happens now-the chance of that is not insubstantial-Americans undoubtedly would not have access to the hundreds of medicines made in China.

We have known of this critical vulnerability for years, and every American administration this century is at fault for this critical dependence on a hostile China. The current administration is taking steps to onshore manufacturing, but onshoring will take years at the current pace.

If China goes to war with us now, Americans will be deprived of medicines and the consequences will be catastrophic.

If we assume the worst does not occur, the disruption to supply chains could still be substantial. Companies are nimble, however, so they will reconfigure their supply chains quickly. Costs will increase, but I do not expect a substantial reduction in pharmaceutical production.

Response to Question 2

If the United States acts on an emergency basis-a total mobilization of society-I think it would take a little over two years to onshore the most-used generics and other medicines.

A total mobilization would include the President invoking the Defense Production Act and Congress giving the President additional war-time powers to onshore production.

Response to Question 3

China has the world's largest strategic petroleum reserve-perhaps as much as 140 days of import cover-and China has alternative sources of oil. A complete closure of the Strait of Hormuz by itself should not significantly disrupt China's production of pharmaceuticals.

Response to Question 4

There are, as some have argued, several reasons why China would not deny pharmaceuticals. Beijing is deterred by the prospect of retaliation, such as America denying China advanced cancer treatments and other things available only here.

More important, Beijing would be cutting off important revenue streams. Yes, America has to buy, but China as a practical matter has to sell. This is especially true as the Chinese economy is now deteriorating.

The United States in the so-called "trade war" has more leverage over a trade-dependent China than China has over the U.S. The Trump administration, however, has chosen not to employ much of this leverage. If China were to threaten to cut off pharmaceuticals or actually do so, the administration would almost certainly employ all the tools at its disposal.

Response to Question 5:

There are a number of technical fixes. The U.S., for example, should establish a "federal buyer's market" and prioritize American-made products for, among others, the Pentagon, the Veterans Administration, and Medicare. If American-made medicines are not available, the government should try to buy those produced in friendly countries.

Congress should require sellers to disclose country of origin, and it's necessary to close loopholes that now allow foreign-made products to be labeled "Made in America."

It's also time to eliminate the FDA's red tape, which unnecessarily delays approvals and increases costs.

Congress must also ban the importation of medicines that are either uninspected or inadequately inspected. Moreover, it is way past time to vigorously enforce Section 307 of the Tariff Act of 1930, which prohibits the importation of goods made with forced labor.

Ultimately, cost is the name of the game. Beijing suffocates foreign competitors by lowering prices and by flooding markets with artificially high supplies. U.S. manufacturers would feel confident of moving production to American soil if they felt sure that Washington was fully committed to protecting them from vicious Chinese price tactics.

There are also non-technical fixes. Washington can restart domestic production with incentives, such as low-cost loans-the first Trump administration experimented with this approach with a proposed \$765 million loan to Eastman Kodak in 2020 to make active pharmaceutical ingredients-and, more important, an enhanced investment tax credit.

Tariffs are also needed so these measures will have a chance to succeed.

Finally, we need collaborative international policies so that we have access to the production of friendly countries.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"FOREIGN DEPENDENCE: HOW CHINA CAPTURED AMERICA'S DRUG SUPPLY"

MARCH 11, 2026

QUESTIONS FOR THE RECORD

Rosemary Gibson**Senator Elizabeth Warren****Question 1:**

You are part of a working group that is performing quality risk assessments of drugs on the Department of Defense's pharmaceutical supply chain. In your testimony, you indicated that around two of the thirteen generic drugs analyzed so far by the working group (or 15 percent) have serious manufacturing defects. How significant are these findings, and how can the Department of Defense use these findings to inform its procurement decisions?

Response to Question 1:

Thank you for the opportunity to respond to these questions. Please note that I receive no compensation with regard to the quality risk assessments.

In my testimony I reported that 13 different generic drugs were tested including all products sold by manufacturers and re-packagers.

For example, in the case of one of the drugs, metoprolol, which is prescribed for heart failure and chest pain, 25 different metoprolol products were tested.

For all 13 generic drugs tested including all their manufacturers and re-packagers, 15% of the total number of products tested have manufacturing defects. This level of defects reflects very poor quality in virtually any modern manufacturing context. World class manufacturing would have less than 1% defects and closer to .01%.

The Department of Defense can use these findings to inform procurement decisions and avoid purchasing products with high levels of toxins and dissolution failures.

Question 1a:

a. How can the working group's findings be used to support the onshoring of domestic manufacturing?

Response to Question 1a:

Quality has been found to be correlated with location. In locations/countries where FDA has limited ability to perform its full regulatory functions due to limited respect for U.S. law and regulations, products made there may be more likely to have product defects. Additional research is being conducted on this point.

Question 1b:

b. How can other federal procurement practices - such as long-term contracts or domestic purchasing requirements - help address the vulnerabilities exposed by the working group's findings?

Response to Question 1b:

Long-term contracts, guaranteed volume purchasing, and price floors are contract features that would attract U.S. owned and operated generic drug and API manufacturers.

Question 2:

New reporting indicates that the closure of the Strait of Hormuz due to the Trump Administration's war in Iran threatens the United States' supply of generic drugs. Around half of the country's generic prescriptions originate in India - a country that "relies on the Strait of Hormuz for the arrival of key inputs in drug manufacturing including petroleum-based materials," according to reporting by CNBC.

a. What supply chain disruptions could the war trigger, and how would these disruptions affect Americans' ability to access their prescriptions?

b. Which pharmaceuticals would be most seriously compromised by the war?

c. How much would any such disruptions cost to the U.S. health care system, patients, or taxpayers?

d.What would these supply chain disruptions mean for national security and military readiness?

e.If the Strait of Hormuz remains closed, how long would it be before Americans experience the effects of significant pharmaceutical supply chain disruptions, including drug shortages?

Response to Question 2:

I do not have knowledge and expertise to answer questions 2-4. A general comment is that any prolonged disruption of essential medicines can adversely affect national security. In the case of China, its control over the global supply of key starting materials coupled with a prolonged disruption of upstream material for antibiotic production could be extraordinarily serious. In a matter of weeks, Americans could experience the impact of supply chain disruptions.

Question 3:

If the war against Iran causes serious pharmaceutical supply chain disruptions, how long would it take for the United States to address vulnerabilities in its supply chain and resolve subsequent drug shortages? What actions could the United States take to remedy these disruptions, and how much would these actions cost?

Response to Question 3:

I do not have knowledge and expertise to answer questions 2-4. A general comment is that any prolonged disruption of essential medicines can adversely affect national security. In the case of China, its control over the global supply of key starting materials coupled with a prolonged disruption of upstream material for antibiotic production could be extraordinarily serious. In a matter of weeks, Americans could experience the impact of supply chain disruptions.

Question 4:

China is one of the biggest buyers of oil from Iran, buying more than 80 percent of Iran's shipped oil. How much does China's ability to manufacture finished drug products, active pharmaceutical ingredients, and key starting materials rely on this supply of oil, and how would disruptions to Iran's oil supply due to the war between the United States and Iran affect China's supply of pharmaceuticals? How would these disruptions to China's manufacturing capacity of pharmaceuticals in turn disrupt the United States' pharmaceutical supply chain?

Response to Question 4:

I do not have knowledge and expertise to answer questions 2-4. A general comment is that any prolonged disruption of essential medicines can adversely affect national security. In the case of China, its control over the global supply of key starting materials coupled with a prolonged disruption of upstream material for antibiotic production could be extraordinarily serious. In a matter of weeks, Americans could experience the impact of supply chain disruptions.

Question 5:

The United States has seen China ban or threaten to ban its export of critical minerals in response to the Trump Administration's trade agenda, jeopardizing national security. Given the Trump Administration's war against Iran and its intervention in Venezuela - and the impact this could have on China's oil imports - what is the likelihood of China retaliating against the United States's actions by restricting or banning the export of pharmaceuticals, including final dosage forms, active pharmaceutical ingredients, and key starting materials, to the United States?

a.What would a ban on pharmaceutical exports from China mean for Americans' ability to access their prescriptions?

b.How soon after a ban on pharmaceutical exports from China would the United States experience disruptions in its pharmaceutical supply chain, including drug shortages?

c.How many pharmaceuticals on the Food and Drug Administration's essential medicine list would be impacted by a ban on pharmaceutical exports from China?

d.What would be the impact of such a ban on national security?

e.What would be the impact of such a ban on the ability for the department of defense to keep service members healthy and maintain military readiness?

Response to Question 5:

China has reportedly threatened to withhold generic drugs and critical inputs at least since 2008 during the heparin contamination that killed many Americans. Further, it threatened to withhold antibiotics in early 2020 during the pandemic. Hence, such threats are not new.

What is new is that the U.S. has become more dependent on China and hardly any action has been taken in recent decades to reduce dependence.

Looking ahead, the impact of a ban on exports would depend on the scope and duration.

Within months, if not weeks, hospital and retail pharmacy shelves would be depleted of vital medicines as would the military health system.

While the U.S. government has known about this risk for many years, as noted, little action has been taken which is in contrast to how a threat to ban exports of critical minerals generated immediate action by the government and private sector to boost domestic production. Similar actions are needed in this sector.

For example, China Rx exposed in 2018 how dependent the U.S. is on China for antibiotics and again, eight years later, no action has been taken to create domestic sources for end-to-end production here. Meanwhile, China's leverage over the U.S. as well as the EU regarding antibiotics has increased.

Question 6:

What short- and long-term actions should the Administration and Congress take to protect the U.S. pharmaceutical supply chain from disruptions, including during periods of international conflict or against foreign adversaries' retaliation?

a. How would increased domestic manufacturing of pharmaceuticals help achieve this goal?

b. How would the U.S. population benefit from government-owned, government-operated or government-owned, contractor-operated pharmaceutical manufacturing facilities?

Response to Question 6:

An immediate first step is to stockpile APIs for critical generics where foreign dependency poses a national security concern. The focus here is not to "boil the ocean" but instead focus on the most critical life-sustaining generics.

Next, the federal government should support public-private partnerships with U.S.-owned companies to make APIs for critical medicines in the U.S. Federal procurement should give preference to critical generic medicines and APIs made in the U.S. with long-term contracts, price floors, and volume-based contracts.

In the Medicare program, hospitals can be provided incentives to procure domestically produced essential generics with critical inputs made in the U.S.

As for government-operated manufacturing facilities, it is unclear how that would be implemented.

Question 7:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in direct additional health care expenditure?

Question 8:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in indirect costs resulting from higher rates of illness?

Question 9:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in higher rates of illness and increased medical complications?

Response to Question 6-9:

In response to questions 6, 7, 8 and 9, an emerging body of literature is documenting the cost of poor quality generics due to exacerbation of serious medical conditions, and additional medical expenses for patients, their families and society at large. The testing team would be pleased to share some of this literature if this is of interest.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"FOREIGN DEPENDENCE: HOW CHINA CAPTURED AMERICA'S DRUG SUPPLY"

MARCH 11, 2026

QUESTIONS FOR THE RECORD

Dr. Chan Harjivan**Senator Elizabeth Warren****Question:**

New reporting indicates that the closure of the Strait of Hormuz due to the Trump Administration's war in Iran threatens the United States' supply of generic drugs. Around half of the country's generic prescriptions originate in India - a country that "relies on the Strait of Hormuz for the arrival of key inputs in drug manufacturing including petroleum-based materials," according to reporting by CNBC. What supply chain disruptions could the war trigger, and how would these disruptions affect Americans' ability to access their prescriptions?

Response:

A Hormuz closure would stress three interdependent nodes simultaneously: maritime transportation, petrochemical feedstock availability, and Key Starting Material (KSM) supply for API manufacturing. India—which supplies roughly half of all U.S. generic prescriptions—depends on petroleum-based raw materials routed through the Strait. Rising input costs and production delays in India would cascade directly into U.S. drug availability. China compounds the risk: Indian firms source approximately two-thirds of their key APIs from China, and that dependence reaches 87 percent for antibiotic ingredients. Disruptions to Chinese feedstock costs would further strain the world's dominant upstream pharmaceutical supplier. The result for American patients would be reduced drug availability, significant price increases, and shortages of essential medicines, with the greatest impact on those managing chronic conditions.

Question:

Which pharmaceuticals would be most seriously compromised by the war?

Response:

Generic sterile injectables—including oncology drugs such as carboplatin and cisplatin, antibiotics, anesthetics, and critical care medications—would be most immediately affected. Sterile injectables are particularly vulnerable because they have no simple substitutes, require precise manufacturing, and depend on cold-chain logistics. Antibiotics present a second acute risk: Chinese suppliers hold near-monopolies on penicillin and cephalosporin intermediates, including 6-aminopenicillanic acid (6-APA), the critical KSM underlying amoxicillin and several other widely used antibiotics. India manufactures 47 percent of all API volume used for chronic conditions in the U.S.; cardiovascular drugs, diabetes medications, and essential antibiotics representing tens of millions of daily prescriptions would all be at elevated risk.

Question:

How much would any such disruptions cost to the U.S. health care system, patients, or taxpayers?

Response:

Drug shortages generate direct costs—higher drug acquisition prices, pharmacy and nursing labor for workarounds, wastage, and premium sourcing fees—as documented in Vizient research and analyses published in JAMA and by the HHS Assistant Secretary for Planning and Evaluation (ASPE). Indirect costs are equally significant: delayed surgeries, extended hospital stays, and preventable complications from treatment interruptions add costs that dwarf the price of the original medicine. The U.S. system has minimal surge capacity, having seen more than 3,000 generic product discontinuations since 2010 due to unsustainably low reimbursement. A Hormuz-driven supply shock would be of a scale the system is structurally unprepared to absorb.

Question:

What would these supply chain disruptions mean for national security and military readiness?

Response:

The U.S. military procures from the same commercial generic drug supply chains as the civilian health system. Disruptions to sterile injectables, antibiotics, and chronic disease medications would impair military treatment facilities' ability to care for service members and maintain force readiness. Beyond the direct military impact, pharmaceutical supply chain resilience is a dimension of national security in its own right: the ability of a geopolitical event or an adversary to constrain access to essential medicines represents a strategic vulnerability comparable to energy or semiconductor supply chain exposure. Pharmaceuticals should be designated as critical infrastructure accordingly.

Question:

If the Strait of Hormuz remains closed, how long would it be before Americans experience the effects of significant pharmaceutical supply chain disruptions, including drug shortages?

Response:

The effects would be felt within weeks. Just-in-time inventory practices throughout the pharmaceutical distribution system mean most hospitals and distributors carry only weeks of stock for many generic medicines. Shortages of carboplatin and cisplatin are already documented. Indian manufacturers operating on thin margins cannot readily absorb rapid input cost increases; a prolonged closure would force production cutbacks. A closure lasting more than a few weeks would generate visible U.S. drug shortage reports; one lasting months would produce a systemic crisis across multiple therapeutic categories.

Question:

If the war against Iran causes serious pharmaceutical supply chain disruptions, how long would it take for the United States to address vulnerabilities in its supply chain and resolve subsequent drug shortages? What actions could the United States take to remedy these disruptions, and how much would these actions cost?

Response:

There are no adequate short-term solutions. Rebuilding pharmaceutical manufacturing capacity requires years of investment and regulatory work; onshoring API production at meaningful scale would cost billions and take three to five years at minimum. Near-term mitigations include expanding the Strategic National Stockpile with critical APIs and finished dosage forms, facilitating emergency imports from allied partner countries with existing API capacity, and activating FDA compounding and substitution authorities. Critically, upstream supply chain visibility—which the U.S. currently lacks—is itself a solution: without knowing where each API and KSM is manufactured, policymakers cannot identify chokepoints, prioritize stockpiling, or activate contingency plans. The Clear Labels Act would enable this mapping for finished dosage forms and APIs; USP's KSM mapping work would remain essential. Mechanisms to measure and reward resilience, quality, and geographic diversification would create durable incentives over time.

Question:

China is one of the biggest buyers of oil from Iran, buying more than 80 percent of Iran's shipped oil. How much does China's ability to manufacture finished drug products, active pharmaceutical ingredients, and key starting materials rely on this supply of oil, and how would disruptions to Iran's oil supply due to the war between the United States and Iran affect China's supply of pharmaceuticals? How would these disruptions to China's manufacturing capacity of pharmaceuticals in turn disrupt the United States' pharmaceutical supply chain?

Response:

China's API and KSM manufacturing is heavily energy-intensive, and the Chinese government subsidizes energy costs for its pharmaceutical sector—a primary reason Chinese suppliers have achieved near-monopoly positions in categories such as penicillin intermediates, aspirin, and acetaminophen. Disruptions to China's Iranian oil supply would increase those energy costs and create feedstock shortages for petroleum-derived pharmaceutical chemicals. Given that China supplies eight percent of U.S. generic APIs directly and substantially more through Indian intermediation—and that India sourced 87 percent of its antibiotic ingredients from China by value as of 2024—any meaningful reduction in Chinese manufacturing output would rapidly translate into Indian production shortfalls and U.S. drug shortages. India's PLI scheme has begun reducing some of this dependence, but the transition is incomplete, particularly for antibiotics.

Question:

The United States has seen China ban or threaten to ban its export of critical minerals in response to the Trump Administration's trade agenda, jeopardizing national security. Given the Trump Administration's war against Iran and its intervention in Venezuela - and the impact this could have on China's oil imports - what is the likelihood of China retaliating against the United States's actions by restricting or banning the export of pharmaceuticals, including final dosage forms, active pharmaceutical ingredients, and key starting materials, to the United States? What would a ban on pharmaceutical exports from China mean for Americans' ability to access their prescriptions?

Response:

The impact would be severe. Although China directly supplies only three percent of finished oral doses and 9 percent of injectables consumed in the United States, its upstream dominance means its true influence is far greater—a report to the U.S.-China Economic and Security Review Commission found the U.S. is “substantially more exposed to Chinese raw pharmaceutical ingredients,” with India often serving as a conduit. A ban covering KSMs would effectively halt Indian production of amoxicillin and related penicillin-based antibiotics within weeks. For patients, the result would be rationed antibiotics in hospitals, delayed or cancelled chemotherapy, forced substitutions, and significant price spikes. Tens of millions of Americans relying on daily generic medicines for chronic conditions would face treatment uncertainty, with lower-income patients and those with serious illnesses most severely affected.

Question:

How soon after a ban on pharmaceutical exports from China would the United States experience disruptions in its pharmaceutical supply chain, including drug shortages?

Response:

Disruptions would begin almost immediately. Just-in-time inventory practices throughout the distribution system mean the pipeline from a Chinese export ban to a U.S. drug shortage is measured in weeks for the most critical categories. For products already in shortage, the timeline would be shorter still. A simultaneous Hormuz closure and Chinese export ban would create a multi-vector supply crisis for which the U.S. health system has no adequate response capacity under current policy frameworks.

Question:

How many pharmaceuticals on the Food and Drug Administration's essential medicines list would be impacted by a ban on pharmaceutical exports from China?

Response:

USP's Medicine Supply Map (MSM) research provides the most granular available data. India produces 27 percent of the U.S. supply of APIs designated essential under the FDA's Essential Medicines, Medical Countermeasures, and Critical Inputs list or the WHO's Essential Medicines List—and Indian production of those APIs is itself heavily dependent on Chinese KSMs. A Chinese export ban would therefore indirectly compromise a large proportion of essential medicines consumed in the United States. A precise count requires the multi-tier supply chain mapping the U.S. currently lacks, underscoring the urgency of requiring manufacturers to report tier-2 and tier-3 supplier information.

Question:

What would be the impact of such a ban on national security?

Response:

A Chinese pharmaceutical export ban would constitute a national security threat of the first order. China's demonstrated willingness to use supply chains as geopolitical instruments—evidenced by its restrictions on rare earth elements and critical minerals—makes this scenario credible. The near-term consequences would be severe: rationed antibiotics in military and civilian hospitals, constrained infectious disease treatment capacity, and degraded population and workforce health. These systemic effects, even without targeted weaponization of specific military medicines, would represent a major strategic vulnerability. Precisely quantifying the national security impact would require comprehensive data currently unavailable, but the direction and severity of harm are not in doubt.

Question:

What would be the impact of such a ban on the ability of the Department of Defense to keep service members healthy and maintain military readiness?

Response:

The Department of Defense procures pharmaceuticals from the same commercial generic drug supply chains as the civilian market. A ban affecting KSMs, APIs, or finished dosage forms would constrain availability of medicines essential to military readiness: antibiotics, analgesics, cardiovascular medications, and critical care injectables. The extent of DoD's independent strategic pharmaceutical stockpiles would determine the precise timeline before readiness degraded, but the underlying dependence on commercially sourced generic medicines means a large-scale Chinese export ban would impair military medical readiness and potentially affect force availability. This alone justifies treating pharmaceutical supply chain security as a defense priority.

Question:

What short- and long-term actions should the Administration and Congress take to protect the U.S. pharmaceutical supply chain from disruptions, including during periods of international conflict or against foreign adversaries' retaliation? How would increased domestic manufacturing of pharmaceuticals help achieve this goal?

Response:

Increased domestic manufacturing reduces exposure to geopolitical disruptions by shortening supply chains, reducing adversarial upstream dependencies, and building surge capacity that currently does not exist but domestic manufacturing alone cannot solve the problem in the near term—it must be paired with allied diversification through the Bio5 framework with the EU, Japan, South Korea, and India. Short-term priorities include expanding the Strategic National Stockpile with critical APIs and finished drugs, enacting advanced purchase commitments by Tricare and the VHA to provide manufacturers the revenue certainty needed for long-term investment, and mandating tier-2 and tier-3 supplier reporting. Medium- and long-term levers include CHIPS Act-style tax credits and grants for domestic API and KSM manufacturing, regulatory harmonization through mutual recognition agreements, and investment in continuous flow manufacturing and AI-enabled process control. One critical point: KSM dependency remains a risk even when finished drug or API manufacturing is onshored. A durable strategy must address the full upstream chain.

Question:

How would the U.S. population benefit from government-owned, government-operated or government-owned, contractor-operated pharmaceutical manufacturing facilities?

Response:

Government-owned manufacturing facilities offer a targeted capability for producing strategically important medicines that the commercial market consistently underproduces due to structural incentive failures. The benefit would be concentrated in two areas: greater assurance of supply continuity for essential medicines during disruptions, and a price anchor during shortage conditions. However, government-owned manufacturing is expensive, and important questions about governance and operational efficiency warrant careful analysis. Advanced purchase commitments, long-term contracts, and resilience-weighted reimbursement are likely more cost-effective near-term interventions; government-owned facilities may play a complementary role for a defined set of the most strategically critical molecules.

Question:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in direct additional health care expenditure?

Response:

Shortages generate direct costs throughout the health care system: higher acquisition prices for alternative agents, pharmacy and nursing labor for workarounds, wastage from unused preparations, and premium sourcing and expedited shipping fees, as documented by Vizient. Exposure to unsafe or adulterated pharmaceuticals—such as the valsartan contamination of 2018 and heparin adulteration of 2008—adds further direct costs through recalls, replacement procurement, monitoring, and clinical management of harmed patients.

Question:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in indirect costs resulting from higher rates of illness?

Response:

When patients cannot access prescribed medicines, treatment is interrupted, and underlying disease progresses. For chronic conditions—cardiovascular disease, diabetes, cancer, epilepsy—interruptions increase the risk of acute events requiring emergency care, hospitalization, and long-term complication management, all generating costs that far exceed the cost of the unavailable medicine. Delayed chemotherapy due to shortages of carboplatin and cisplatin has been associated with worse outcomes and increased mortality. Treatment delays do not simply defer costs; they generate new and higher costs through worse clinical outcomes and extended treatment courses.

Question:

How do pharmaceutical supply chain challenges, drug shortages, or exposure to unsafe pharmaceuticals result in higher rates of illness and increased medical complications?

Response:

Supply chain failures increase illness and complications through treatment interruption, forced substitution to less effective alternatives, and direct patient harm from substandard or adulterated medicines. Forced substitution increases the risk of adverse drug events, subtherapeutic dosing, and clinical failure. The moral and clinical distress placed on providers who must ration scarce medicines—deciding who receives a critical chemotherapy agent or antibiotic when supply is insufficient—is itself a systemic consequence that undermines the integrity of care. Supply chain resilience is a patient safety issue. Addressing it is not only an economic and national security imperative—it is an ethical one.

Senator Raphael Warnock**Question:**

Health care providers across Georgia are concerned about the growing shortage of pharmaceutical drugs, including generic medications. Due to limited access, patients must wait longer for their treatments or turn to alternative drugs. You highlight how procurement reforms at federal agencies like the Department of Defense can address generic drug shortages and incentivize domestic manufacturing of pharmaceutical drugs. What type of procurement reforms should Congress pursue to ensure states like Georgia have access to quality medications?

Response:

The most impactful reform is adopting quality-based contracting frameworks that break the current race to the bottom in generic drug pricing. Federal purchasers—Tricare, the Veterans Health Administration, and Medicaid programs—currently award contracts primarily on lowest price, driving manufacturers toward cost-cutting that undermines quality and eliminates the margin needed to sustain domestic or allied production of essential medicines. The Drug Shortage Comprehensive Recovery and Improvement (DSCRI) framework and related proposals would reform contracting to reward manufacturers for quality, resilience, and domestic or allied-nation sourcing. Multi-award contracts preserve supplier diversity; long-term contracts provide the revenue predictability manufacturers need to invest in infrastructure. CMS reimbursement reforms incentivizing medicines made with domestic or allied APIs would shape incentives across the entire commercial market—with broader impact than direct government procurement alone. For states like Georgia, these systemic reforms are the most durable path to reliable access to quality medications.

Question:

According to a Government Accountability Office report, there have been inspection workforce shortages at the Food and Drug Administration (FDA) since 2018. From November 2021 to June 2024, the vacancy rate of investigators who oversee drug manufacturers increased from 9 percent to 16 percent, leading to fewer safety inspections of generic drugs. The Trump administration also dismissed more than 3,500 FDA employees in April 2025, further exacerbating the FDA's inspection workforce capacity.

You mention how limited FDA inspection workforce capacity hinders the agency's ability to regulate generic drugs and conduct quality inspections in foreign countries like China and India. How can Congress help stabilize the FDA inspection workforce and improve oversight over foreign manufacturing of generic drugs?

Response:

Congress should prioritize funding to restore the FDA's foreign inspection capacity. The FDA's inspection program is chronically under-resourced relative to the scale of overseas manufacturing it oversees; as I noted in my testimony, OAI outcomes in India are 13 percent-compared to two percent in Europe and eight percent in the U.S.-reflecting both real quality variability and insufficient inspection frequency. Domestic manufacturers face a structural disadvantage because U.S. facilities are inspected far more frequently than foreign counterparts without commensurate benefit to overall supply safety. Congress should direct the FDA to implement a risk-based inspection model calibrated to a facility's prior history, product criticality, and supply chain concentration-regardless of location. Risk-based border inspection authorities and point-of-care quality testing tools provide an additional layer of assurance against substandard products entering the U.S. market. Congress should also support mutual recognition agreements with trusted regulatory partners-the EU, Japan, and comparable advanced economies-to share inspection data and free FDA resources for the higher-risk environments in India and China where they are most needed.

Statements for the Record



**AARP
STATEMENT FOR THE RECORD
for the**

**UNITED STATES SENATE
SPECIAL COMMITTEE ON AGING
on**

**FOREIGN DEPENDENCE:
HOW CHINA CAPTURED AMERICA'S DRUG SUPPLY**

**March 11, 2026
Washington, DC**

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AARP appreciates the opportunity to submit this statement for the record and commends the Committee for holding today's hearing, *Foreign Dependence: How China Captured America's Drug Supply*. We value the Committee's bipartisan efforts to examine the safety and stability of the U.S. drug supply chain and the consequences that supply chain vulnerabilities pose for older Americans.

AARP has long maintained that every person should have reliable access to high-quality, affordable prescription drugs to support their health and well-being. Persistent and worsening shortages of essential medicines underscore the instability of the drug supply chain and the real-world consequences these disruptions can have for patients. The federal government can play an important role in proactively identifying risks and addressing weaknesses in the supply chain before they result in further harmful shortages. We value the Committee's attention to ensuring that critical medications – such as blood pressure drugs, statins, and cancer treatments – remain safe, accessible, and affordable for older Americans.

Supply chain-related drug shortages, whether due to manufacturing disruptions, breakdowns in distribution, or natural disasters, can delay or deny necessary care, sometimes forcing providers to rely on less effective alternatives. This is especially concerning for older adults: research indicates that nearly [three-quarters](#) of individuals affected by drug shortages are between the ages 45 to 85. For older Americans managing chronic health conditions, even short disruptions in medication access can have serious consequences for health, independence, and peace of mind.

When drug shortages occur, there are often few policy options that can immediately resolve the problem. For that reason, policymakers must prioritize proactive efforts to study, prepare for, and prevent supply chain disruptions before they become crises.

AARP recognizes that drug shortages are driven by complex and multifaceted causes that will require coordinated, long-term solutions. For example, we support the Administration's August 13, 2025, Executive Order to create a strategic reserve of active pharmaceutical ingredients (APIs) essential to national health and security, including an emphasis on strengthening domestic sourcing. Establishing an API reserve could help ensure that domestic manufacturers and compounders have access to vital ingredients during shortages or supply disruptions.

We also support the bipartisan *Mapping America's Pharmaceutical Supply (MAPS) Act* (S. 1784), which would require the Department of Health and Human Services to work with federal agencies and the private sector to map the full supply chain for selected essential medicines. A comprehensive end-to-end understanding is critical to identifying potential vulnerabilities and preventing disruptions before they impact patients.

In addition, continued efforts to improve transparency and data sharing across the pharmaceutical supply chain – including better visibility into manufacturing locations, ingredient sourcing, and potential bottlenecks – could help policymakers and regulators anticipate risks earlier and respond more effectively when disruptions occur.

When supply chains are unstable, the consequences extend beyond drug shortages. Disruptions can contribute to higher prices, delayed treatments, and increased financial strain on older adults

and their families. High and rising drug prices already force many Americans to make difficult choices, including skipping doses, delaying care, or sacrificing other basic needs. Because older Americans rely on prescription drugs more than any other population – often four to five medications each month – ensuring a stable and resilient supply chain is critical to their health and financial security.

AARP thanks the Senate Aging Committee for its continued focus on ensuring that older Americans have stable access to the medications they rely on to stay healthy and independent. The Committee has long played an important role in elevating issues affecting older Americans, and its attention to drug supply challenges is an important contribution to strengthening patient protections. We appreciate your leadership in examining supply chain vulnerabilities and look forward to continuing to work with policymakers to strengthen the resilience of the U.S. pharmaceutical supply chain. If you have any additional questions, please contact Gidget Benitez.



March 11, 2026

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, *Foreign Dependence: How China Captured America's Drug Supply Chain*

Dear Chairman Scott and Ranking Member Gillibrand:

Thank you for holding this hearing on the United States' dependence on China and other nations for pharmaceuticals, including active pharmaceutical ingredients (API). The American Society of Health-System Pharmacists (ASHP) is the largest association of pharmacy professionals in the United States, representing over 65,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health system community pharmacies, and recognizes how this issue impacts patient access to critical medications.

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.

Underlying Causes of Dependence on China and Other Nations for Prescription Drugs: Economic factors that undermine investment in manufacturing² and supply-chain reliability are the root causes of the U.S. drug supply chain's dependence on foreign manufacturers—and of most severe and persistent shortages. These economic challenges are driven by extreme price competition among generic manufacturers. For example, the lower profitability of generic drug manufacturing has caused

¹ <https://www.ashp.org/drug-shortages/current-shortages>

² <https://news.nd.edu/news/extreme-price-competition-in-pharmaceutical-industry-may-put-patients-at-serious-health-risk-study-shows/>

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companies to completely stop manufacturing certain less-profitable drugs.³ To address these economic pressures, generic manufacturers have become reliant on less expensive production facilities in China and other countries. The U.S. prescription drug supply chain's overreliance on foreign production of generic drugs, along with geopolitical risks, threaten our national healthcare security.

Recommended Solutions: To effectively address the United States' reliance on foreign drug manufacturers and protect seniors' access to quality pharmaceuticals, we strongly urge policymakers to focus on the key drivers of generic drug shortages: quality, transparency, and supply chain issues and larger healthcare marketplace trends that have placed intense economic pressure on the overall cost of generics. These solutions can be applied to both domestic and foreign manufacturers to provide greater resiliency and quality in the United States' drug supply chain, as well as less reliance on any single manufacturer geographic location.

Encourage New Manufacturers and New Manufacturing Sites: Entering the market to manufacture a generic drug is a multi-year process that requires significant investment in scientific, manufacturing, and regulatory functions. This makes it difficult for new manufacturers to enter the market and increase supply when shortages occur. Policymakers should encourage new manufacturing sources from both domestic and reliable foreign partners. To address these issues, and spur increased manufacturing, we recommend:

- FDA waive generic drug user fees for generic drugs described in 506C(g) of the Federal Food Drug and Cosmetics Act, for which 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.
- Congress require the federal government to use its purchasing power to encourage greater supply chain diversity and redundancy by spreading federal purchasing for any critical generic drug — determined by the Department of Health and Human Services to be at risk of shortage — across at least three different manufacturers with approved ANDAs. Federal purchasers should require that manufacturers rely on different contract manufacturers. Federal contracts should require manufacturers to 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. To ensure quality and transparency, federal agencies should give preference to manufacturers that participate in FDA's quality management maturity (QMM) program and voluntarily make their metrics publicly available.⁴
- Congress authorize the Centers for Medicare & Medicaid Services to provide an add-on payment to providers for critical generic pharmaceutical drugs determined by HHS to be at risk of experiencing a shortage, if those providers certify that they have entered an agreement to acquire at least 50%

³ <https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages#xj4y7vzkg>

⁴ 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 Strategic National Stockpile. (<https://news.ashp.org/news/ashp-news/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations>)

of their historical purchase volume for those products via long-term contracts. To ensure investment in supply chain stability and quality, the agreement must include a requirement that manufacturers maintain a six-month buffer supply of finished product as well as meaningful penalties for failure to supply contracted products, including when manufacturing disruptions result from regulatory violations or supplier disruptions. To be eligible for pass-through payments providers must demonstrate that their suppliers participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.⁵

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. To increase provider and consumer transparency into quality issues, we recommend:

- Manufacturers must provide country-of-origin labeling for pharmaceuticals and API. Every American and provider of care should have the right to know where their pharmaceuticals are manufactured. Today, that information can be voluntarily provided by manufacturers, but it is not required. Research has shown that patients and pharmacy purchasers show a higher preference and willingness to buy products from the U.S. or Canada compared to products from India or China when the country of origin is made available to them.⁶ Knowing where drugs are manufactured can also help government agencies, private investors, and researchers to better understand the drug supply chain and decide where to invest resources to address vulnerabilities.
- The FDA finalize, and make public, QMM, so that purchasers can buy from manufacturers less likely to experience a shortage.
- The 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. This would be particularly helpful in navigating foreign pharmaceutical quality issues.

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 drug manufacturing disruptions. 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.⁷ To ensure FDA can enforce the law and respond 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.

⁵ Recommendations from ASHP and other healthcare providers in 2021 called for FDA to make these metrics public. <https://news.ashp.org/news/ashp-news/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations>

⁶ https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4639108

⁷ <https://docs.house.gov/meetings/IF/IF14/20230511/115917/HMTG-118-IF14-20230511-SD006.pdf>

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.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tom Kraus', is positioned above a light yellow rectangular background.

Tom Kraus
American Society of Health-System Pharmacists