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BEHIND THE LABEL: FOREIGN OWNERSHIP AND CONTROL IN AMERICA'S DRUG SUPPLY CHAIN

HEARING

BEFORE THE

SPECIAL COMMITTEE ON AGING

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BEHIND THE LABEL: FOREIGN OWNERSHIP AND CONTROL IN AMERICA'S DRUG SUPPLY CHAIN

Wednesday, July 15, 2026

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

The Committee met, pursuant to notice, at 3:33 p.m., Room G50, Dirksen Senate Office Building, Hon. Rick Scott, Chairman of the Committee, presiding.

Present: Senator Scott, Moody, Husted, Gillibrand, Warren, and Alsobrooks.

OPENING STATEMENT OF SENATOR RICK SCOTT, CHAIRMAN

The CHAIRMAN. The U.S. Senate Special Committee on Aging will now come to order. The Ranking Member and I were thrilled to see the Older Americans Reauthorization Act pass the Senate yesterday. This legislation is critical to protecting seniors' independence and reaffirms Congress' commitment to the older Americans who built and served this country.

As Chairman of this Committee, I have been privileged to lead the charge in reauthorizing the OAA with the Ranking Member Gillibrand. We have seen firsthand through multiple hearings the positive impacts legislative solutions can have on seniors and caregivers alike, giving dignity and strength to those living out their golden years.

I am especially proud to have led this effort in the Senate with the Ranking Member. I would like to personally recognize and thank her for her hard work and partnership on this legislation. I now urge the House of Representatives to quickly pass the OAA and send it to President Trump's desk.

I also want to thank my Senate Republican and Democrat colleagues for their support of our seniors through the OAA. Here is a question most people have never thought to ask, do you know who actually makes your medicine? Not what is on the bottle, but who owns the facility? Who controls the ingredients? Does a foreign government have any influence over the decision of what goes into them?

Most Americans don't know, and in many cases, neither does the Federal Government. Seniors rely on prescription drugs more than any other age group. More than 88 percent of older Americans report being prescribed at least one medication in the past year.

Nearly all of those prescriptions are filled with generic drugs, and a huge share of those generic drugs are manufactured in facilities overseas by companies with complex ownership structures that the FDA, CFIUS, and other agencies can't fully trace. For most products, that is a trade question. For medicine, it is a matter of life and death. We have seen what happens when something goes wrong with a faulty supply chain. Unfortunately, people die. We have seen what happens when our supply chain gets constrained. Unfortunately, people die. I have said it before, there is no reason why we should be letting our adversary, Communist China—they have decided to be our adversary—control our medicine supply chain. If they wanted to, they could restrict exports tomorrow of the critical ingredients needed for life-saving medicines.

The difference between a trade disruption and a public health emergency is how dependent we are on the country doing their restriction. Right now, we are very dependent. Today, we are going to examine a different but related problem. Not just what drugs are—where drugs are made, but who owns the companies making them. Foreign ownership and control can create leverage over our drug supply that is largely invisible to the Federal Government so there is not a federal agency that has been designed to understand this.

FDA doesn't have full visibility into it and current disclosure rules don't require the transparency needed to even know where the risks are and it goes even further than that. Most people think about foreign threats to our drug supply in terms of what's on the shelf but there is another problem that almost nobody is talking about. When American patients participate in a clinical trial, American regulators authorize that trial.

American patients take on the risk, but the data those trials produce, what works, what doesn't, what the next generation treatments should look like, can end up flowing directly to a foreign government that doesn't like us, legally with no federal agency able to stop it. That means Communist China doesn't have to steal our medical breakthroughs, we just hand it over to them. We have witnesses today who have worked on these problems from inside the Government. They are going to help us put this on the record. Today I am announcing the Pharmaceutical Investment Oversight and Accountability Act with Ranking Member Gillibrand, and with Senator Warren. Legislation requires the FTC and CFIUS to report to Congress annually on foreign investment in pharmaceutical manufacturing and related technologies. Transparency is the first step, but it is just the first step. This hearing is going to help us identify what has to come after that.

The American people, and especially seniors, deserve to know who actually controls the medicines keeping them alive. I would like to recognize Ranking Member Gillibrand.

OPENING STATEMENT OF SENATOR KIRSTEN E. GILLIBRAND, RANKING MEMBER

Senator GILLIBRAND. Thank you, Chairman Scott, for today's hearing. Thank you to our witnesses. We appreciate your expertise and testimony. As the Aging Committee continues to examine a range of factors that put seniors' access to essential medicines at

risk, we keep hearing the outsized influence of foreign actors on our drug supply chain.

We know that America relies too heavily on China and India for the foundational components to manufacture generic drugs, the key starting materials and the active pharmaceutical ingredients. It is troubling how foreign actors continue to deepen their impact by expanding ownership, investment, and control of our supply chain.

This poses a significant risk to the American public, especially because we currently do not and cannot see the full extent of our upstream dependency on foreign actors within the supply chain. This is in part because these countries try to disguise their involvement and influence in ways that our witnesses will discuss later in the hearing.

It also happens because we need stronger tools to understand, evaluate, and manage these modern supply chain risks. We must bolster federal oversight efforts and increase transparency on how foreign capital impacts American health care infrastructure. This will strengthen our health and national security without discouraging trusted investment.

I am proud to support the work Chairman Scott and Senator Warren do with their Pharmaceutical Investment Oversight and Accountability Act, but we also have to align policy goals and targeted investments to diminish foreign dominance in our drug supply chain and maintain our global leadership in biopharmaceutical innovation.

This involves addressing market factors in the U.S. that have led to a race to the bottom for generic drugs. Congress must work with industry to make sure manufacturers and purchasers consider quality, not just cost, when they source key pharmaceutical ingredients and final dose medicines.

Foreign countries like China have rapidly scaled up innovation for novel therapies through efforts like clinical trial reform, targeted Government investment in drug development, and improved coordination between early research and commercial scale manufacturing.

While we do not need to exactly replicate the steps they have taken, we must acknowledge that they are moving at a much faster pace than we are, increasing our dependence on their clinical trials and components for essential medicines. We can't let foreign actors, much less our adversaries, surpass us in innovation. It will only increase our reliance and deepen their control over crucial American health infrastructure and supply chains.

I look forward to hearing from our expert witnesses today. I am committed to working with my colleagues to improve our tools to understand, evaluate, and manage modern supply chain risks so we can strengthen our health and national security. Thank you.

The CHAIRMAN. Thank you, Ranking Member Gillibrand. Now, I would like to welcome our witnesses. They are here to help the Committee understand where foreign ownership creates real risk in the drug supply chain and what the Federal Government can actually do about it.

First, I would like to recognize Hon. Nazak Nikakhtar—how did I do? In 2018, she was unanimously confirmed as the Department of Commerce's Assistant Secretary for Industry and Analysis, per-

formed the duties of Undersecretary for Industry and Security, performing the non-exclusive functions and duties while nominated.

She was Commerce Lead on CFIUS, and oversaw the Government's first Whole of Government Supply Chain Assessment Initiative. She now chairs the National Security Practice of Wiley Rein. Thank you for being here. Please begin your testimony.

STATEMENT OF HON. NAZAK NIKAKHTAR, PARTNER & CHAIR OF THE NATIONAL SECURITY PRACTICE, WILEY REIN LLP, WASHINGTON, D.C.

Ms. NIKAKHTAR. Chairman Scott, Ranking Member Gillibrand, and members of the Committee, thank you for hosting this important hearing and leading important legislation to address critical issues. My name, again, is Nazak Nikakhtar. My testimony today is informed by my work in trade, national security, and supply chains over the course of 25 years as an economist, attorney, and policy expert.

The threats posed by China's growth in biotech, fueled by IP theft and misappropriation and massive state subsidies, and a distorted economy that consistently underprices the rest of the world is well established, so I will not spend time of that. Yet these realities provide the context in which I will discuss our legal shortcomings and propose solutions.

In 2024–2025, China surpassed the United States in biotech innovation, deal value, and in clinical output. Its innovations are outpacing ours. For every $100,000 in U.S. biotech R&D spending, America has one scientist, China has three. China also dramatically outpaces us in STEM graduates by two times and 10 times more in engineers.

Also, China's distorted economy intentionally keeps prices low and transfers wealth to the Chinese Communist Party, and the CCP uses its cash-flow to underprice the rest of the world in biotech goods and services and subsidizes our industries at a scale that dwarfs ours.

These predatory economic practices are along with the well-established reality of pervasive IP theft, as well as clinical trials being conducted in China without any regard to the welfare of the population, is very alarming. To underscore, China is a foreign adversary under U.S. law because its aim is to harm our Nation, our citizens, and our allies so an adversary's ability to reach into and gain greater control of our pharmaceutical supply chain obviously poses a risk to America, our citizens, and to our allies.

We need to look no further than what has happened in the semiconductor, batteries, auto, critical minerals, and robotics sectors as examples of what is yet to come. As to recommendations, first, most Chinese biotech investments in the U.S. seek to acquire American IP and sensitive personal data and disrupt domestic markets through market manipulation.

To the extent CFIUS jurisdiction exists, many transactions are cleared today with mitigation measures, but almost always violations of mitigation measures won't be detected by the U.S. Government. This is a risk we cannot afford to take with a foreign adversary.

Whenever investments by China come under CFIUS's existing legal jurisdiction for national security review, we need to institute

a presumption of denial, meaning that the parties need to justify why the U.S. Government needs to approve this transaction. I have never encountered, in my time in the Government and private practice, any scenario where a Chinese investment in a U.S. biotech company did not pose a serious risk to being misused by the CCP to effectuate its Mil-Civ fusion strategy to America's detriment.

Second, CFIUS's jurisdiction doesn't cover most greenfield investments and joint ventures in the United States, which has obviously now become China's preferred way of investing. Legal jurisdiction needs to be extended by Congress through the passage of FIRRMA 2.0. and, or the President needs to institute an IEEPA based Executive Order to close the gap as it pertains to foreign adversaries.

Time is running out and these gaps remain wide open today, enabling predatory FDI to occur largely undetected. Third, we need to impose broader export controls on emerging and foundational biotechnologies, biomaterials, and related data that are exported to China for pharmaceutical manufacturing and trials.

Currently, all this flows virtually unrestricted to China, the CCP, and the People's Liberation Army. Broadening controls will permit biological materials and data to be treated, in the CFIUS context, as critical technologies, mandating CFIUS review. Without question, we can better control data through current export laws, and we should. Fourth, we need to address the fact that U.S. investments in Chinese biotech occur significantly through corporate licensing deals and venture capital.

While BINSA, the Biotech Investment National Security Act of 2026, is an example of a positive step forward, it needs to be passed, and the implementing regulations need to be broad enough to cover all forms of capital flow. Comprehensive bans are effective. Nuanced regulations enable widespread circumvention. Fifth, we need to import prohibitions on biotech materials produced in China. We have trade laws and forced labor prohibitions to do that to prevent the American population from being harmed.

My final point is this. With respect to anybody claiming that these recommendations will increase U.S. prices, this is a red herring. China's growth in biotech is only a recent event. Prior to China's grow, the U.S. pharmaceutical industry faced economic pressures that stemmed from unrelated issues.

If we have pricing issues at home, we need to address them at home. Relying on China does not solve our competitiveness problem, it only adds to it. Thank you, and I look forward to your questions.

The CHAIRMAN. Thank you. Next, I would like to introduce Stephen Ezell. He is the Vice President for Global Innovative Policy at the Information Technology and Innovation Foundation, where he directs their Center for Life Sciences Innovation.

He spent his career studying how ownership structures and innovation policies shape global competitiveness, including where foreign control creates hidden risks in strategic industries. Thanks for being here. Please begin your testimony.

STATEMENT OF STEPHEN EZELL, VICE PRESIDENT FOR GLOBAL INNOVATION POLICY, INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION (ITIF), WASHINGTON, D.C.

Mr. EZELL. Good afternoon, Senator Scott, Ranking Member Gillibrand, and members of the Committee. I appreciate the opportunity to testify today, and I appreciate this special Committee for examining the critical issue of foreign ownership control and influence, especially with regard to China and America's drug supply chain.

The United States and China are locked in a fierce struggle for leadership in advanced technology industries, as China challenges America for global leadership across a range of sectors, from aerospace and automobiles to semiconductors and AI, to biopharmaceuticals. China first identified biopharmaceuticals as a ″strategic and emerging industry″ in 2007 but since then, China's growth in the industry has been tremendous, as China's value added in this industry has grown from just $15 billion in 2002 to $190 billion by 2024.

China seeks dominance across all phases of the biopharmaceutical supply and innovation chain. All the way from the manufacturing of key starting materials, KSMs, and active pharmaceutical ingredients, to generic and innovative drugs, in addition to the conduct of the clinical trials and the basic science behind them.

We are here today about how China has come to dominate globally in KSMs and APIs, accounting for 94 percent of the KSMs for amoxicillin and 74 percent of heparin that America uses but policymakers must understand that China's drug prowess isn't just APIs and generics. China now accounts for 31 percent of the new drug development pipeline globally.

China has surpassed the U.S. now in clinical trial starts for new oncology drugs, and overall their share of ongoing clinical trials for new drugs, the most innovative ones in the world, is now just three percent off the U.S. share. China has deployed every possible policy lever conceivable to turbocharge its biopharmaceutical competitiveness.

To be sure, some of these are legitimate, such as increasing R&D investment, educating scientists, or reforming clinical trial procedures, but a great many practices are unfair, such as rampant IP theft, non-market subsidies, and predatory pricing practices that enables Chinese producers to sell APIs for prices often 40 to 50 percent below global levels and there is another unfair strategy.

Intentional Chinese obscuration about the true ownership nature, or CCP, or PLA links of Chinese companies servicing the U.S. pharmaceutical supply chain. Recent ITIF reports have documented such Chinese false flagging or brand obfuscation in sectors from aerospace to clean energy, to biotechnology as China directs its companies to downplay the company's home country identity when they operate in the United States. ITIF's written testimony provided several case studies in the biotechnology industry, including Beijing Genomics Institute and Wuxi AppTec.

BGI, a leading provider of precision medicine services, which now operates the world's largest genomic sequencing capability, brands itself in America under the firm Complete Genomics, which it ac-

quired in 2012. It brands itself as Complete to obscure the fact that it is owned by the BGI and directly linked to the CCP and PLA.

The Chinese biotech Wuxi Pharmatech acquired Minnesota-based biologics and medical device testing firm AppTec Laboratory Services in 2008, transforming the entity into Wuxi AppTec. The company is now a world-leading contract research development and manufacturing organization.

While the company has sought to disclaim its China ties, Wuxi AppTec maintains an extensive network of relationships with the CCP, is involved directly in the Chinese military civil fusion development strategy and operates the PRC's state key laboratory of drug lead compound research. Its CCP party vice secretary Li Wenbun has stated that ″party members are the technical backbone of Wuxi AppTec.″

To deal with these obscuration practices, ITIF recommends that Congress should expand the Corporate Transparency Act to require Chinese origin companies operating in high-tech sectors in America to report beneficial ownership and operational control, including minority stakes, joint ventures, offshore subsidies, and IP transfer rights.

Companies that fail to provide full transparency should be barred from doing business in the United States. For entities owned or controlled by companies from designated countries of concern, the FTC should issue guidance on truth in branding practices, requiring companies to clearly disclose this foreign ownership or their foreign ownership in marketing, branding, and web communications.

ITIF's written testimony provides further policy recommendations for how America can enhance the security of our drug supply chain, from investing in novel bio-manufacturing processes, to fend shoring, and strategic stockpiling.

We must recognize we are in a fierce struggle for biopharmaceutical leadership, and it is critical that Congress implement policies that effectively support the industry, but also ensure that Chinese predatory trade and economic practices don't harm American patients, workers, and companies. Thanks, and I look forward to your questions.

The CHAIRMAN. Thank you. Now, I would like to introduce Edward You. He is a former FBI Supervisor Special Agent who spent over 20 years working on biosecurity and emerging technology threats at the FBI, the White House, and the Office of the Director of National Intelligence.

He represented the United States at the United Nations Biological Weapons Convention and has been featured on CBS's 60 Minutes for his work protecting U.S. biotechnology. He now runs EHY Consulting, LLC. Thanks for being here. Please begin your testimony.

STATEMENT OF EDWARD YOU, FOUNDER AND PRINCIPAL CONSULTANT, EHY CONSULTING LLC, FAIRFAX STATION, VIRGINIA

Mr. YOU. Good afternoon, Chairman Scott, Ranking Member Gillibrand, and I want to thank the Committee for this opportunity. I am going to be doing something a little bit different. I ap-

preciate the title of today's hearing, looking at behind the label. I am going to ask you to look beyond the label.

What I mean by that is the acknowledgment that biotechnology has become so advanced in my 20 years in the FBI, now currently in my consultancy. You have heard disparate technologies being laid out. What I am witnessing, and we should be acknowledging, is that there is absolute convergence of these technologies happening.

What this is translated into is that biotechnology is impacting multiple critical infrastructure sectors. It is not just health. It is also agriculture, manufacturing, renewable energy production so it is strategic in its nature, and by the way, the fact of that matter is the Chinese government has acknowledged that. You are seeing that in a lot of their statewide policies, their 15th Five Year Plan. They are acting on it.

Mr. Chairman, you already mentioned about the CAR-T cell therapy issue, and the fact that our own FDA has cleared multiple Chinese startups with CAR-T cell therapies. It is a breakthrough cancer treatment, and they are being brought over to the U.S. and being put into U.S. patients, and the resulting clinical trial data is then being sent back to China.

What that means is that that data is then supercharging their AI to analyze and come out with the iteration for the next round of therapeutics but then, what is even worse is that our companies as it was mentioned is licensing those products.

Then our government is funding it through reimbursements, through Medicare. It is a double, triple whammy, and it is something that we need to be acknowledging but with that in mind, it also means that data is absolutely the new oil, and we need to be looking at it that way. The thing about this is that oil doesn't—data doesn't spoil.

That means it is going to be a continuing challenge. It also means that we challenge cyber security. It is not traditional cyber security. It impacts Medicare and Medicaid. It impacts health records, especially for our senior citizens who are dependent upon that. We have to acknowledge that that is what is happening in this space.

To broaden it even further, I also want to include agriculture, because the U.S. has historically been a powerhouse in agriculture. That has been on the backbone of our economy. The point is, is that now agriculture is not just a commodity or for food. It is now being targeted as a possible solution for renewables, for biofuels, but also for pharmaceuticals.

We are looking at the evolution of not just farm to fork, but farm to fiber, farm to fuel, and farm to pharmacy. With that in mind, the Chinese have already declared that as a priority in their most recent plans.

They just launched a 5-year smart farming plan to integrate AI, robotics, automation, to supercharge their ability to expand their agricultural manufacturing capabilities, not just, again, for traditional, but also for their future pharmaceutical capabilities as well.

How is this all looking for us? If you look at China's 15th Five Year Plan, their Healthy China 2030 Strategy, but more importantly, their China Standards 2035 Strategy, what that means is

that they already know it is not just about the technology, it is not just about implementation. It is understanding how do they determine what the rules of the road is for the global markets.

That they understand that if you are able to influence the standards, you will influence the markets, and therefore we have to become subservient to that so the issue here is that unless we understand what the implications are, my recommendations are, one, is understanding that it is absolutely strategic in nature—that we are in the midst of this global biotech space race. Second is I recommend looking at the National Security Commission on Emerging Biotechnology that is supporting Congress. A lot of their legislative recommendations address everything I just mentioned.

Third, we absolutely need to do a better job in assessing the risks associated with biotechnology and the bioeconomy because historically, when the National Security Community, including the Intelligence Community, comes to the bodies like this, what are the predominantly characterized threats? It is pandemics or an engineered bioweapon, but we are talking about something more strategic now, and we cannot be isolated in our silos. We absolutely have to acknowledge the convergence.

As it stands right now, we are not established to understand holistically what these threats are. I think the most important one is we just need to out-compete. You do not win a space race by playing defense all the time. It is more than just CFIUS and protections and export control. We out-compete, we out-innovate, and we are not established to do that right now.

Finally, though, if we don't, what we are losing is not just market share, but we are losing in the promise of protecting our senior population, but also we are not fulfilling the promise of the generation that we leave the world a better place, and we put ourselves in a position to have our children to be able to succeed beyond us.

We are failing that right now. With that, I thank you again for this opportunity and I welcome your questions.

The CHAIRMAN. Thank you. Ranking Member Gillibrand, I think you are going to introduce the next witness.

Senator GILLIBRAND. Thank you, Mr. Chairman. I would like to introduce Rush Doshi. Dr. Doshi is a C.V. Starr Senior Fellow for Asia Studies and Director of the China Strategy Initiative at the Council on Foreign Relations.

Previously, Dr. Doshi was the Deputy Senior Director for China and Taiwan on President Biden's National Security Council, drafting the Administration's China strategy, and aiding the launch of AUKUS, a security partnership for Indo-Pacific region between Australia, United Kingdom, and United States. You may begin.

STATEMENT OF RUSH DOSHI, PHD, C.V. STARR SENIOR FELLOW FOR ASIA STUDIES, DIRECTOR OF THE CHINA STRATEGY INITIATIVE, COUNCIL ON FOREIGN RELATIONS, ASSISTANT PROFESSOR, GEORGETOWN SCHOOL OF FOREIGN SERVICE, WASHINGTON, D.C.

Mr. DOSHI. Chairman Scott, Ranking Member Gillibrand, distinguished members of the Committee, thank you very much for the opportunity to testify today. My argument today is simple. We moved our pharma supply chain offshore. We then became dependent on China for essential medicines.

Now we are making the same mistake again in biotechnology, and none of this is good for our patients. My testimony draws from a year-long study we published last month of the Council on Foreign Relations, but in my limited time today, I want to focus on just three priorities from that report. The first is essential medicines.

We want to reduce our dependence on China on these medicines. The second is our biotechnology innovation ecosystem. We are shipping that system to China, and we are losing the ability to generate innovation at home. The third is our biomanufacturing ecosystem.

We are offshoring that to China as well, and we are increasingly unable to make the medicines of the future here in America. These trends are serious, but with your leadership, they are reversible. I will now turn to address each in turn. First, essential medicines. A drug label might say, Made in America, but our team looked at the data and found the upstream inputs, what we call, of course, KSM, key starting material, or API, active pharmaceutical ingredients, increasingly come from China and only from China.

That creates a dangerous dependency. Take amoxicillin. We write 60 million prescriptions a year, but China controls 94 percent of the world's starting material. Or take heparin, 12 million Americans receive it every year in hospitals, but 80 percent of global crude supply is from China.

In fact, nearly 700 medicines approved for use in the United States depend on at least one upstream chemical produced solely in China. How did this happen? We focused on price, not resilience. Meanwhile, China ran the rare earth's play in pharma. They extended subsidies, tolerated pollution, and created prices to lock in a global monopoly position. It all happened fast. American amoxicillin production fell from nearly 100 percent of our market to 0 in just 12 years.

What should we do? First, we need to find our upstream dependencies through legislation like clear labels and address them. Second, we to change incentives. Medicines that use Chinese inputs should face higher tariffs and lower Government reimbursement rates than medicines that use allied inputs. Third, we should work with our allies. We cannot bring everything back so we should divide and conquer dependencies together.

Fourth, we should stockpile finished drugs and their upstream inputs so we can weather disruption. Finally, we build supply. That means funding leapfrog innovation from cell-free methods to green chemistry and providing low-cost capital. A single $50 million grant made an Austrian plant competitive with China in penicillin.

We can do the same here. The second trend I would like to address is the offshoring of our biotech innovation ecosystem. Our system is breaking down. American pharma companies are licensing therapies developed in China instead of investing in therapies developed in America.

In the last five years, they committed $53 billion to Chinese assets that now make up one-third of new drug pipelines. These vast sums are rapidly building China's innovation ecosystem while starving our own. Why is this happening? Partly it is because China is genuinely innovative, but a larger part is because China

has a looser regulatory regime. To put biologics in humans, we have to go through a formal FDA process. They just have to ask a hospital review board for a green light.

American pharmaceutical companies can get initial data that a therapy might work faster from Chinese companies than from American companies, and with that, dollars flow accordingly so what do we do? First, we should regulate but not prohibit in-licensing from China. We want to reward Chinese innovations that help patients, but we want to disincentivize arbitrage that hollows out our system.

We can use differential tax rates, differential reimbursement, or regulatory scrutiny of licensing under the Biotech Investment National Security Act, or BINSA, to find a middle ground between bans and deregulation. Second, we have to strengthen our system. We need to reform our clinical trial process to move faster to first in human trials, drawing perhaps from Australia's model. That will make arbitrage less likely.

We have to fund basic science now more than ever to keep our ecosystem going. The third trend I would like to address is the offshoring of our biomanufacturing capability. We are losing the ability to make the medicines of tomorrow. Roughly 80 percent of U.S. biopharma companies now work with Chinese contract manufacturers like Wuxi Bio, who gain experience and knowledge that compounds their lead over us, all financed by us.

Meanwhile, we are locked in to deals with them because biomanufacturing is hard to move from one facility to another. When we do bring it back home, we are increasingly dependent on Chinese upstream inputs, so we can't do it without them. How do we fix this? Well first, the Biosecure Act rightly disincentivizes some of the offshoring, but we also need to build our own capacity with low-cost loans, a national center for advanced biologics manufacturing, and investments in leapfrog production methods. Second, we need to incentivize diversification.

Federal funders, NIH, BARDA, the Defense Department, and regulators like the FDA should require China risk plans or a qualified alternative manufacturer in the United States or an allied country before a program reaches a defined milestone.

Let me end with this. American purchasers, and above all American taxpayers, account for roughly 70 percent of global pharmaceutical profits. That spending should be consistent with our supply chain security, our innovation ecosystem, and our strong manufacturing base, and good for all patients. Thank you for your time, and I look forward to your questions.

The CHAIRMAN. Great. I want to thank each of you for your testimony. Let me ask you a simple question. How many warships and fighter planes do we buy from China? Yeah, zero right? Why don't we? They probably get it cheaper, right? Because we don't want to be dependent on them.

I mean, we are building a military, so we are not dependent on them. We don't want our service men and women dependent on their equipment. What I don't understand is, why are we buying any drugs from China?

Ms. Nikakhtar, you were Congress' lead on CFIUS. CFIUS is built around the idea of control, but in this industry, real control

can come from a minority stake, a board seat, licensing deal, or data cross access right.

When you were sitting in that chair, were there pharmaceutical or biotech deals you were worried about that CFIUS simply had no clear authority to touch?

Ms. NIKAKHTAR. I am sorry, I did not hear all of it. Were you asking about the scope—how much of it? It is pretty astounding. The U.S. Government, we don't have a good sense of what CFIUS doesn't touch, because you get Chinese companies who pretend like they want to invest in American companies, pretend like they go through the due diligence, go in the data room, get all the information they need, and they say, oops, we don't want to invest in you, and none of it comes before CFIUS.

You have versions of that going on and on, so there is no way—even if an FDI doesn't occur, you don't know how much of the predatory actions have actually robbed our companies of their sensitive data and it is not just including IP, right. It is the data, it is their know-how, it is how they test, etcetera.

We have got a real problem in not detecting things, which is why I really commend your and Senator Gillibrand's legislation on just trying to get better visibility into what is going on, so legislation is at least buttressed by more facts.

The CHAIRMAN. Does a board seat come to CFIUS?

Ms. NIKAKHTAR. Is a board—.

The CHAIRMAN. If they were just putting somebody on a board. They didn't make any investment. They just said, oh, I have got this great scientist from China who is going to go on some company's board. That wouldn't come in front of CFIUS, right?

Ms. NIKAKHTAR. In very few instances, it would, but by and large, it wouldn't. That board seat could get, again, as you are pointing out, access to sensitive information, but only in very limited instances if other conditions are met, only if others trigger CFIUS jurisdiction.

The CHAIRMAN. How about licensing deals? Do they all come in front of CFIUS?

Ms. NIKAKHTAR. Nope. Not if there is no investment.

The CHAIRMAN. How about data? What if they just paid the fee for data access right?

Ms. NIKAKHTAR. They are doing lots of that, and they are doing sneakier ways to get data, and that does not come under U.S. Government's review jurisdiction.

The CHAIRMAN. Mr. Ezell, your testimony says China controls the key starting materials for 94 percent of amoxicillin, 74 percent of heparin, and 100 percent of the ingredients of drugs that treat high blood pressure.

Every blood pressure pill in this country traces back to a single source Chinese ingredient. That is right, correct? What happens if they just stop giving it to us? Talk about what is going to happen to a senior. We don't get anything tomorrow.

Mr. EZELL. Yes, exactly. The critical point is that China is looking for leverage over the United States. It has identified critical minerals. It has identified rare earth magnets at critical areas it can get leverage.

There is no question that biotechnology, KSMs, and the APIs are special choke points that they could use to weaponize against the United States at their time of choosing should we not have an ability to respond to that contingency.

The CHAIRMAN. Mr. You, in your years at the FBI, what methods did foreign state actors use to gain influence over U.S. pharmaceutical and biotech companies that would never trigger a CFIUS review, and the FDA would never see coming?

Mr. YOU. That is a broad question, sir, because it is a full court press. Let me start by saying that I think, understanding about the bioeconomy, understanding that China—it is silver bullet for them, right, because they actually have real world challenges.

They have population sustainability issues. They have food security. They have energy insecurity. They are dealing with environmental remediation challenges. Biotechnology offers that to them so you see the full court press and from the whole scope in either funding research and development, acquiring talent development, right, so we have seen that happen right now too, looking at the talent going overseas.

As was mentioned before, looking at investments that may not necessarily trip the bar but then also looking at downstream, too. As I mentioned, the standards aspect of it as well, is that it is not just about theft of IP, but if you also are able to manage what the—things like the International Council for Harmonization, which provides global instructions on how you determine medicine treatments, how you conduct clinical trials, especially for cutting edge treatments like CAR-T cell therapies or mRNA vaccines, which is uncharted territory, they get first mover advantage.

I think that is the way we need to be understanding. That it is not necessarily always us be reactive but understanding that they have huge incentives to make it happen, but it goes back to what I said before, we have to do a better job in understanding how we conduct our risk assessments.

Because yes, we are losing our shirts when it comes to IP theft and a lot of the investments, but then they are absolutely leaning forward on trying to out-innovate us because they need it but then that also means that not only do we have to be able to address that, but we also need to counter that as well too. Meaning that you don't win a space race playing defense all the time. You out-innovate.

The CHAIRMAN. Yes. Dr. Doshi, your report models what happens if China restricts just 25 percent of the inputs for amoxicillin. You find peak shortages in the United States within six to nine months. Can you describe what that looks like inside an American nursing home or hospital?

Mr. DOSHI. Thank you, Senator Scott. This challenge is enormous. Amoxicillin has 60 million prescriptions a year. The ability to have a shortage or an increase in price, I mean, that will ripple through the healthcare system, and that is just one drug where we have a dependency. We have heard about many, many other drugs, and at least 700 have an upstream dependency on KSM that comes from only China so we are talking about potentially a magnitude of impact that would be devastating to seniors.

The CHAIRMAN. All right. Ranking Member.

Senator GILLIBRAND. The biotechnology space race is likely to define this century, and the United States's continued lack of strategic investment risks seeding our competitive edge in global development. The National Security Commission on Emerging Biotechnology's 2025 report cautioned that the U.S. is dangerously close to falling behind China and urged immediate action to scale biomanufacturing.

If the United States fails to maintain global leadership in biotechnology, in what ways would this impact seniors' health security and their ability to access the high quality medicines that they need?

Mr. YOU. Thank you for the question so it translates in more than just what we tend to think of. Like the medical tourism is something that we tend to bring up. It is more existential threat than I think we fully appreciate, especially again, with the convergence of AI.

The nightmare scenario I see is not just becoming completely dependent upon a foreign supply chain for our critical medicines, but if you game it out, if you look at the coming storm of the internet of things, of the interconnected world, of 6G, and not understanding where our data is going and how it could then be leveraged and where they out innovate, the nightmare scenario from where I sit is that we may end up seeing that every single biological input that sustains us, not just our seniors, but us as individuals, our food, our medicine, our energy production, what happens if that all is influenced by an authoritarian regime that is antithetical to not only economically, but to our standards and our values. I think we need to understand that that is a slippery slope that we are about to embark on if we do lose that first mover advantage.

Anecdotally, when we had the wake-up call in the first space race—when the Soviets launched the Sputnik satellite, that was a wake-up call moment. One of the things that Congress did was pass the National Defense Education Act, which dropped billions of dollars from K through 12 to college education to make sure that it shored up our workforce, the future computer scientists, engineers, physicists, to make sure that we maintained our advantage.

If we acknowledge that this is space race, we need bold moves like that to be able to counter it, because otherwise, that nightmare scenario I just articulated could potentially become a reality.

Senator GILLIBRAND. Yes. You previously discussed developing a bioeconomic strategy to ensure the U.S. retains its global competitive edge. What should the pillars of this proposal be, and what agency or coordinating body should be charged with implementing such a proposal?

Mr. YOU. I want to reference, as you mentioned, the National Security Commission on Emerging Biotechnology. One, they had a recommendation that there should be a coordinating office within the executive branch, which I acknowledge.

Quite frankly, something like the NSCEB, which is set to sunset this year, from my standpoint, is a little bit of a shame, because that has been a phenomenal body to kind of do a survey of where biotechnology—what the current status is and be able to engage the different sectors in academia and private sector to kind of fore-

cast where it is going, and then support Congress with the potential policy recommendations.

There is that but quite frankly too, that one of the challenges that I faced personally during my time at the Bureau, and it still exists today, and I just touched on my recommendations, is that we need to do a better job in doing the risk assessments. Because if the Intelligence Community is forecasting biotechnology, and if the resulting products that are provided to you, the decisionmakers, is looking at pandemic preparedness or a bioweapon, those are important, yes.

If it is not also incorporating what is happening in the bioeconomy space, then we are flying blind. It is not just what the risks are, but it is actually missing out on the opportunity spaces where what are the next greenfield areas that we should be launching into? As I mentioned before, the U.S. is an agricultural biomanufacturing powerhouse, and we are just not leveraging that.

Senator GILLIBRAND. Yes. Dr. Doshi, what advantages does China have over the U.S. in biotechnology development? How did they gain these advantages, and what steps should the U.S. take to regain them? If you have any recommendations on the last two questions, please include those.

Mr. DOSHI. Thank you very much, Ranking Member Gillibrand. I will just start by saying that the first advantage they have right now is that they have invested significantly in their capacity so they are able to do bio manufacturing at scale for far less than we can, often below probably cost. That is one enormous manufacturing advantage, but it is perhaps not the most important advantage.

What I am more concerned about right now is the fact that their clinical trial process or their pre-IND investigations are able to move much faster than ours. In China, if you want to get a biologic into a human being, you just go to a hospital and you get a green light from their ethics board. In our country, we have to go through the FDA. The difference in time can be a year but for a pharma company in America, when they have to compare buying an American asset or licensing a Chinese asset, the Chinese asset comes with that very exquisite, special de-risked data.

They are willing to pay a premium for it. That premium comes at the expense of patient access and quality and other kinds of considerations that we care about. Patient rights, for example but it is still a powerful incentive. Those two forces together mean that China is hollowing out drug discovery, while also basically taking biomanufacturing away from the United States.

Our solutions—very quickly in the time left—are first, to fix our clinical trial process through reform, and the FDA is considering that right now. Number two, to incentivize and boost investment into our biomanufacturing capability and number three, to de-risk from Chinese biomanufacturer by creating incentives not to rely on biomanufacturing abroad. Some of that has happened under Biosecure, but there is more to be done.

Senator GILLIBRAND. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Husted.

Senator HUSTED. Thank you, Mr. Chairman. Thanks to you and the Ranking Member for hosting this—working on this important

issue. Welcome to all the witnesses today. I know that there was a point in time in America's past where we thought it was a good idea to export when we let China into the World Trade Organization.

We decided that collectively as a country, at least the policymakers at the time, that it would be a good idea to make things in other places because it was cheaper to make them there but as you talk to people in different industry sectors, I know I am more familiar with the manufacturing sector, they not only tell you that we lost our jobs and we lost our companies, but we lost the talent.

We actually lost the talent, the engineers, the people that know how to make things, do complicated, efficient, effective manufacturing processes, whether that be for rare earth, whether that would be for manufactured goods, chips, electronics.

I am curious about what you think the impact of the outsourcing of things in the pharmaceutical sector have had on our ability to actually compete from the standpoint of talent. Any of you want to—have a thought on that? Go ahead. Yes, thank you.

Ms. NIKAKHTAR. Yes, I appreciate the question. I mean, we—semiconductors is a really good example, because we had the brain drain when we offshored everything to Asia. Then when we decide we want to invest, not only do we not have enough engineers and experts and we don't have enough investors who understand the technology to know where to invest.

I do a lot of manufacturing, and I do a sort of building domestic industry. What is super fascinating is that with the money that is going to revitalize domestic industry right now in the Government, companies are investing, and they are partnering with local nearby universities to develop the workforce that will go into those factories.

From my perspective, the brain draining needs to be stopped, but once we reinvest here, it is those companies who are going to colocate with universities, train those students to rebuild the workforces that we are going to lose.

Senator HUSTED. Yes, they go hand in hand, but we are at a disadvantage at the moment. We need to build that talent pipeline, but it doesn't exist to the extent that it needs to. Is that correct?

Ms. NIKAKHTAR. In biotech, it should be, but in other sectors, we have lost a lot, so we need to build. I think in biotech, it still exists, but we really need to make sure that we don't lose it.

Senator HUSTED. Yes. Mr. Ezell, I am just curious, how do large purchasers of medicines such as hospitals and health systems currently assess the supply chain risk that they have as it relates to the risk of selecting drugs? How does that—how they think about it?

Mr. EZELL. I will answer that, but also, if I may add to Nikakhtar's comment, is there a whole range of technologies that we invented in American labs and universities that are now manufactured, scaled, and commercialized in Asia, especially China.

Things like flat panel television, solar panels, lithium-ion batteries. These are things that America created, but we can't manufacture them in America so we need a comprehensive manufacturing strategy, as Ms. Nikakhtar talked about, to ensure that the

technologies of the next generation, new things like gene editing, synthetic biology happen here in the United States.

Senator HUSTED. I will just interject on that point, that apparently there is a virtue in an economy that is more virtuous perhaps than the lowest price.

Mr. EZELL. Precisely. Because we care about, you know, innovating the next generation of products, services, and drugs that benefit Americans.

Senator HUSTED. Because that is dependability, it is efficiency, it is those other things, reliability. All of those are also virtues in an economic decision.

Mr. EZELL. You know, on that point, by the way, when we let China into the WTO, China had a grand total of $200 million of foreign currency reserves. By 2025, that was $4 trillion.

Guess where that came from? A $7.2 trillion trade surplus with the United States over the past 20 years, which has gone to a $1 billion foreign technology acquisition fund that has snapped up a number of American and Western companies.

We have permitted China to use the trade surplus they got from us to not only finance their, you know, innovation and R&D wherewithal, but to go out and buy our own companies in a very surreptitious interface.

Senator HUSTED. Look, this is important that people understand it. Like, we put ourselves in this position.

Ms. NIKAKHTAR. We did. We need to correct our vocabulary too. China is not cheaper. It is just a distorted price.

Senator HUSTED. Yes.

Ms. NIKAKHTAR. It can manipulate up and down once it gets monopoly to our detriment.

Senator HUSTED. Well, do you want to touch on it, I know I am out of time but do you want to touch on the supply risk and how you think about that.

Mr. EZELL. You know, I think it is something that we with policymakers can equip hospitals to better understand those dynamics. You know, certainly the legislation you have called for Senator Scott and Warren, you know, I think would help hospitals have——

Senator HUSTED. Well, it creates understanding and awareness. You know, why should the average American care about knowing about this? You have touched on some of it. Is there another—would you like to, anyone quickly, with the Chairman's permission—why the average Americans should about this issue. Why it is vital to them to know these kinds of things.

Ms. NIKAKHTAR. I will give one example that will resonate with every American. China right now controls our vitamin supply chain that goes in our food. They can easily whether intentionally or accidentally, look at COVID, introduce pathogens in our foods supply chain.

Let's say they really want to give America the medicine to get better, but they use all of their capacity at home. We have nothing. In America we can direct companies to make more, but when those supply chains are located abroad, we can't. That is why every American should care.

Mr. YOU. I wanted to also showcase a potential opportunity. This is a little anecdote that came off from Operation Warp Speed, so

at the time there was a key component that went into one of the vaccines that we happened to have an extreme shortage because it came from South America and we were scrambling to try to find a source of that.

One of the things that we tried to propose is that this component, chemical, could have been manufactured through synthetic biology. You could program basically baker's yeast to synthesize it. If we had done that, we could, you know, deputize all the microbreweries across the U.S. to then ferment it and distill it.

That is just a small snapshot of what we potentially could do here in the U.S. if we just invested in that core biomanufacturing capacity. It is not just about taking back what we lost but it is also about, what are we doing strategically to really super chart what we already have?

That includes developing our workforce, talent base, but then also looking at our infrastructure. Again, that kind of goes back to what I said, is that we just need to do a better job in conducting our risk assessments, because it is not just vulnerabilities, but it also identifies what the opportunity spaces are.

Senator HUSTED. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman. I appreciate the attention that the Chairman and the Ranking Member have given to scrutinizing the United States' dependence on foreign-made pharmaceuticals, and on the impact that has on seniors' access to medicine. It is just powerfully important, and you all have been really ringing the alarm bell on this, and I appreciate it.

I am also especially glad that today's hearing focuses on part of the problem that receives a whole lot less attention and that is the impact of foreign investment in U.S. manufacturing capacity. Foreign direct investment in American pharmaceuticals and medicines has skyrocketed from just over $89 billion in 2020 to nearly $566 billion in 2024. That is an increase of over 500 percent in just that short time.

At the same time, countries like China are now outpacing the U.S. in drug licensing and research and development, challenging America's leadership in biomedical innovation and that is why we have the Committee on Foreign Investment in the United States, CFIUS, whose job it is to investigate these investments for national security risks.

Now, Ms. Nikakhtar, you led the Department of Commerce's participation in CFIUS during your time in Government. Why is it important to scrutinize foreign investments in pharmaceutical manufacturing?

Ms. NIKAKHTAR. Well, there are a number of reasons, and thank you for that question so one important reason is to see, look behind the veil. If it is a company that has actually links to foreign adversaries, somebody has to look at that. It might not be readily apparent, but the U.S. Government needs to look it.

The other one is really important. It is not always about IP theft. If a foreign adversary invests in the United States, we have seen so many instances of them creating disruptions to upstream and downstream supply chains, or actually bankrupt a company, take

all that capability, and offshore it so we don't have it in the United States.

These are just examples, but the realm of predatory FDI into the United States by foreign adversaries—and our allies don't do that. That is the important thing. It is a pattern we see over and over again with foreign adversaries. We need to review it, but also importantly, we need to ban those transactions.

Senator WARREN. This is a really great point. I am just going to start with something that is just even more threshold to get started. We need greater visibility into it.

Ms. NIKAKHTAR. Much greater visibility.

Senator WARREN. We need to be able to see what is happening with these acquisitions. Obviously, it is not just national security that is at risk here. It is whether or not Americans get access to essential medications. Now, that is the essential reason behind why Congress passed legislation back in 2018 during the first Trump Administration that expanded the scope of CFIUS's review to better capture foreign investment in the biotech companies that are so critical to U.S. innovation but here is what troubles me.

A recent report from the bipartisan National Security Commission for Biotechnology found numerous instances of foreign-owned companies still acquiring American pharmaceutical and biotech companies without undergoing any review whatsoever. Ms. Nikakhtar, why are biotech and life science acquisitions still falling through the cracks? We actually changed law on this. Why is this still happening?

Ms. NIKAKHTAR. There are a number of reasons. I will mention the key. Usually, and I see this over and over again, it makes me want to pull my hair out, and I am surprised I have any hair left. Congress legislates and gives the executive branch comprehensive authority, and the executive branch self-limits its implementation of those authorities. It constrains all the authority that Congress gives it. That is what happened with FERMA and number two, there is a lot of transactions that are simply just voluntary for CFIUS.

Companies can elect not to notify the U.S. Government, and how will the U.S. Government find out about it? Number three, CFIUS jurisdiction doesn't extend to most greenfield investments, joint ventures, so guess what—how China circumvents CFIUS? It goes down those avenues where CFIUS doesn't exist. They know the lawyers to hire. They go hire them—help me craft this to circumvent CFIUS jurisdiction. There is no way we can find out.

Senator WARREN. Well, it is obvious that there is a lot of work to do. At a minimum, we need more visibility into what is happening in these transactions when it has the potential to influence such an important part of our pharmaceutical chain, so today, I think Chairman Scott and the Ranking Member have already talked about it, but I am going to do it one more time.

Chairman Scott, Ranking Member Gillibrand, and I are introducing a bill to do just that. The Pharmaceutical Investment Oversight and Accountability Act would require the Federal Government to uncover who owns and controls key parts of our drug supply chain, and then to investigate the effect of foreign investment on our ability to make essential medications and maintain innova-

tion right here at home. Now, I am glad we are doing this, but frankly, we shouldn't stop there.

The bill is one provision in my larger Pharmaceutical Supply Chain Defense and Enhancement Act which would pair oversight of foreign investment in the U.S. pharmaceutical industry with greater use of federal purchasing power to create a sustained demand so we can make these markets work domestically.

Mr. Doshi, how would leveraging federal procurement power make our pharmaceutical supply chain more resilient and strengthen domestic pharmaceutical manufacturing capacity?

Mr. DOSHI. Thank you, Senator Warren. Thank you for your leadership on this issue. I will be very brief in my answer. The U.S. Government has incredible purchasing power, but right now we effectively focus on low cost, not resilience, and not quality. As a result, people are not incentivized, purchasing groups are not incentivized to purchase, you know, with any knowledge of upstream KSM or API dependency.

That means they buy, perhaps, into the Chinese dependency that we already have. That is a huge problem. It could change, and it wouldn't necessarily be that expensive to change it for many of these generic drugs. We are talking about differences in price of pennies on the dollar.

Finding a way to leverage the procurement power of the Government and its ability to set standards across the industry is indispensable to solving this problem and creating predictable, stable demand, which brings on more supply.

Senator WARREN. Yes, I really appreciate it. I think that is exactly right. The Pharmaceutical Investment Oversight and Accountability Act is a really important place to start but cracking down on foreign investment alone is just one tool in the toolbox. We are in an emergency situation, and we need to be using all the tools we have to make more medicines here at home. That should include federal contracting and procurement policy.

I look forward to continuing to work with my colleagues on this and hope we can advance some serious legislation here. Thank you all for being with us. Thank you.

The CHAIRMAN. We are now going to hear from Senator Alsobrooks.

Senator ALSOBROOKS. All right. Thank you so much to Chairman Scott and Ranking Member Gillibrand for holding today's hearing. I want to say thank you as much as well to our witnesses for being here.

For seniors in Maryland and across our country, the security of our drug supply chain is not merely a policy conversation. It can be a matter of life and death. Those disruptions can especially be dangerous for older Americans, many of whom are managing multiple chronic conditions and depend on consistent access to medications.

Even a brief delay can put their health at risk, and I know this most especially because I am a part of what they call the sandwich generation, where I have recently realized that I went from at some point carrying around a stroller in my trunk and now carry around a wheelchair for my mom, for whom I am her caregiver.

That is why this conversation cannot only be about where a drug is manufactured or who owns a facility. It must also be about whether our federal agencies have the information, staffing, and tools necessary to identify risks early, respond quickly, and prevent disruptions from becoming shortages that reach patients. Real security means catching problems before an older American is left waiting for a medicine that they cannot safely go without.

My first question is for Mr. Ezell. It is true that we often talk about drug shortages as though they appear overnight. By the time a patient is told that the medication is unavailable, there may have already been months of warning, a quality concern, a delayed inspection, or a product without a backup manufacturer.

My question is, why is our system still designed to manage shortages after they happen, instead of acting when the warning signs first appear?

Mr. EZELL. Well, drug shortages reflect a culmination of root issues that have snowballed over time. There are key factors, such as low profit margins that we have talked about for APIs that cause hospitals or the Government to purchase offshore, geographic production concentration, and manufacturing complexity, quality concerns.

There is a lack of incentive and too much financial risk to produce less profitable drugs, like statins and antibiotics and cancer medications, so these are, you know, very complex challenges that have built over time, haven't been adequately addressed in Americans' health security and health resilience.

That is all of what we are talking about. We also have to recognize that—amoxicillin, heparin, antibiotics, these are distinct products that have distinct, you know, aspects across the global supply chain, so we need to have tailored strategies for how we are going to deal with these particular drug shortages on a case by case basis.

There is not going to be a one-size fits all solution here, but we need a comprehensive set of policies like we are talking about to deal with these types of challenges. One thing I think we have to do, it has been mentioned today, is we have got to invest in technology and innovation. I think that a lot of the challenges we face in APIs and generic drugs and critical minerals are the same.

What we have to do is invest in new refining, processing, and biomanufacturing processes so that we can manufacture these types of things cost-effectively and in an environmentally friendly and at scale to the United States. I think policymakers should look at the manufacturing USA network of advanced product and process institutes that was stood up during the Obama administration.

We should stand up a manufacturing USA for critical minerals and APIs so that we there can conduct the PhD level research to develop these new processes and ensure that they occur in the future here in the United States, so we address these types of shortages.

Ms. NIKAKHTAR. May I add one more thing? I think we would see a lot more investments, Senator, if investors knew that China wouldn't underprice them, so investment is key, but that investment will come a lot easier if they knew that they would be pro-

tected. The value of the investment would be to be protected from dumping practices, for example.

Senator ALSOBROOKS. Thank you. Just one more question for Mr. Doshi. I want to bring you in on that same point, so when the same essential medicines fall into shortage again and again, that pattern begins to look like more than an isolated manufacturing or market problem, so at what point should recurring shortages of essential medications be treated as a national security warning, not simply as a public health or market failure?

Mr. DOSHI. Thank you, Senator. I think the warning point was COVID. We should have understood that the shortages we were experiencing beginning in COVID, that continued after COVID, and that we still encounter now were a sign that something was wrong in the supply chain. What was wrong wasn't simply concentration on China, although that is a big part of it for KSM but what was also wrong was that we didn't actually know what was upstream.

We didn't know our upstream dependencies, so we might have a label, we may have a drug that has the right label on it. We may say it is TAA compliance, so it comes from an allied jurisdiction, but we don't know upstream where the chemicals that go into that drug come from.

Now is the time with efforts like Clean Labels to basically—or Clear Labels, excuse me, to make sure we know exactly where the upstream dependencies are so we can get ahead of them. We should build resiliency, not just in API, not just a drug finishing, but again, in the KSM portion of the supply chain as well.

Senator ALSOBROOKS. Thank you.

The CHAIRMAN. Thank you, Senator Alsobrooks. Ms. Nikakhtar, Senator Warren, Gillibrand, and I are all announcing this legislation today that is going to require a report from Congress every year, so what is next? What is step two, and what is step three?

Ms. NIKAKHTAR. Okay, luckily, once we have better visibility into the problem, we have got to do a couple of really important things.

We really have to build at home, which means, you know, workforce development, giving the companies the capital and the incentives that they need to rapidly build, but the build will not go anywhere unless we have protections in place. Because right now, across the U.S. industrial base, investors are worried that China is going to underprice them so we understand the scope of the problem.

I should also add, you know, customs has really incredible data -- how you are going to access that proprietary data is going to be a separate issue. Everything that crosses our border, customs has in a really great level of detail so visibility, this legislation is excellent. I was really pleased by looking at it. Enhance visibility, then we know what to build. We incentivize the building, and we protect, and then I think we have a home run.

The CHAIRMAN. Thanks. Mr. Ezell, in March and April, China made two degrees—put two degrees into effect, as I understand them. One of them makes it a punishable offense for a company to cooperate with foreign supply chain origin tracing. have Already used it against a company facing a European investigation. Congress is trying to mandate a disclosure. Beijing is trying criminalize it. How does this end and what do we do?

Mr. EZELL. Yes, Senator. You are referring to two new decrees that were promulgated in this past several months by China. These are decrees 834 and 835. Decree 834 would generate an effect on March 31st, would establish that China's industrial supply chain security is an ″independent regulatory concern.″

Decree 835 establishes a framework for identifying and responding to foreign acts that China views as improper use of extraterritorial jurisdiction. Essentially, what they are trying to do is to lay groundwork to even say we wouldn't even have the ability to go in and inspect their API factories if it were taken to that extreme.

I think American policymakers need to be absolutely forceful that this is an industry that directly affects the lives of American citizens, and we will indeed have the ability to go and inspect their facilities and not let 834 or 835 get in the way of that. There is a lot we need to be doing as your reports in the past have laid out in achieving parity in the inspections and dealing with the asymmetries, we have now where inspections must be announced in the United States, but they are not announced ahead of time in China.

We need to make it clear that we are not going to allow this disparity to happen anymore. We need to properly staff and resource the FDA so that they have the capability they need to conduct more extensive APIs of Chinese facilities and others like in India if we are going to continue to use them.

The CHAIRMAN. Thanks. Mr. You, your testimony calls clinical trial data a strategic national asset. American patients take the risk, and American regulars authorize the trial. Is there anything today that stops the data of those patients generated from ending up in the hands of a foreign government? I mean, we allow this to happen, right?

Mr. YOU. Yes. Thanks, Mr. Chairman. It is more challenging than you actually realize. It is about the existing policies and how do we harmonize that. I am sorry if I sound like I broke a record, but it goes back to how do we conduct our risk assessments. Just let me just give you a real-world scenario, so say we take your DNA sequence. I won't do that personally, but you take that one sequence, and it is all contextual.

Meaning that if you take your sequence and you submit it as a volunteer for an NIH research project, then you are going to be provided a consent form and be identified for some of the risks. Which, by the way, a lot of the things that we talked about as far as risk exposure is not covered, for example, that your data might be used by China for generating the next breakthrough pharmaceutical. We don't cover that. That same sequence can then be used as a patient.

As it stands right now, HIPAA doesn't quite cover all the different applications. It transcends privacy. Now you are looking at national security and economic implications. Then finally, that same sequence, if you submit it and say you have mailed it off to a commercial DNA sequencing company to find out—I want to find out what percentage of ethnicity I am, right, that is completely covered—is not covered by the FTC or some other consumer protections as it stands right now.

Even our harmonization of that same DNA sequence, it all depends on how it is being applied, and so there are gaps. That is why we are—basically we are setting ourselves up to be vulnerable.

The CHAIRMAN. All right, thank you. Mr. Doshi, your report says federal oversight of DNA synthesis is scattered across multiple agencies and that the Government lacks visibility into the commercial supply chain.

You also recommend a White House level coordinating body and a joint FDA, Commerce monitoring function for pharmaceuticals. Is the core failure today fragmented authority, missing data, both? Which agency should be held accountable for maintaining a government wide map of foreign ownership and control across the drug supply chain?

Mr. DOSHI. Thank you for the question, Mr. Chairman. It is both. One problem, which I know you have focused quite a bit on, is the information that we need. We don't have all the information, whether that is on investments in our supply chain or on the upstream dependencies that we have.

Those dependencies are often talked about in the context of small molecule drugs, like API and KSM, but we also have the dependencies in biotech that are emerging. Biomanufacturing in the U.S. now has significant upstream dependencies where we rely on China, and so we don't all the information. On the information side, we have got gaps. On the coordination side, we would need some kind of White House like body, I think, to bring all the different agencies together to get after this problem.

There are many agencies that are involved, and all of them have different kinds of data. FDA data, customs data, excuse me, Department of Commerce data, all of that can be combined to give us a better picture of where our dependencies are. Then coordinated solutions are also going to require some degree of the Government coming together coherently to figure out how to do policy, industrial strategy, if you will, to compete with China.

If I may, Mr. Chairman, let me add one additional point. Earlier you asked about national—the State Council Directive 834 and 835 out of China. I just had to add that this set of directives is absolutely insane. It is a crazy combination of directive that prohibit—they criminalize pretty much any kind of normal behavior in China. If we tried to move a factory out of China, that could be criminal. If we try to not have compliance with an FDA inspection, that could be criminal.

The important thing here is that these three directives create a sword hanging over the neck of every U.S. company operating in China, and they should all be aware of it. I think it is incumbent upon all of us, Congress, and the executive branch to help inform these companies of the growing risks. What has occurred now is so shocking that I think even the Chinese don't fully understand the implications if we decide to take it seriously.

Ms. NIKAKHTAR. May I add something just because it is an important question. The 1260, the 1260H List is a perfect example of where the Government fails so Congress legislates, let's say you create a body in the White House or somewhere else.

Then they are not going to look at all the companies that they need to for foreign ownership and risks, and then what, then the Chinese are going to sue. Then, they are dropped off the list, right?

There has got to be a mandate that there is really robust, comprehensive reviews of as many companies as humanly possible and standards for that. There should be something like CFIUS—a CFIUS Presidential determination cannot be litigated. A U.S. Government designation cannot be litigated.

The CHAIRMAN. That makes sense. Ranking Member.

Senator GILLIBRAND. Mr. Ezell, fully onshoring the generic drug supply chain at this moment is functionally impossible and strategically counterproductive. Reliance on a single location, even if the U.S., can leave our system exposed to environmental and operational barriers that may completely halt production and jeopardize access to essential medications.

There are ways to minimize risk and promote resilience in building a globalized supply chain. Why is it more feasible and beneficial to coordinate with allies to produce generic drugs than isolating production within the U.S.? How can we enhance this coordination with allied nations to reduce reliance on malign actors like China?

What advanced manufacturing technologies should U.S. drug developers adopt to support the supply chain, and how could the Federal Government encourage adoption of these practices?

Mr. EZELL. Thank you for the question, Senator. You are absolutely right. The United States cannot solve this problem alone. We need to enroll allies who share common challenges we do, as in the Chinese dependence.

You know, there are distinct capabilities that countries such as Mexico, South Korea, or India could bring to the table that we can support. If you look at South Korea for instance, it presents a compelling manufacturing partner, not primarily because of cost, but also due to its advanced manufacturing capabilities, strong IP protections, improving capacity and pharmaceutical production.

In the more complex APIs, we can turn to Korea for support there. This is an area we could look at in the USMCA renewal with Mexico to set up a US-Mexico collaboration for API and precursor material manufacturing. We obviously have the U.S.-India Trust Initiative, where we are looking to deepen partnership with India in areas like semiconductors and AI. Critical minerals and APIs drugs should be a critical part of this.

We should work with India both on the supply and the demand side. On the supply side, we could work—we can direct the U.S. Development and Finance Corporation to deploy more capital in India to support loan guarantees and total rest insurance for their API manufacturing. We could, you know, purchase more APIs from India, which is more trustworthy, I would think, than China.

Senator GILLIBRAND. Thank you. Ms. Nikakhtar, based on your experience, does CFIUS have sufficient authority to identify and mitigate national security risks associated with foreign acquisition of critical pharmaceutical and biotechnology assets, or are there gaps Congress should address? How can CFIUS continue to encourage trusted foreign investment, while ensuring strategic competi-

tors cannot gain undue influence over America's pharmaceutical supply?

Ms. NIKAKHTAR. The better CFIUS works, the better certainty it gives investors in the United States that the rug isn't going to be pulled out from under them from predatory FDI. CFIUS does a pretty good job of looking at a company's ownership and working its way, all the way up to the ultimate beneficial owner.

What I found that CFIUS isn't so good at is the interagency does not agree about the national security threats. When that happens, the chair sort of has the authority to sort of override other agencies' views so that is one thing. The other thing I see—so the disagreement among the CFIUS members is a big issue that has to be addressed.

The other issue that has to be addressed is mitigation measures. Harmful foreign investment in the United States is in many times cleared with national security agreement and mitigation measures but when you are looking at really harmful acts by harmful actors, they have every incentive to hide it. They are not going to give it to this CFIUS mitigation monitor and say, look, I am guilty.

With foreign adversaries, these mitigation measures don't work. Then there is a final issue we talked about. There shouldn't be mitigation measures with foreign adversary with every incentive to cheat, but the final thing is that there is just, CFIUS jurisdiction doesn't apply to so many transactions. Then, you know, many of them are voluntary. We really got to close these gaps because American industries who invest here deserve the protections that CFIUS offers.

The CHAIRMAN. Well, thank each of you for coming. We have got a lot of work to do. I think we are making some progress. I think we've got a path—hopefully, the Clear Labels this year. Hopefully, we will have a clear path to some other things. The Ranking Member has been a great partner in getting this done.

Look forward to continuing to work with members on both sides of the aisle. The security of the drug supply chain is not a partisan question. Every Senator on this Committee has seniors in their state who are at risk. 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. Thank you all.

[Whereupon, at 04:45 p.m., the hearing was adjourned.]

APPENDIX

Prepared Witness Statements

Testimony of Hon. Nazak Nikakhtar

Chair, National Security Practice, Wiley Rein, LLP

Testimony Before the Senate Special Committee on Aging[1]

"Behind the Label: Foreign Ownership and Control in America's Drug Supply Chain"

July 15, 2026

Chairman Scott, Ranking Member Gillibrand, and members of the Committee, thank you for hosting this critically important hearing. My name is Nazak Nikakhtar. I am an international trade and national security attorney, economist, former Georgetown University Law School adjunct professor, former civil servant in the U.S. Government, and former Assistant Secretary[2] and Under Secretary[3] at the U.S. Department of Commerce.

I spent the past 25 years of my career focused on U.S.-China economic competition and national security issues from the vantage points of America and our allies. My focus today is on the legal tools that we need to better deploy in winning America's biotechnology race against the People's Republic of China.

Chinese Advancement in Biotechnology

The threats posed by China's growth in biotechnology fueled by intellectual property ("IP") theft and misappropriation, massive state subsidies, and a distorted economy that consistently underprices the rest of the world is well-established, so I will not spend time on that. Yet these realities provide the context in which I will discuss our legal shortcomings and solutions.

To be clear, China's growth in biotechnology is dwarfing America's (and the rest of the world's) presence in this sector. In 2024 – 2025, China surpassed the United States in biotechnology innovation, deal value, and clinical output.[4] At present, China is neck-in-neck with the United States in emerging biotechnology sciences (e.g., precision medicine, brain-

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[1] The views and opinions expressed in this testimony are mine only and do not represent the views of Wiley Rein, LLP or any of the firm's clients.

[2] Unanimously confirmed in 2018.

[3] Performing the non-exclusive functions and duties while nominated (2019).

[4] Aaron Blotnick, *The Year China Surpassed the USA in Biotech Innovation, Deal Value, and Clinical Output*, SynBioBeta (Jan. 22, 2026), *available at* https://www.synbiobeta.com/read/the-year-china-surpassed-the-usa-in-biotech-innovation-deal-value-and-clinical-output.

computer interfaces, and biomanufacturing),[5] competing at costs that are roughly one-third of the United States' costs (e.g., biopharma drug discovery programs).[6]

For every $100,000 in U.S. biotechnology research and development ("R&D") spending, America has one scientist and China has three.[7] China's investment in biotechnology also outpaces the United States whether measured by pharmaceutical deals, clinical trial activity or licensing deals.[8] Plus, America fuels China's biotechnology growth through supply chain dependence, outbound capital investments, and IP transfers through licensing deals and other corporate agreements.[9]

Additionally, China dominates STEM talent volume, producing around 4 million STEM graduates and over 70,000 STEM PhDs annually (compared to approximately 40,000 in the United States),[10] and China graduates roughly ten times more engineers than the United States.[11] Further, China has a larger population, more schools, and more students being educated abroad and working abroad. Most of them return to China (whether at will or by force) to grow the country's lead.[12]

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[5] *U.S. vs. China: Government Action on Key NSCEB Recommendations*, Nat'l Sec. Comm'n on Emerging Biotechnology, *available at* https://www.biotech.senate.gov/us-vs-china-govt-action-on-nsceb-recs/.

[6] Yanzhong Huang, *A Biopharmaceutical Superpower: China's Rise, Its Limits, and What Comes Next*, Ctr. for Int'l Relations & Sustainable Dev., *available at* https://cirsd.org/horizon-article/a-biopharmaceutical-superpower-chinas-rise-its-limits-and-what-comes-next/.

[7] *New Study: China Biopharma Gains Global Ground*, We Work for Health (Mar. 16, 2026), *available at* https://www.weworkforhealth.org/post/new-study-china-biopharma-gains-global-ground.

[8] Aaron Blotnick, *The Year China Surpassed the USA in Biotech Innovation, Deal Value, and Clinical Output*, SynBioBeta (Jan. 22, 2026), *available at* https://www.synbiobeta.com/read/the-year-china-surpassed-the-usa-in-biotech-innovation-deal-value-and-clinical-output.

[9] For example, roughly 79% of U.S. pharmaceutical companies utilize Chinese contract manufacturing organizations ("CMOs") for drug development/production. *See* Erin Rosenbach, et al., *Critical and Emerging Technologies Index*, Belfer Ctr. for Sci. & Int'l Affairs, Harvard Kennedy Sch. (June 5, 2025), *available at* https://www.belfercenter.org/critical-emerging-tech-index. While American firms invested $153 billion in pharmaceutical and biotechnology R&D in 2024, which is over half of the global total, China's industrial policies (including subsidies) enabled Chinese biotechnology firms to run clinical trials twice as fast and at a fraction of the costs of those in the United States. This has resulted in a massive surge in Western capital flowing into China. *See* Yeon Woo Lee, *The next tech war? Why biotech may become a new US-China battleground*, South China Morning Post (June 2, 2026), *available at* https://www.scmp.com/economy/global-economy/article/3355700/next-tech-war-why-biotech-may-become-new-us-china-battleground.

[10] Remco Zwetsloot, et al., *China is Fast Outpacing U.S. STEM PhD Growth*, Ctr. for Sec. & Emerging Tech., Georgetown Univ. (Aug. 2021), *available at* https://cset.georgetown.edu/publication/china-is-fast-outpacing-u-s-stem-phd-growth/.

[11] Paul Eremenko & Ashish Srivastava, *China graduates 1.3 million engineers per year, versus just 130,000 in the U.S. We need AI to bridge the gap*, Fortune (Jan. 14, 2026), *available at* https://fortune.com/2026/01/14/china-graduates-1-3-million-engineers-per-year-us-shortage-ai-tools/.

[12] Yanzhong Huang, *A Biopharmaceutical Superpower: China's Rise, Its Limits, and What Comes Next*, Ctr. for Int'l Relations & Sustainable Dev., *available at* https://cirsd.org/horizon-article/a-biopharmaceutical-superpower-chinas-rise-its-limits-and-what-comes-next/ (referencing China's talent repatriation programs in biotech).

It should also be underscored that the Chinese government controls most of China's revenue and wealth whereas in the United States, the private sector does. With the second largest gross domestic product ("GDP") in the world,[13] this means that the Chinese government has more capital to fuel the growth of its state champions through subsidies than United States could ever provide in grants and loans through U.S. Government programs.

And then there is the well-known Chinese program of state-sponsored IP *theft*, where Chinese entities acquire American IP for virtually nothing after our companies spend billions in R&D and product development.[14] Plus, the fact that Chinese companies conduct clinical trials without the human health and welfare safeguards that we have in the United States and the West is another way that China's biotechnology sector is growing at a pace that dwarfs ours and other countries.

I understand that most individuals testifying before Congress argue that that America needs to take its eyes off China and instead invest in its own educational system, R&D and corporate growth. Yes, we do need to invest more, promote innovation, advance R&D, and enable our corporations to grow more quickly, but we cannot do so by simultaneously exporting our technology and capital to China and continuing to use China as our manufacturing hub – this would be at expense of America's interests. Maintaining this current trajectory with China is a mistake, especially when China is making indigenous investments at a much larger and faster scale, while we are fueling China's growth even more by transferring U.S. technology, capital, manufacturing output, and know-how to it. Quantitative data show that China's growth in biotechnology innovation and manufacturing mirrors America's decline. In other words, we are ceding our own capabilities to China. This is shortsighted, and we need to look no further than what happened to the U.S. semiconductor, GPU, battery, autos, critical minerals, and robotics sectors as examples of what is yet to come.

Recommendations

The hard truth is that America needs to limit its entanglement with China's biotechnology sector before China's misuse and exploitation of American capital, supply chains, IP, and trust undermine our competitive interests to a permanently detrimental point. I provide several recommendations that constitute concrete steps that are needed to assure America's technological resilience, leadership, and overall success. Anything less will cede the competition to China, given China's meteoric rise.

First, most Chinese biotechnology investments in the United States seek to acquire American IP and sensitive personal data and/or to disrupt the domestic market through market

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[13] GDP by Country (2026) – IMF, Worldometer, *available at* https://www.worldometers.info/gdp/gdp-by-country/.

[14] *Findings of the Investigation into China's Act, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation Under Section 301 of the Trade Act of 1974*, Off. of the U.S. Trade Rep. (Mar. 22, 2018), *available at* https://ustr.gov/sites/default/files/Section%20301%20FINAL.PDF.

manipulation. To the extent transactions are examined by the U.S. Government for national security risks where the Committee on Foreign Investment in the United States ("CFIUS") jurisdiction exists, many are cleared with mitigation measures. But almost always, violations of mitigation measures will not be detected by the Government. This is a risk we cannot afford to take with China and other foreign adversaries. Whenever investments by China and other foreign adversaries come under CFIUS's existing legal jurisdiction for national security review, we need to institute a presumption of denial for each foreign adversary.[15] I have never encountered any scenario where a Chinese investment in a U.S. biotechnology company did not pose a serious risk of being misused by the Chinese Communist Party ("CCP") to effectuate its Military-Civil fusion strategy to America's detriment.[16]

Second, given that CFIUS jurisdiction falls short by not covering most greenfield investments and joint ventures in the United States, legal jurisdiction needs to be extended by Congress through the passage of a FIRRMA[17] 2.0 and/or the President needs to issue an IEEPA[18]-based Executive Order that closes the legal gap as it pertains to foreign adversaries. Time is running out and the gaps remain wide open today, enabling predatory FDI to occur undetected and unaddressed.

Third, we need to impose broader export controls on emerging and foundational biotechnologies and biomaterials that are exported to China and other adversaries for pharmaceutical manufacturing and trials. Additionally, we need to impose export controls on U.S. exports of genetic, cell, and other forms of biological data. We should impose controls on data by either defining them as goods subject to the EAR[19] or by controlling the software that enables sensitive data to flow to our adversaries using the EAR. Currently, without these controls, biological materials and data flow virtually unrestricted to China, the CCP, and the People's Liberation Army.

Fourth, we need to address the fact that Chinese investments in United States and U.S. investments in Chinese biotechnology occur significantly through corporate licensing deals and venture capital.[20] While the Biotech Investment National Security Act of 2026 (or "BINSA")[21] is

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[15] Sectors may be designated by reference to NAICS codes (North American Industry Classification System).

[16] *Report on Biotechnology in the People's Republic of China's Military-Civil Fusion Strategy*, Int'l Sec. Advisory Bd. (Oct. 2024), *available at* https://www.state.gov/wp-content/uploads/2024/12/ISAB-Report-on-Biotechnology-in-the-PRC-MCF-Strategy_Final_Accessible.pdf.

[17] *Foreign Investment Risk Review Modernization Act of 2018* ("FIRRMA"), Pub. L. No. 115-232, subtit. A, tit. XVII, 132 Stat. 2173 (2018) (codified as amended at 50 U.S.C. § 4565), implemented by 31 C.F.R. pt. 800 *et seq.*

[18] *International Emergency Economic Powers Act* ("IEEPA"), Pub. L. No. 95-223, tit. II, 91 Stat. 1626, 1626-33 (1977) (codified as amended at 50 U.S.C. §§ 1701-1706).

[19] *Export Administration Regulations* ("EAR"), 15 C.F.R. ch. VII, subch. C (Parts 730-774).

[20] Recently, Chinese drugmakers have increasingly licensed programs to U.S. firms and funded partnerships, while U.S. lawmakers push to restrict these cross-border intellectual property transfers and capital transfers.

[21] *Biotech Investment National Security Act of 2026*, H.R. 9102, 119th Cong. (2026).

a positive step toward restricting U.S. capital flows to Chinese companies, it does not go far enough. What I have witnessed during my service in the Executive Branch over nearly a decade is that our Government does not regulate comprehensively to ban high-risk transactions when it has the legal authority to do so. My fear with BINSA is the same as with the Comprehensive Outbound Investment National Security Act of 2025 ("COINS Act")[22] – that, in implementation, the Executive Branch will limit some means of capital transfer but not others, enabling various forms of *legal circumvention*. The result will be no real curtailing of capital outflows. As such, we need comprehensive outbound investment bans for the biotechnology sectors in China and other adversary nations. Comprehensive bans minimize the opportunity for circumvention. Nuanced regulations do not.

Fifth, we need import prohibitions on biotechnology materials produced in China under Section 232 of the Trade Expansion Act of 1962, as amended,[23] IEEPA, Section 307 of the Tariff Act of 1930, as amended,[24] and the Uyghur Forced Labor Prevention Act,[25] given the health and safety risks these materials pose, and given China's prevalent human rights abuses, IP misappropriation, predatory economic practices, and potential to weaponize biotechnology to seriously harm the United States and the rest of the world.

My final point is this. With respect to anyone claiming that these recommendations will increase U.S. prices, that is a red herring. China's growth in the biotechnology industry is only a recent event. Prior to China's growth in this sector, the U.S. pharmaceutical industry faced economic pressures that stemmed from unrelated issues, for example, domestic regulatory hurdles. Relying on China to research and produce our drugs does not solve our competitiveness problem, it only adds to it.

The reality is that the more we offshore our R&D and production to China's markets, the more we will be substituting China's workforce and economic model in place of ours. In this way, we are undermining our own R&D base, educational system, innovation, population health, business viability, and strength of our values as Americans. We cannot continue relying on China's distorted predatory market instead of America's own manufacturing and innovation base. Doing so will accelerate the demise of industries, market, health, values, and technological leadership in America.

Thank you and I look forward to answering your questions.

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[22] *Comprehensive Outbound Investment National Security Act of 2025*, tit. LXXXV, National Defense Authorization Act for Fiscal Year 2026 (enacted Dec. 18, 2025).

[23] 19 U.S.C. § 1862.

[24] *Id.* § 1307.

[25] *Uyghur Forced Labor Prevention Act* ("UFLPA"), Pub. L. No. 117-78, 135 Stat. 1525 (2021) (codified as amended at 22 U.S.C. § 6901; amending the Tariff Act of 1930; enforced under 19 U.S.C. § 1307).

ITIF | INFORMATION TECHNOLOGY & INNOVATION FOUNDATION

Testimony of:

Stephen Ezell
Vice President, Global Innovation Policy
Director, Center for Life Sciences Innovation
Information Technology and Innovation Foundation

Before the:

U.S. Senate Special Committee on Aging

Hearing on:

"Behind the Label: Foreign Ownership and Control in America's Drug Supply Chain"

July 15, 2026
SD-G50, Dirksen Senate Office Building
Washington, DC

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INTRODUCTION AND SUMMARY

The Information Technology and Innovation Foundation (ITIF) is an independent 501(c)(3) nonprofit, nonpartisan research and educational institute that has been recognized repeatedly as the world's leading think tank for science and technology policy. ITIF is honored to testify before the Senate Special Committee on Aging on the topic of "Foreign Ownership and Control in America's Drug Supply Chain."

This testimony will first examine how key elements of biopharmaceutical supply chains—notably for key starting materials (KSMs) and active pharmaceutical ingredients (APIs)—have been increasingly offshored, principally to China (but also to India). The testimony will then briefly summarize how China has become an increasingly successful competitor in the global biopharmaceutical industry. It will then examine how one component of China's strategy is to obfuscate ownership or control over actors in the biopharmaceutical supply chain and thereby to downplay the extent of its influence in the sector. Another aspect of this is how China leverages grey markets and obfuscates its exports unregulated or poorly regulated products, such as peptides, and how China engages in extensive biopharmaceutical intellectual property (IP) theft. The testimony concludes with policy recommendations, grouped into three broad themes: 1) addressing the challenge of Chinese "false flagging" and obfuscation; 2) addressing America's increasing drug supply chain vulnerabilities; 3) broader policies to advance U.S. biopharmaceutical competitiveness.

U.S. DRUG SUPPLY CHAIN VULNERABILITIES

As the Council on Foreign Relations recently wrote, "For decades the United States has allowed its pharmaceutical supply chain to migrate offshore in pursuit of lower business costs, a process accelerated by regulatory inertia and inadequate public investment."[1] Indeed, America is increasingly reliant on China for active pharmaceutical ingredients (APIs)—the biologically active components in medicines that produce their intended therapeutic effects, and which are a foundational element of drug security and pharmaceutical innovation.[2]

It wasn't always that way, however. In the early 1980s, most API production took place in Europe and the United States. Data compiled by the U.S. Pharmacopeia from the U.S. Food and Drug Administration's (FDA's) active API Drug Master Files (DMFs) show that, in 1981, Europe held 63 percent of the overall share of DMFs, while the United States held 25 percent. India and China held virtually none.[3] By 2024, that picture had reversed. Europe's share had dropped to 6 percent, while the U.S. share had fallen to just 3 percent. Meanwhile, China and India accounted for 45 and 43 percent of active API DMFs, respectively.[4] Today, China thus plays a key role in the production of basic chemical precursors and key starting materials, while India primarily specializes in later-stage API synthesis and generic drug manufacturing, with much of India's raw material for APIs originating in China.[5]

This geographic concentration reflects several factors that have developed over decades. A key driver is cost. An IQVIA report notes that API manufacturing costs are about 30 to 35 percent lower in India and 35 to 40 percent lower in China compared to the United States, creating incentives for offshore API production.[6] Lower labor and operational costs, cheaper raw materials, and historically weaker environmental standards are several of the factors that have enabled these cost differentials, creating strong offshore economies of scale.[7]

As it has in many other advanced-technology industries (such as solar panels or legacy semiconductors), China has used an aggressive underpricing strategy in APIs to knock out foreign competitors and come to dominate global market share (positioning China to either raise prices later—or to weaponize control over supply chains it's come to dominate for geopolitical leverage). Indeed, some Chinese producers have in recent years cut prices on key API starting materials by 40 to 50 percent, an aggressive pricing strategy that can squeeze other competitors out of the market.[8]

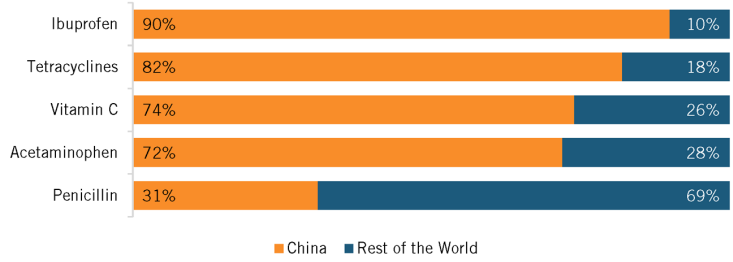
This is not simply a reflection of efficiency gains—it is enabled by direct Chinese state support. Chinese API producers benefit from a combination of direct production subsidies, below-market land and energy costs, preferential financing from state-owned banks, and more permissive environmental regulations.[9] State support extends to infrastructure and industrial clustering: government policy has subsidized the creation of dedicated pharmaceutical manufacturing zones, including API "super factories" and explicitly included biomedical technology on the list of high-tech fields supported by key financial subsidies.[10] This support allows Chinese producers to sustain prices that would be commercially unviable without government backing. The strategic objective appears to be consistent with market consolidation: By pricing competitors out, Chinese API producers can secure dominant positions in key upstream segments, reducing other producers' ability to compete and increasing global dependence on Chinese supply.

KSMs constitute the upstream building blocks used to manufacture APIs.[11] China is trying to corner production of these KSMs just as it is APIs. Across all medications, nearly 41 percent of KSMs used in U.S.-approved active pharmaceutical ingredients are produced only in China, and 16 percent from India.[12] China controls the raw or key starting materials for 94 percent of amoxicillin, 74 percent of heparin, and 70 percent of acetaminophen.[13] China also enjoys significant global concentrations for the following KSMs: angiotensin II receptor blockers (100 percent of APIs use China sole-sourced KSMs); blood glucose-lowering drugs (excluding insulins), 94 percent; direct acting antivirals, 83 percent; antineoplastics, 71 percent; antibacterials, 66 percent; statins, 62 percent. For its part, India dominates global production of several key KSMs, including high-ceiling diuretics (100 percent of APIs use India sole-sourced KSMs); X-ray contrast media, iodinated, 86 percent; and anti-dementia drugs, 80 percent.[14]

With China dominating so much of the KSMs that represent the key inputs to APIs, it's no wonder that China is also coming to dominate global API production, making the United States increasingly dependent on China for API imports. Indeed, as figure 1 shows, the United States imports 90 percent of its ibuprofen from China, 82 percent of tetracyclines (a broad-spectrum class of antibiotics primarily used to treat bacterial infections, including acne and Lyme disease), 74 percent of Vitamin C, and 72 percent of acetaminophen.[15]

These figures showcase significant U.S. exposure and vulnerability to China for critical elements of the biopharmaceutical supply chain. For instance, more than 600 medications—including over-the-counter and prescription medications—contain acetaminophen.[16] In 2022 alone analysts estimated that the United States administered 49.8 million amoxicillin prescriptions.[17] Heparin is a critical medication in modern medicine, with an estimated 265 million doses provided to Americans annually and administered to more than 12 million hospitalized Americans each year.

Figure 1: U.S. imports of APIs, 2024[18]



Overall, the Brookings Institution estimates that Chinese-produced APIs are involved in at least one-quarter of the drug volume sold within the United States, however estimates of U.S. reliance on Chinese-made APIs reach to as high as 47 percent, when factoring indirect impacts from India's reliance on China for inputs such as KSMs to the APIs India produces.[19] India's exact reliance on Chinese APIs, intermediates, solvents, and reagents to produce their own API's isn't easily quantifiable, but Indian producers are heavily reliant on Chinese components for antibiotics, fluorine-rich drugs such as statins, and blood pressure medications.[20]

CHINA'S BIOPHARMACEUTICAL COMPETITIVENESS

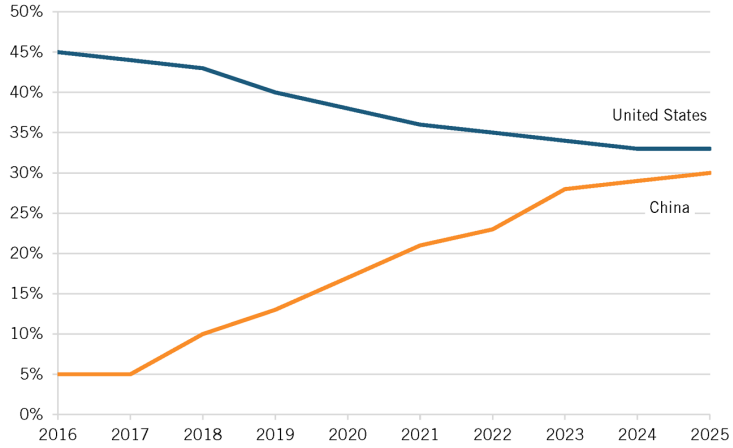
It's critically important that policymakers understand it's not just that China is cornering markets for KSMs and APIs, but that China represents an increasingly viable competitor throughout the entirety of the biopharmaceutical supply and *innovation* chain, as ITIF detailed in a recent report on China's burgeoning biopharmaceutical competitiveness.[21] It starts with increasingly competitive Chinese science and research and development (R&D). For instance, over the decade from 2015 to 2024, the number of biotechnology publications in China increased by 162 percent, from about 2.1 million to 5.4 million.[22] China now stands second behind only the United States in Patent Cooperation Treaty (PCT) patent publications in biotechnology and pharmaceuticals.[23]

China has become an increasingly attractive location for the conduct of clinical trials. In fact, China is catching up to the United States in trials of the most-innovative drugs, including those with new mechanisms of action or that use advanced technologies to treat diseases. In 2016, just 5 percent of global clinical trials for innovative drugs were conducted in China, compared with 45 percent in the United States. This gap has now shrunk substantially, with 30 percent of all innovative drug trials taking place in China—a 500 percent increase—compared with 33 percent in the United States. (See figure 2.)

One reason why China is now a more-attractive location for clinical trials is that improvements to China's regulatory processes have sped up the timeline from early discovery to new drug application in China by 50 to 70 percent.[24] In total, Chinese firms can now take a drug from discovery to the start of human trials in about half the global industry's average time.[25] Research from PhRMA finds that the average duration of a phase I clinical trial conducted in China in 2025 is now over 50 percent shorter than phase I trials conducted in the

United States. Similarly, the average cost of a phase I clinical trial in China was 43 percent less expensive than a phase I trial in the United States.

Figure 2: China and U.S. companies' share of worldwide clinical trials for innovative drugs, 2016–2025[26]



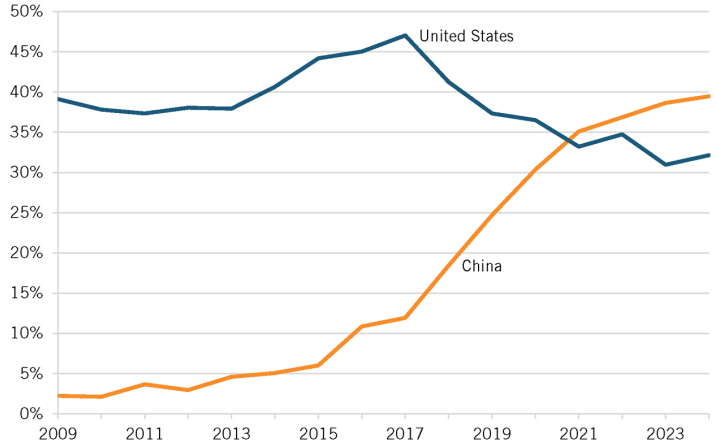
China is even now beating the United States in oncology R&D. In 2024, China overtook the United States in research output in oncology for the first time, with over 2,600 research publications compared with 2,481 from the United States.[27] Additionally, according to a report from IQVIA, China-based companies accounted for 39 percent of global oncology clinical trial starts in 2024, up from only 5 percent in 2014. (See figure 3.) China surpassed the United States in share of global oncology clinical trial starts in 2021, and now accounts for a 7 percentage-point higher share than the United States. Between 2020 and 2024, China launched 84 new active substances in oncology, more than double the 37 it had launched from 2015 to 2019.[28]

China today accounts for 31 percent of the global drug pipeline after its share of global pharmaceutical output mushroomed from 2.7 percent in 1995 to 17.3 percent in 2022.[29] Demonstrating how the quality of biopharmaceutical innovation has dramatically increased in China, the number of out-licensing deals from China increased by a factor of 31, from 5 deals in 2015 to 157 in 2025, while the value of those deals increased by a factor of 54 over that timeframe, from $2.5 billion to $135.7 billion.[30]

In summary, China is becoming an increasingly fearsome biopharmaceutical competitor. In the future, it may not be the United States depending on China for KSMs and APIs, but also for cutting-edge medicines such as cancer drugs. It should be noted that China has achieved this position through legitimate policies such as infrastructure, incentives, capital accumulation, R&D investments, and workforce development, among others. Other practices, however, raise significant concerns. Indeed, China has deployed a panoply of "innovation mercantilist" practices such as IP theft, industrial subsidization, the sale of unregulated products,

and obfuscating the role of Chinese firms in the drug supply chain, policies that enable Chinese firms to operate outside the constraints faced by competitors in market-based economies.

Figure 3: Share of oncology trial starts by company headquarters location, 2009–2024[31]



CHINESE OBFUSCATION OF COMPANIES AND ACTIVITIES IN THE BIOPHARMACEUTICAL SUPPLY CHAIN

As ITIF wrote in "How Some Chinese Companies Obscure Ties to China and What Policymakers Should Do About It," some Chinese companies obscure their ownership and strategic intent in the U.S. economy, gaining access to markets, talent, IP, and even U.S. government subsidies.[32] Indeed, China regularly directs its companies to "downplay the company's home-country identity" when operating abroad. In some cases, this has led to branding imitation and ownership obfuscation that blur the line between adaptation and deception. Overall, these practices advance China's economic, industrial, and event military interests.

Chinese False Flagging

Outside the biopharmaceutical industry, a clear example of Chinese "false flagging" from ITIF's aforementioned report is Continental Aerospace Technologies (CAT), a company that presents itself as American, with patriotic branding, while ultimately operating within a Chinese state-owned defense-industrial structure. CAT traces its roots to Continental's historic role in U.S. aviation, including supplying engines for U.S. aircraft and military vehicles during World War II. Yet, the company's ownership changed materially after Teledyne Technologies sold Teledyne Continental Motors in 2010 to Technify Motor (USA), which, despite the "USA" name, was a vehicle tied to the Aviation Industry Corporation of China (AVIC), a Chinese state-owned aerospace and defense conglomerate.[33] The Committee on Foreign Investment in the

United States (CFIUS) approved the transaction, and the company continues to operate in Alabama as a U.S.-based employer and manufacturer. Today, China's state-owned Assets Supervision and Administration Commission owns 100 percent of AVIC and, through it, a significant share of CAT.

It can be challenging to identify false flagging in the global biopharmaceutical supply chain because it is highly fragmented and often involves multiple layers of manufacturers, contract research organizations (CROs), contract development and manufacturing organization (CDMOs), suppliers, distributors, investors, and licensing partners. The challenge is particularly relevant when Chinese-linked entities participate through minority equity stakes, venture capital investments, offshore holding companies, joint ventures, subsidiaries, etc. In such cases, a company may appear to be independent while maintaining relationships with Chinese parent companies or state-backed investors. The concern is that U.S. policymakers may lack sufficient visibility into ownership, governance arrangements, and strategic affiliations to accurately assess supply-chain dependencies and potential risks.

Nevertheless, ITIF endeavored to find examples where Chinese companies operating in the drug supply chain are making an effort to hide their ownership, affiliation, or ties to the Chinese Communist Party (CCP). It offers three case studies: Beijing Genomics Institute, GenScript Biotech, and WuXi AppTec.

Case Study 1: Beijing Genomics Institute's Acquisition of Complete Genomics

Beijing Genomics Institute (BGI) acquired Complete Genomics, a California-based company in 2012.[34] This acquisition was cleared by CFIUS in 2012 when the national security significance of genomic data and sequencing was less understood.[35] In 2023, the Bureau of Industry and Security (BIS) added BGI Research and BGI Tech Solutions based out of Hong Kong to the Entity List, indicating that their collection and analysis of genetic data poses a significant risk of contributing to Chinese government monitoring and surveillance and also poses a significant risk of diversion of sensitive data to China's military programs.[36] Following this, the House Select Committee on the CCP wrote a letter to the Department of Defense (DOD) in 2024 stating that MGI (an entity founded as a subsidiary of BGI Group) and Complete Genomics are subsidiaries of BGI, describing how the Complete Genomics brand is used in the U.S. market, concealing ties to MGI, BGI, and ultimately the CCP and the People's Liberation Army (PLA). Both BGI and MGI are included in the DOD's 1260H list (a DOD inventory of Chinese military companies operating in the United States).[37] Innomics and STOmics were also identified as subsidiaries of BGI, operating in the United States under the name BGI Americas Corporation.[38]

Numerous subsidiaries operating in the United States under BGI without clear affiliations constitutes an intentional strategy, making it difficult for American companies and businesses to understand who they are truly working with. In June 2026, BGI announced it will pursue the company's long-term goal of extending life sciences technologies into daily-life scenarios by aiming to develop handheld rapid genetic testing kits for consumers, consumer cosmetics, and wellness products, and expanding into personalized microbiome products.[39] With BGI Americas still headquartered in the United States, it's unclear how accessible personalized medical products developed by BGI will be to Americans in the future.

Case Study 2: GenScript Biotech

GenScript Biotech was founded in New Jersey in 2002 and has since grown into a multinational biotechnology conglomerate, becoming the majority shareholder in several subsidiary firms and maintaining operations in over 100 countries. Today, the firm is headquartered and operates largely out of Nanjiang County, China.[40] As a CDMO, GenScript Biotech provides U.S. firms and government entities with custom gene synthesis services.[41] The current CEO of the firm, Shao Weijui, previously served as the chief operating officer and CCP committee secretary for GenScript.[42] GenScript operates three main subsidiaries in the United States: Legend Biotech, ProBio Technology, and Bestzyme. Legend Biotech, a smaller, lesser-known firm, is headquartered in New Jersey and incorporated in the Cayman Islands, but has an intermediate holding company in Hong Kong, and its largest shareholder was once GenScript.[43] In 2024, GenScript relinquished its majority-shareholder status, but the firm still exerts "significant influence" over Legend.[44] Legend previously partnered with Johnson & Johnson in 2017 to develop a cancer cell therapy, CARVYKTI, indicating close ties with leading American biotech firms.[45]

In 2024 and again in 2025, the House Select Committee on Strategic Competition Between the United States and the CCP sent letters to the director of National Intelligence and the director of the Federal Bureau of Investigation (FBI) requesting intelligence and law-enforcement information on GenScript and its ties to the PRC.[46] The letters note that GenScript's role as a CDMO which has partnered with U.S. companies and government entities poses potential risks to U.S. biotech IP and advances the PRC's technological capabilities. The letter also urges the agencies to investigate GenScript's subsidiaries, such as Legend Biotechnology, which present themselves as American firms but have clear ties to the PRC.[47]

Case Study 3: WuXi AppTec

WuXi AppTec is a contract research, development, and manufacturing organization (CRDMO) that provides laboratory testing, drug discovery, and manufacturing services to the pharmaceutical and life sciences industries. Chinese biotech firm WuXi PharmaTech acquired Minnesota-based biologics and medical device testing firm AppTec Laboratory Services in 2008, transforming the company into WuXi AppTec, maintaining part of the American firm's name. WuXi AppTec has claimed that it does not, and will not, pose a national security risk to any country (in a response to the U.S. BIOSECURE Act).[48] Yet WuXi AppTec maintains an extensive network of relationships with the CCP, is involved in the Military-Civil Fusion Development Strategy, and has alignment with the People's Republic of China's (PRC) national development plans. Indeed, according to WuXi AppTec's CCP party group vice secretary Lin Wenbun, the company's culture promotes the notion that "Party members are the technical backbone" of the organization.[49]

Indicative of WuXi AppTec's deep connections to the Chinese government, the company operates the PRC's "state key laboratory of Drug Lead Compound Research," which carries out research to promote the Chinese economy and military development. Moreover, lawmakers have found that investments into Wuxi came from multiple PLA affiliated investment funds.[50] In addition to this, concerns were raised in 2024 that a U.S. client's data was transferred to Beijing without consent.[51] These concerns led to WuXi AppTec being listed on the DOD's 1260H list of companies. (In response, Wuxi has rejected accusations of Chinese military affiliation and filed a lawsuit contesting this.)[52]

WuXi historically has had a major impact on the global pharmaceutical industry, involved in one-quarter of drugs commercialized in the United States, with 65 percent of its reported revenue in 2023 (valued at over $5 billion) due to U.S. contracts.[53] The firm has become a pillar of the Western pharmaceutical supply chain, developing long-standing relationships with U.S. leaders in pharmaceutical development, including Pfizer.[54] The commissioner of the U.S. China Economic and Security Review Commission has called WuXi an "integral part of most American pharmaceutical companies."[55] While WuXi AppTec may not be so much a case of "false flagging," it's certainly a case of the company making an effort to conceal its incredibly deep ties to the CCP and PLA.

Gray Market Companies and Counterfeit Products

A related issue—though technically separate from issues of obfuscation of corporate ownership or control—pertains to entities operating in grey markets or peddling counterfeit products. Chinese firms have engaged in selling unregulated products in U.S. markets, and often at price points (often one-fifth retail prices) that undermine legitimate competitors. This is particularly evident in the peptide industry, which has seen the emergence of a large, ill-regulated Chinese export market.[56]

Sometimes looking for cheaper drugs, Americans and patients around the globe are purchasing untested, unregulated "drugs" from e-commerce platforms such as TikTok Shop through gray markets.[57] When these products are ordered online, often shipping from China, one-third of such products tested by Finnrick in the United Kingdom failed to pass basic quality checks. This means the substance sold to consumers did not contain what the label claimed, it had substandard purity of less than 98 percent, or the dosing amount was more or less than stated.[58] The labeling of gray market products sold online is causing Americans to obtain unsafe products. Products are labeled in fine print and sold as being for laboratory use only or not for use in humans while being directly marketed to members of the American public. Counterfeiting legitimate household name products such as Wegovy may appear to be legitimate to American consumers, while in reality consumers are receiving an entirely different product.

Indeed, the GLP-1 industry has been hit particularly hard by counterfeit products. Chinese and Turkish companies and pharmaceutical middlemen have become increasingly prevalent with the rising popularity of drugs such as Wegovy and Ozempic.[59] Many counterfeit products may contain some semaglutide but are not formulated in the same way as reputable companies' approved products. Often being produced by disreputable suppliers, these products are also at risk of containing dirty needles, being improperly stored, or containing an entirely different compound.[60] Patients worldwide suspected of ingesting counterfeit GLP-1s have suffered loss of consciousness, swelling of the face and throat, and even death.[61]

Different regulatory approaches worldwide also make it challenging to ensure quality medications are being delivered to patients, and that counterfeit products aren't circulating.[62] The sheer volume of counterfeit medications also poses a challenge, making it difficult to intercept them all. In February 2024, illegal pharmacies in the United States filled more than 734,000 GLP-1 prescriptions, and a cybersecurity firm took down over 250 websites selling fake versions of GLP-1drugs.[63] Given the complexity and sophistication of counterfeit production companies, it's becoming increasingly difficult to identify when drugs are counterfeited. Novo Nordisk and Eli Lilly have sued several entities seeking to stop them from selling

products claiming to contain the active ingredients used in their products, but more robust policies should exist to protect American consumers and businesses from fraudulent products.[64]

The profits from online peptide sales in the United States also pose another unanticipated problem: Chinese-based manufacturers that traditionally produce synthetic opioids like fentanyl and their precursors have been profiting from the popularity of peptides.[65] Cryptocurrency payments to gray-market peptide suppliers reportedly totaled $27 million in the first quarter of 2026, a 150 percent increase from the fourth quarter of 2025.[66] Companies are utilizing cryptocurrency to evade capital controls, maintain cross-border efficiency, and achieve perceived anonymity.[67] The growth in payments to Chinese-based synthetic opioid producers from the gray market for peptides serves as another challenge for the United States to overcome in fighting the opioid crisis and protecting the health and safety of all Americans.

IP Theft and Non-Disclosure of Adversarial Affiliations

There have been many reports of Chinese biomedical researchers working at U.S. universities, often on National Institutes of Health (NIH) grants, and taking the IP developed in their labs back to China.[68] For example, in 2020, the U.S. Department of Justice charged the chair of Harvard University's Chemistry and Chemical Biology Department, Charles Lieber, with aiding China with "one count of making a materially false, fictitious and fraudulent statement" regarding his work with organizations tied to the Chinese government, while on NIH funding.[69] In 2020, Ohio citizen Yu Zhou was sentenced to prison for conspiring to steal trade secrets concerning the research and treatment of different medical conditions, including cancer, from Nationwide Children's Hospital's Research Institute to sell to China.

In July 2025 Li Yunhai was detained by U.S. Customs and Border Protection and later charged with the theft of trade secrets.[70] Li had accepted a position as a postdoctoral fellow at the University of Texas MD Anderson Cancer Center in 2022 to work on breast cancer treatments while simultaneously receiving grant money from China's National Natural Science Foundation and conducting research for a Chinese university hospital.[71] His research in the United States was funded by an NIH grant.[72] Li uploaded information to his Baidu account with the intention of preventing U.S. government officials from discovering that he possessed the data when he made a return trip to China.[73]

Moreover, Chinese state-sponsored actors have targeted biopharma firms for IP theft, including through cybertheft and rogue employees.[74] That theft is sometimes through direct means whereby scientists working at U.S. biopharma companies steal IP and then transfer it to China. For instance, in 2018, Yu Xue, a leading biochemist working at a GlaxoSmithKline research facility in Philadelphia, admitted to stealing company secrets and funneling them to Renopharma, a Chinese biotech company funded in part by the Chinese government.[75] In October 2023, intelligence chiefs from the Five Eyes countries—Australia, Canada, Great Britain, New Zealand, and the United States—accused China of IP theft in sectors including biotechnology.[76]

POLICY RECOMMENDATIONS

As noted, this testimony offers policy recommendations, grouped into three themes: 1) addressing the challenge of Chinese "false flagging" and obfuscation; 2) addressing America's increasing biopharmaceutical supply chain vulnerabilities; and 3) broader policies to advance U.S. biopharmaceutical competitiveness.

Addressing the Challenge of Chinese "False Flagging" and Obfuscation

The U.S. government needs to more comprehensively approach transparency, ownership disclosure, and risk management of Chinese investment in the U.S. economy, especially within defense, dual-use, and enabling industries. The following recommendations explain how the U.S. government can strengthen its systems to reduce vulnerabilities to Chinese techno-industrial predation.

Strengthen CFIUS Screening and Oversight

As of 2020, CFIUS is implementing the Foreign Investment Risk Review Modernization Act of 2018 (FIRRMA) in its screens.[77] FIRRMA states that CFIUS should also factor into its reviews "whether a covered transaction involves a country of special concern that has a demonstrated or declared strategic goal of acquiring a type of critical technology or critical infrastructure that would affect United States leadership in areas related to national security."[78]

Congress should expand FIRRMA to widen the definition of what would affect U.S. leadership. CFIUS's mandate should encompass not only threats to U.S. leadership "in areas related to national security" but also industries critical to economic and strategic competitiveness, such as civilian aerospace engines, aerial work platforms (AWPs), and advanced batteries.[79]

CFIUS should also create a comprehensive registry of all Chinese-origin companies operating in the United States, including subsidiaries, joint ventures, firms with Chinese financing, and entities with partial Chinese government ownership. To ensure that the list is accurate and up to date, CFIUS should leverage private sector open-source intelligence providers to both identify Chinese-controlled entities that may otherwise evade detection and ensure that the registry remains accurate and up to date.

Expand Ownership Disclosure

Congress should expand the Corporate Transparency Act to require Chinese-origin companies operating in U.S. "national power" industries—industries that enable a strong military or give the United States leverage over other nations, especially China—to report beneficial ownership and operational control, including minority stakes, joint ventures, offshore subsidiaries, and IP transfer rights.[80] Using CFIUS's registry, the Securities and Exchange Commission should collect detailed information on ownership and decision-making structures, while the Department of Commerce should verify compliance and monitor access to dual-use technology and strategic assets. Companies that fail to provide full transparency should be barred from doing business in America, and CFIUS and Commerce should have authority to enforce restrictions or divestment where necessary to protect U.S. national security.

Proactively Use NDAA and CFIUS Authority

Congress should direct National Defense Authorization Act (NDAA) authorities that the NDAA for FY26 mandate that agencies expand Section 1260H and related authorities to ensure that Chinese-origin companies in defense, dual-use, and enabling industries cannot indirectly advance military capabilities.[81] This should include explicit prohibitions on contracting, technology sharing, and participation in federally funded programs. The NDAA should also direct agencies to require ongoing reporting for Chinese companies, covering IP transfers, supplier relationships, and workforce development activities.

Block Subsidies to PRC-Financed Companies

Federal agencies, led by the Office of Management and Budget, should bar companies with PRC financing from receiving U.S. government funding, tax incentives, or other financial support. The same should apply to companies with involvement in China's military or dual-use programs. These checks should span both national and subnational levels, with CFIUS coordinating with state-level economic development offices. U.S. state policy has sped ahead on foreign adversary defensive regulation, but in many cases, these laws are flawed and could be better harmonized to national-level security priorities.[82]

Federal agencies such as the Department of Energy (DOE), DOD, National Science Foundation (NSF), and the Department of Transportation, as well as federal agency-linked consortiums such as USCAR (the United States Council for Automotive Research), should also implement pre-award due diligence to screen for Chinese ownership, operational control, or dual-use access before awarding grants or cooperative agreements. This would ensure that U.S. taxpayer funds support domestic innovation rather than foreign industrial strategies.

In addition, the Department of the Treasury, through CFIUS, working with funding agencies, should require companies that receive U.S. federal funding to obtain explicit U.S. government approval before relocating operations or substantial portions of their workforce or IP to China. This requirement would ideally be designed to not prevent legitimate global business activity but rather ensure that taxpayer-funded investments are not diverted to foreign jurisdictions in ways that could undermine U.S. strategic industrial capabilities.

Clarify Brand Obscuration Practices

Companies such as CAT and BGI maintain U.S. branding to obscure foreign ownership, misleading stakeholders and regulators. The Federal Trade Commission (FTC), with congressional authority as needed, should issue guidance on truth-in-branding and ownership disclosure by requiring companies in defense, dual-use, or enabling industries, including biopharmaceuticals, to clearly disclose foreign state ownership or control in marketing, websites, and communications.

In addition, for Chinese companies operating in defense, dual-use, or enabling industries, Congress should consider legislation or FTC rulemaking to mandate disclosure of foreign state ownership or control in a standardized and visible manner.[83] This requirement would not apply to benign consumer sectors, where branding obfuscation poses minimal national security or economic risk, but would prevent companies in critical sectors from misleading U.S. consumers, investors, or regulators about their foreign affiliations.

Centralize Interagency Due Diligence

The Treasury Department, along with the departments of Commerce, War, and other relevant agencies, and with oversight from the House and Senate intelligence committees, should establish a single, interagency due-diligence database that integrates CFIUS, Commerce, and federal grant-funding data to screen all potential recipients of federal awards, contracts, and research grants. As the Select Committee on the CCP's *Fox in the Henhouse* 2025 report and a recent article, "Why Is the U.S. Defense Department Funding China's Military Research?" underscore, a lack of data interoperability has enabled Chinese defense-linked institutions to

receive U.S. funding through loopholes in agency coordination.[84] A unified system bringing together in-house capabilities and outsourced procured capabilities would automatically flag any entity on federal restriction lists (e.g., the Entity List, Section 1260H list, or the NS-CMIC list) before awards are approved.

Another area of improved intelligence sharing would be for CFIUS to integrate trade intelligence into its screens. The Commerce Department's trade enforcement arm routinely collects detailed information on foreign corporate ownership, subsidy networks, and state involvement, producing rich data that overlaps with the national security risks CFIUS evaluates. There are no clear formal mechanisms for synthesizing such information, and the Government Accountability Office has documented interagency coordination gaps across U.S. efforts to mitigate national security risks from foreign investment in the U.S. economy.[85] CFIUS should establish a formal analytic mechanism—led by Treasury in coordination with the Commerce Department's International Trade Administration and BIS—to integrate dumping, subsidy, and export-control data into investment reviews.

Addressing U.S. Biopharmaceutical Supply Chain Vulnerabilities

There are a number of steps the United States should take to reduce its biopharmaceutical supply chain vulnerabilities.

Facilitate Domestic Reshoring Through Manufacturing Innovation

Whether it comes to APIs, KSMs, critical minerals, or rare earth elements (REEs), the only way the United States (and allied nations) are going to compete with China is through technological innovation, notably ones that develop superior refining and processing techniques in a cost-competitive and ideally environmentally friendly manner. Advanced manufacturing technologies—including continuous manufacturing and advanced chemistry—will be central to this effort. This is why ITIF has called for the creation of a Manufacturing USA Institute (a network of currently 17 institutes focused on developing advanced manufacturing product and process technologies) for critical minerals and REEs.[86] (An alternative approach would be to create a new NSF Industry/University Cooperative Research Center (I/UCRC) focused on this.)[87] Given the significant similarities between chemistry- or chemical-based KSMs/APIs and critical minerals/REEs, the remit of such an institute could extend to also innovating new processes for KSM/API development.

Recent advances in biomanufacturing illustrate the significant potential. As Drew Endy, a member of the bioengineering faculty at Stanford University, has explained, novel bio-based and bio-fermentation processes now "make possible the biosynthesis of active pharmaceutical ingredients through bio-brewing-based processes…we can actually leverage yeast to create a set of medicinal alkaloids" including for many key APIs.[88] By leveraging engineered organisms such as yeast to produce many key APIs, these methods can significantly reduce both environmental impacts and reliance on traditional chemical synthesis.

At the same time, continuous manufacturing offers a pathway to disrupt the batch-based production model that has dominated API manufacturing. Rather than scaling production through large, capital-intensive batch facilities, continuous manufacturing based on flow chemistry enables smaller, more flexible systems that operate continuously and efficiently.

The United States is already making significant efforts to accelerate domestic API production. Phlow Corp. is a public-private partnership (PPP) which develops and domestically manufactures APIs and finished drug products that are essential for the United States. Phlow seeks to secure essential medicine manufacturing by building domestic API manufacturing capacity and maintaining a reserve of critical APIs to mitigate supply disruptions in times of disruption or emergency.

In addition to Phlow's work, other early efforts demonstrate the promise of this approach. CONTINUUS Pharmaceuticals, for example, is developing an integrated continuous manufacturing platform that takes raw materials, synthesizes and purifies APIs, and produces final dosage forms all in a single system that can operate 24/7. Whether advanced manufacturing technologies can help close the cost gap with Chinese production remains an open question. CONTINUUS's prototype results show that it reduced costs by 30–50 percent, solvent use by more than 60 percent, energy costs by 50–60 percent, facility footprint by roughly 90 percent, and lead time from months to less than 48 hours.[89] These cost reductions could help reduce the gap if replicated at commercial scale. However, achieving those results outside of controlled pilot conditions requires solving challenges in process scale-up, workforce training, regulatory approval, and supply chain integration. The federal government should support independent techno-economic assessments of what cost parity between U.S. advanced manufacturing and Chinese conventional production would require, and at what production scale it becomes commercially viable.

Strengthen Strategic Stockpiling

Aside from developing new manufacturing and refining processes for APIs, the United States should strengthen strategic stockpiling of them. One initiative the United States has undertaken to begin addressing near-term supply vulnerabilities is SAPIR, the Strategic Active Pharmaceutical Ingredient Reserve, a federally supported effort led by the U.S. Department of Health and Human Services (HHS), including the Administration for Strategic Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA), in partnership with companies such as Phlow Corp.

SAPIR is not designed as a passive stockpile. Rather, it constitutes an integrated system for pharmaceutical resilience. Its core components include domestic manufacturing capacity for critical APIs and inputs, a distributed storage network for rapid response in times of crisis, analytical testing infrastructure to ensure ingredient quality, and conversion capabilities to rapidly turn stored ingredients into finished medicines. These activities are coordinated through a centralized platform for inventory, forecasting, and deployment, leading SAPIR to be a "living" reserve that combines stockpiling with production and logistics.[90]

Phlow's work is a critical part of SAPIR. Through its BARDA-supported contract, the company is working to build an innovative end-to-end domestic supply chain for essential medicines, including the production of chemical precursors, APIs, and finished drugs in partnership with other organizations.[91] This effort combines manufacturing scale-up with upstream R&D and process innovation. In particular, Phlow is advancing continuous-flow and green chemistry manufacturing techniques to produce APIs more efficiently, at a higher quality and a lower cost than traditional batch production.[92] Such technologies are intended to make domestic production economically viable while reducing reliance on foreign suppliers.

Strategic stockpiling, as a complement to supply chain diversification through friendshoring and domestic manufacturing growth, can serve as an important buffer against disruptions while long-term production and

innovation ecosystems are developed. Yet it's important to acknowledge that stockpiling and near-term domestic capacity building are not self-sustaining solutions if the underlying cost differences between American and Chinese producers remain large. The viability of domestic reshoring at scale depends on either closing that gap through manufacturing innovation, offsetting it through policy tools such as advance purchase commitments and tax incentives, or accepting that strategic resilience for a defined set of essential medicines warrants ongoing public investment, much as the United States accepts the cost of maintaining other strategic reserves. Policymakers should be transparent about which of these mechanisms they are relying on for different types of API. As noted, much of the effort depends on advancing new biomanufacturing processes for APIs—including continuous manufacturing and novel synthesis methods—which in turn requires sustained investments in R&D, specialized workforce training, and scale-up capabilities. Therefore, initiatives such as Phlow's work on SAPIR are critical not only for safeguarding near-term resilience, but also for catalyzing the technological and industrial base needed for increased domestic production.

Support Domestic Reshoring in Puerto Rico

Congress should leverage the tax code to encourage greater levels of medicines manufacturing in Puerto Rico. For example, **Congress should reinstitute Section 936 of the Internal Revenue Code, which, when originally enacted in 1976, released pharmaceutical manufacturers from taxes on profits made in Puerto Rico and other U.S. territories.** Section 936 contributed to making Puerto Rico a pharmaceutical manufacturing powerhouse, and while the biopharmaceutical sector does still contribute 30 percent of Puerto Rico's gross state product, the phase-out of the provision from 2006 to 2016 contributed to a shrinking of the sector and a 40 percent reduction in the territory's manufacturing job base. In 2024, the territory produced $48.3 billion in pharmaceutical exports, representing 74 percent of its total exports, with 60 facilities and 13,917 employees in the sector.[93] Yet this capacity exists despite, not because of, the federal tax environment. Congress should restore the tax credit in Section 936 for biopharmaceutical production in Puerto Rico and other U.S. territories.[94] This would signal a federal commitment to expanding this domestic production base, generating additional API and finished drugs within the United States at a scale that no other domestic location could match in the near term.[95]

Expand Nearshoring and Friendshoring to Diversify Supply Chains

Preceding sections have outlined domestic reshoring strategies—including manufacturing innovation, the SAPIR initiative, and Puerto Rico's underutilized capacity—that could expand API production in the United States. These efforts are necessary but not sufficient, as even such a fully executed domestic reshoring agenda would leave the United States short of the supply chain independence needed to withstand a major disruption or a deliberate Chinese supply cutoff. Nearshoring, friendshoring, and allied coordination could complement U.S. production by diversifying supply chains without requiring every stage of manufacturing to occur domestically, while reducing concentration risk through expanded production across trusted jurisdictions.

A U.S.-Mexico collaboration for API and precursor material manufacturing, for instance, could build on Mexico's growing chemical and manufacturing sector while maintaining proximity to U.S. markets, leveraging existing industrial capabilities and strengthening regional resilience.[96] Such a partnership could involve several factors: (1) a bilateral working group to identify priority APIs for joint production; (2) financing through the U.S. Development Finance Corporation for Mexican pharmaceutical

manufacturing facilities; (3) harmonized FDA-COFEPRIS (Mexico's health regulatory authority) inspection protocols to streamline market access for Mexican-produced APIs, and (4) joint infrastructure investments in dedicated pharmaceutical manufacturing zones near the U.S.-Mexico border, reducing logistics costs and enabling just-in-time supply chains.

Similarly, friendshoring with allies—such as India and South Korea—could support diversification in both production and innovation.[97] South Korea represents a compelling friendshoring partner not primarily because of cost, but also due to its advanced manufacturing capabilities, strong IP protections, and proven capacity in pharmaceutical production. While Korean wages tend to be higher, meaning that Korean API production would not be as price-competitive with Chinese production, South Korea's value proposition lies in higher-value, technically complex APIs and advanced manufacturing partnerships—areas where quality, reliability, and innovation matter more than unit cost. Bilateral cooperation should focus on APIs where technical complexity or quality requirements make Korean producers competitive, and on mutually supporting R&D to develop next-generation manufacturing platforms. South Korea possesses established capabilities in pharmaceuticals and advanced manufacturing, and bilateral cooperation between the two countries could include joint R&D initiatives, co-investment in emerging manufacturing technologies, and improved data-sharing to map and understand shared supply chain vulnerabilities. These partnerships would help reduce reliance on concentrated sources—especially China—while preserving efficiency and scale through coordinated production across trusted allies.

The United States should also increase its reliance on India through a coordinated combination of procurement, financing, and regulatory tools. Indeed, drugs and APIs have been identified as a key opportunity for U.S.-India collaboration as part of the U.S.-India "TRUST" initiative.[98] On the demand side, federal purchasing authorities, including BARDA, the War Department, and the Centers for Medicare & Medicaid Services (CMS), could deploy advance market commitments to provide Indian API producers with the revenue predictability needed to justify capacity investments. A White House determination under the Defense Production Act in December 2023 expanded BARDA's authority to issue such commitments for essential medicines and medical countermeasures, providing a legal avenue for this approach.[99] In parallel, CMS reimbursement policy could prioritize medications for preferred Medicare formulary placement for drugs that source APIs from trusted Indian suppliers.[100]

On the supply side, U.S. development and industrial finance tools could support India's API capacity expansion. The U.S. International Development Finance Corporation (DFC), which has approximately $3.8 billion already deployed in India—making it the agency's largest single-country market—could provide loan guarantees and political risk insurance for API facilities and chemical intermediate plants in India, particularly those aligned with U.S. essential-medicines priorities.[101]

Regulatory cooperation is also critical: Expanded FDA technical assistance, faster inspection scheduling, and early scientific engagement can lower compliance costs and shorten time-to-market for Indian producers scaling advanced or continuous manufacturing. Finally, joint U.S.–India initiatives to localize key starting material production—supported by tax credits, export-import financing, or allied co-investment—could reduce India's starting material dependence on China. India currently imports most of its API key starting materials from China, with roughly 87 percent of India's imported antibiotic ingredients by value coming from China, meaning that a simple shift in final API assembly without addressing upstream inputs would

leave the supply chain exposed.[102] Diversification that includes these materials, not just finished APIs, would be key to turning procurement reorientation into durable supply chain resilience.

Strengthen Oversight of Foreign API Manufacturing

Another enduring challenge in global pharmaceutical supply chains consists of asymmetries in inspection and enforcement across jurisdictions. While the FDA applies Current Good Manufacturing Practice (CGMP) requirements to all facilities supplying the U.S. market, oversight of foreign facilities—particularly in China—has historically been more limited and has been subject to greater operational constraints than for domestic manufacturers.[103]

Prior to the COVID-19 pandemic, FDA inspections abroad were often pre-announced and conducted less frequently than domestic inspections. The pandemic further disrupted these processes, reducing foreign inspections and increasing reliance on host-country regulatory oversight, resulting in a backlog that constrained U.S. visibility into foreign manufacturing conditions and practices. Although inspections have since resumed, structural factors, including limited staffing, logistical barriers, and broader geopolitical frictions, continue to affect the FDA's ability to maintain consistent, on-the-ground oversight of facilities in China.[104]

The inspection regime's limitations in China are not merely logistical; they reflect a structural information asymmetry that Beijing is difficult to remedy under current conditions. Unlike domestic U.S. facilities, which can be inspected with no warning, FDA inspectors in China must obtain a business visa and schedule inspections in advance, providing facilities with effective forewarning of oversight visits. This advance notice creates opportunities for facilities to stage compliance by concealing deficiencies, updating incomplete records, and coaching workers before inspectors arrive.[105]

As Rosemary Gibson, author of *China RX* and a witness before the U.S.-China Economic and Security Review Commission, has commented, the FDA faces a regulator's dilemma: It must choose between allowing potentially defective medicines from non-compliant suppliers to remain on the market or exacerbating drug shortages by banning these suppliers. The dilemma was created because the United States has allowed itself to become dependent on a single adversarial source.[106] This cannot be solved through better inspection protocols alone. Congress should require that all inspections of foreign facilities be unannounced, and that no APIs or finished drugs may be imported from any facility that hasn't passed an FDA inspection within the preceding three years.

In May 2025, the FDA announced the expanded use of unannounced inspections at foreign manufacturing facilities that produce essential medicines intended for American patients. This followed a pilot program in China and India, which aimed to ensure that foreign plants are subject to the same level of regulatory oversight and rigor as domestic companies. The FDA also announced it would evaluate the agency's policies and practices for improvements to its foreign inspection program to ensure that the FDA is the gold standard for regulatory oversight.[107]

These inspection asymmetries have important implications. They may affect competitive dynamics, as differences in inspection frequency and enforcement intensity can translate into variation in effective compliance costs across jurisdictions. At the same time, they can contribute to reduced supply chain

transparency, limiting regulators' ability to carefully assess quality risks, production vulnerabilities, and dependencies in upstream inputs such as key starting materials.

Addressing these challenges requires greater consistency in how regulatory standards are applied globally. The FDA's data show that prior to the pandemic, many foreign facilities had never received in-person FDA inspections.[108] **Congress should authorize and fund a substantial increase in FDA foreign inspection capacity and set a statutory inspection frequency floor for foreign facilities, at minimum, once every three years for any facility actively supplying the U.S. market, and appropriate funding sufficient to achieve that target.** The FDA should also leverage inspection-sharing agreements with trusted regulators such as the European Medicines Agency (EMA) through its Mutual Recognition Agreement (MRA) and Japan's Pharmaceuticals and Medical Devices Agency to extend oversight reach.[109]

Complementing physical inspections with remote monitoring tools and improved access to manufacturing data could further enhance visibility into Chinese production facilities specifically.[110] In parallel, greater transparency around inspection outcomes, along with incorporating compliance track records into federal procurement decisions, could help align market incentives with quality and supply chain resilience goals.[111] More importantly, inspection enforcement is itself a supply chain diversification tool. When the FDA bans imports from non-compliant suppliers, buyers must source elsewhere, prompting a shift toward domestic and allied producers that the supply-side policies discussed throughout are designed to support. Incorporating compliance track records into federal procurement decisions would reinforce this dynamic. Therefore, a more rigorous and consistently enforced inspection regime does not merely protect patients from potentially defective drugs—it actively supports the broader goal of reducing U.S. structural dependence on Chinese pharmaceutical production.

Push Back on China's Promulgation of Decrees 834 and 835

In response to the BIOSECURE Act, and other foreign export controls and investigations, China created Decree 834, which entered into effect on March 31, 2026, and Decree 835, which entered into effect on April 7, 2026.[112] Decree 834 establishes that China's industrial supply-chain security is an independent regulatory concern.[113] Within Decree 834, supply-chain-related investigations and data collection is prohibited if it violates PRC laws or regulations which can include origin tracing, export-control compliance checks, and internal investigations.[114] China's State Council Department is also authorized to investigate discriminatory measures thought to impact the security of China's supply chains.[115] Following an investigation, Chinese authorities can implement countermeasures against foreign organizations or individuals that could harm China's supply-chain security, which can include trade restrictions, visa, and entry restrictions.

Decree 835 establishes a framework for identifying and responding to foreign acts that China views as an improper use of extraterritorial jurisdiction. China's Ministry of Justice and related authorities can investigate and determine if a foreign effort is of improper extraterritorial jurisdiction. If a foreign act is found improper, the Ministry of Justice can issue a public announcement of its findings and can place foreign organizations or individuals on a Malicious Entity List. Entities placed on the malicious entity list can face visa denial, deportation, seizure or freezing of assents in China, transaction restrictions, limitations on import-export activities and investments, fines, product entry bans, and other measures deemed necessary. Chinese citizens

or organizations harmed by an improper foreign act can seek civil compensation. Organizations and individuals cannot engage in activities with individuals on the malicious entities list. A relief mechanism is in place for organizations or individuals subject to countermeasures, with corrective action of countermeasures can be suspended, modified, or removed.

The combination of these decrees means that Chinese counterparts can refuse, limit, or delay information requests, impacting commercial disputes involving China.[116] Companies can anticipate increased foreign regulatory investigations, proceedings, and hurdles. Routine investigations that the United States conducts could trigger countermeasures requiring information disclosure.[117] Any business that modifies its relationship with Chinese counterparties can be at risk, and many critical terms under these decrees remain undefined.[118]

Enforcement of Decree 835 has begun with Nuctech.[119] The European Commission is investigating if government support has provided Chinese companies an unfair advantage and opened an investigation into Nuctech (a security inspection product manufacturer and security solutions supplier). China's Ministry of Justice publicly ordered Nuctech to not cooperate with Europe's investigation. In short, Decrees 834 and 835 raise new questions about the extent to which the United States will be able to capture information about Chinese entities operating in biopharmaceutical supply chains.

Require Products Made by Chinese Companies to Be Labeled as Such

In a 2020 survey, 40 percent of Americans said they would not purchase goods made in China.[120] But while the law requires labeling to show where products are made, consumers often cannot easily discern if a product is made by a Chinese company.[121] For example, many American consumers are likely unaware that their Blue Bottle coffee, their GE Appliances microwave, their Smithfield Foods deli meats, or their Wilson Sporting Goods tennis racket are all products sold by Chinese-owned companies.[122] The same is true of longstanding, distinctly American brands, such as Milwaukee Tool, that are owned by companies located in China or Hong Kong.[123]

Congress needs to take steps to allow consumers to easily identify if they are buying a product owned by a Chinese company. Three difficulties would exist for a manufacturer ownership policy: defining ownership, thinking through liability, and choosing scope.

For ownership, defining what "Chinese-owned" or "Chinese-controlled" means in an era of complex global corporate structures is difficult. ByteDance is incorporated in the Cayman Islands.[124] Shein is headquartered in Singapore.[125] A binary yes-or-no label cannot capture these distinctions without misleading consumers in the process. A better approach would be to differentiate between shades of gray, such as a subsidiary of a Chinese parent versus a company where Chinese mutual funds hold a minority stake in publicly traded shares. In the subsidiary case, the Chinese parent company could fire the board and direct the company's decisions. In the investment case, shareholders benefit from returns but do not govern operations. For the most complicated cases, where elaborate financial arrangements obscure effective control, the Treasury Department could investigate. Milwaukee Tool is an example of a company that might not qualify as Chinese-controlled.

A threshold of 25 percent beneficial ownership is a reasonable starting point, consistent with standards used in anti-financial crime law.[126] But rather than embedding a rigid threshold in statute, **Congress should direct the Department of Commerce, working with industry, to develop a tiered classification framework that**

distinguishes between majority Chinese-owned, Chinese-controlled-with-minority-stake, Chinese-invested-but-not-controlled, and no material Chinese ownership. Milwaukee Tool is precisely the kind of complicated case a tiered framework should be designed to consider.

With the conceptual piece of control in place, the U.S. government would then need to implement a China control regime. Importers of record—the entities that interact with customs at the border—should bear the disclosure obligation, consistent with how existing country-of-manufacture labeling works.[127] A safe harbor should accompany that obligation. Importers should not need to independently verify ownership structures across layers of holding companies but should have to verify where they got that information, such as from a commercial database, government database, or the manufacturer. Importers who conduct due diligence, use approved data sources, disclose in good faith, and update filings when material information changes should not face liability for inadvertent errors. Importers that do not meet that bar should face civil fines, as they already do for inaccurate or misleading country-of-origin markings.[128]

Sellers who make false ownership claims should bear a higher legal risk than importers. They should face a ban on importing goods into the United States, a power that Customs and Border Protection already holds.[129] Finally, regulators should identify country-of-control at the time of import, accounting for the possibility of post-import changes to corporate structure, which would likely only apply to a minimal amount of goods.

The Consumer Labeling for Enhanced API Reporting and Legitimate Accountability for Base Entity Listings (CLEAR LABELS) Act would require all prescription medications dispensed in the United States to include clear labeling that identifies the country, or countries, of origin of both the finished drug product and its individual active pharmaceutical ingredients.[130] The legislation includes: 1) a labeling requirement, under which drug manufacturers would have to clearly display, for each included API in a finished drug product, the name and location of the API's original manufacturer, packer, and distributor; 2) reporting and accountability requirements, under which the FDA would have to maintain and update a publicly accessible electronic database of country of origin information for all APIs used in prescription drugs approved for use in the United States; and 3) enhanced oversight, which would support existing FDA oversight efforts to strengthen monitoring, inspections, and enforcement against manufacturing practices that could impact drug quality or safety.[131]

The legislation sensibly seeks to provide consumers with more visibility into the origins of their medications, and it would provide pharmacists and providers with more data for inventory decisions, recall management, and patient education. The legislation may not need to be so prescriptive as to require unique facility identifiers that enable tracking down to the exact address of the facility. (It's perfectly fine for the FDA and inspectors to have that information, of course, but requiring disclosure of this information to the public may not add significant new value.)

Strengthening U.S. Biopharmaceutical Competitiveness

As ITIF wrote in "China's Burgeoning Biopharmaceutical Competitiveness Demands a US Response," it's time for policymakers to stop "making own goals" that harm the U.S. biopharmaceutical industry and to "set ambitious goals" to bolster U.S. biopharmaceutical competitiveness. This testimony will highlight three of the most significant issues in particular.

Do Not Cut Federal Funding for Basic Research in Life Sciences

Multiple actors, including the federal government, academia, and industry (including both small biotech start-ups and large multinational corporations) play complementary roles at various phases in the U.S. life-sciences innovation process. While "drug populists" on the left argue that government should primarily take over drug development from the private sector, and "drug libertarians" on the right want to remove the government's role entirely and have the private sector play the predominant role in drug development, the reality is that the contributions of both are essential.[132]

Particularly crucial is NIH funding for basic scientific research that aims to extend the frontiers of medical understanding, although it's estimated that approximately one-third of NIH funding supports clinical research (including patient-oriented research, clinical trials, and epidemiological and behavioral studies, as well as outcomes and health services research) that is more applied in nature.[133] NIH-funded research has supported discoveries that have contributed to reduced deaths from cancer and lower rates of disability due to stroke, heart disease, hepatitis B, and osteoporotic fractures.[134] NIH-supported research has also led to the development of anti-AIDS drugs; the discovery of neurotransmitters, which led to the development of anti-depression treatments leveraging selective serotonin reuptake inhibitors (SSRIs); and treatments reducing scar tissue formation.[135]

The American public enjoys a tremendous return from the federal government's investments in basic biomedical scientific research. In fact, each NIH dollar invested yields roughly $2.50 in short-term economic returns and stimulates an additional $8.30 in long-term private-sector R&D investment, underscoring the strong multiplier effect of public science funding.[136] Economists find that, in general, an additional dollar of public contact research added to the stock of government R&D has the effect of inducing an additional twenty-something cents of private R&D investment.[137] However, for the life sciences industry, a dollar of NIH support for research leads to an even greater increase in private medical research, roughly 32 cents.[138]

Unfortunately, the Trump administration's proposed FY 2026 budget proposal sought to reduce NIH funding by a potentially staggering 40 percent, from roughly $48 billion in 2025 to about $27 billion in 2026.[139] Fortunately, Congress rejected these proposals, providing NIH with a total program funding level of $47.49 billion in FY 2026.[140] Nevertheless, the Trump administration has persisted in calling for cuts to NIH funding, with the administration's proposed FY 2027 budget calling for 12 percent NIH cuts in FY 2027.[141] The administration's FY 2027 NIH funding request would also zero out three important NIH institutes: the National Institute on Minority Health and Disparities, the Fogarty International Center, and the National Center for Complementary and Integrative Health. **Congressional policymakers should reject the administration's calls for NIH cuts.** Moreover, **Congress should fund NIH in excess of $50 billion in FY 2027 and further ensure that NIH funding in future years will increase, at the very least, at the rate of inflation.**[142]

Repeal Drug Price Controls

If policymakers are concerned about U.S. drug supply chain vulnerabilities, the number one thing they should do is repeal or refrain from introducing drug price controls. Not only do drug price controls inhibit drug innovation, they also preclude companies from earning the revenues needed to reinvest in domestic supply

chains and exacerbate the need to favor low-cost options for needed services in the drug supply chain, such as the services CRDMOs provide.

America's life sciences companies are devoted to developing innovative drugs that tackle some of the most difficult problems in biomedical science, including solutions to heretofore intractable challenges such as Alzheimer's, Parkinson's, pancreatic cancer, and rare diseases (which affect small patient populations of less than 10,000). But the work is difficult. That's why developing a new medicine can take 10 to 15 years and cost upwards of $2.6 billion, on average.[143] Life sciences companies need to earn revenues from their successful medicines in order to recoup the R&D costs of both their successful and failed efforts, and so they can garner revenues to invest in future generations of biomedical innovation. That's why research finds a statistically significant positive relationship between a biopharma firm's profits from the previous year and its R&D expenditures in the current year.[144] Other research makes this linkage direct, finding that every $2.5 billion of additional biopharmaceutical revenue leads to one new drug approval.

But recent drug price controls introduced by both the Biden and Trump administrations have disrupted market economics and are already having a significant deleterious impact on innovation. Drug price controls in the Biden administration's Inflation Reduction Act (IRA) had an immediate deleterious impact on drug innovation, especially for small molecule drugs.[145] Research firm Vital Transformations found that, from September 2021 to 2024, small-molecule investment funding dropped by 70 percent (in the wake of the promulgation of the IRA legislation).[146] That coincided with a 2023 PhRMA study in which 78 percent of PhRMA member respondents reported that they expected to cancel early-stage small-molecule pipeline projects.[147] The IRA has already forced companies to halt more than 55 drug R&D programs since it became law.[148]

Most-Favored Nation (MFN) drug pricing policies proposed by the Trump administration could be even more damaging to U.S. biopharmaceutical innovation than the IRA drug price controls have been because they would apply to all drugs, not just the specific ones selected for price controls in the IRA. Tomas Philipson and his colleagues at the University of Chicago have found that applying MFN pricing policy to existing drugs in Medicare and Medicaid would reduce U.S. pharmaceutical revenues by 49 percent. They further found that if the drug price controls persisted over a 10-year horizon, the revenue shortfall would result in the loss of 210 new drug approvals, together with 290 post-approval indications, resulting in a combined loss of 500 drugs, or 50 per year. The authors associate this large cut in innovation with a loss of 516 million life-years, corresponding to approximately 6.6 million lives lost worldwide.[149] Especially in the face of burgeoning Chinese biopharmaceutical competitiveness, **Congressional policymakers should repeal the IRA drug price controls and reject the Trump administration's various MFN drug pricing proposals.**[150]

Press Allied Nations to Pay Their Fair Share for Innovative Medicines

The United States has borne a disproportionate share of the cost of pharmaceutical innovation. American patients and taxpayers fund the majority of R&D in the life sciences, bearing the financial risks of drug discovery and clinical trials that benefit nations globally. At the same time, many countries in the Organization for Economic Cooperation and Development (OECD) have implemented price controls on pharmaceuticals, often paying less than is needed to sustain the innovation pipeline they benefit from,

creating free riding on American innovation investment. Individually, each nation benefits from suppressing drug prices while assuming others, particularly the United States, will continue funding breakthroughs. But when every country around the world other than the United States follows this strategy, the global system becomes unsustainable, innovation slows, and patients worldwide lose access to future therapies.[151]

The innovation costs of this free riding are measurable and substantial. If the 32 OECD countries had lifted pharmaceutical price regulations in 2018, the world would have benefited from approximately 25 additional new drugs per year.[152] These are cures that patients never received, treatments that were never developed because the expected return on investment could not justify the risk and expense. China has recognized this weakness in allied cost-sharing and exploited it strategically. By offering lower-cost generics and biosimilars through state-subsidized manufacturing, China has positioned itself as an attractive alternative to sometimes more expensive Western pharmaceuticals. Allied nations facing budgetary pressures driven by price controls have increasingly turned to Chinese suppliers, weakening both private pharmaceutical innovation in the West and allied governments' independence from Chinese supply chains.

The United States should use trade negotiations to correct this misalignment. A prime example for this—indeed, a template—was established in December 2025 when the United States Trade Representative's Office secured a commitment from the United Kingdom that it would pay 25 percent more for new medicines by 2035 as part of a U.S.-U.K. drug pricing deal.[153] Making drug pricing a central issue in bilateral and multilateral trade agreements establishes clear expectations: Nations that implement reasonable pharmaceutical pricing that reflects innovation value receive preferential trade treatment, such as reduced tariffs, faster regulatory approval, and priority access to U.S. research partnerships. Conversely, nations that maintain stringent price controls should face trade consequences. This approach requires the United States to credibly signal a willingness to defect from cooperative trade relationships unless allies contribute their fair share to innovation financing. The goal is not punishment but rebalancing, encouraging OECD nations to raise drug prices to more reasonable levels that sustain the innovation ecosystem.[154]

By raising reimbursement for Western-developed drugs through trade-linked pricing mechanisms, allied nations would simultaneously reduce their economic incentive to source Chinese generics and biosimilars. When German health systems can afford recently developed targeted therapies at fair prices negotiated as part of trade agreements, their need for cheaper Chinese alternatives lacking transparency or quality oversight decreases. Trade-linked pricing thus accomplishes multiple strategic objectives at once: It distributes innovation financing more equitably across wealthy nations, preserves incentives for private pharmaceutical R&D, and reduces allied dependence on Chinese supply chains.

CONCLUSION

ITIF commends the U.S. Senate Special Committee on Aging for taking up the vitally important topic of U.S. drug supply chain security. The hearing comes at a time when China is becoming an increasingly capable competitor in the global pharmaceutical industry, with growing strengths at every level of the biopharmaceutical supply chain, from KSMs and APIs to high-quality science to a compelling clinical trial environment to impressive drug innovations. Responding to this challenge will require the United States to develop a comprehensive, whole-of-government strategy, with strong cross-agency collaboration, to advance U.S. biopharmaceutical competitiveness.[155]

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Beyond the Label: The Strategic Imperative of the Bioeconomy

Written Testimony Submitted to the

United States Senate Special Committee on Aging

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I. Introduction

The resilience of America's pharmaceutical supply chain has become an increasingly important policy issue as concerns have grown regarding foreign ownership, manufacturing concentration, and strategic dependencies within the healthcare sector. These issues warrant continued attention. However, they represent only one dimension of a broader transformation occurring across biotechnology and the global bioeconomy.

This testimony is informed by more than two decades of experience at the intersection of biotechnology, national security, counterintelligence, public health, and emerging technologies, including support for Operation Warp Speed and service advising the United States Government on emerging and disruptive technologies. The observations presented herein are intended to provide a broader strategic framework through which foreign ownership and control within America's pharmaceutical supply chain may be evaluated.

The central proposition of this testimony is straightforward:

America's pharmaceutical supply chain cannot be fully understood in isolation because it is embedded within a broader bioeconomy ecosystem that increasingly influences healthcare, agriculture, manufacturing, artificial intelligence, energy, economic competitiveness, and national security.

Accordingly, understanding what lies *behind* the pharmaceutical label first requires looking *beyond* the label itself.

The country listed on a pharmaceutical package identifies where a product was manufactured. It does not identify where scientific capability resides, where manufacturing expertise is accumulating, where clinical knowledge is generated, who establishes technical standards, where biological data are being transformed into strategic advantage, or where the next generation of biotechnology innovation will emerge. Increasingly, these less visible elements determine long-term national resilience.

The evidence presented throughout this testimony suggests that biotechnology has evolved beyond an individual economic sector to become enabling infrastructure supporting multiple sectors of critical national importance. Viewed through that broader lens, pharmaceutical resilience becomes inseparable from the Nation's capacity to sustain scientific leadership, advanced manufacturing, agricultural productivity, workforce development, and technological innovation throughout the biological century.

II. Beyond the Label

Traditional assessments of pharmaceutical resilience have appropriately focused on manufacturing location, active pharmaceutical ingredient production, foreign ownership, and geographic concentration within critical supply chains. These remain important considerations. Increasingly, however, they no longer capture the principal sources of long-term strategic advantage.

The pharmaceutical label identifies the physical origin of a product. It does not reveal where scientific knowledge is generated, where manufacturing capability is refined, where clinical experience accumulates, where regulatory expertise matures, or where future innovation ecosystems are being developed. Those capabilities increasingly determine which nations possess the capacity to continuously discover, manufacture, improve, and commercialize successive generations of biotechnology.

This distinction reflects an important evolution in strategic competition. Historically, biotechnology policy appropriately emphasized intellectual property protection and preventing unauthorized technology transfer. While those concerns remain valid, competition increasingly extends beyond acquiring today's technologies. Nations are now investing in the scientific, industrial, educational, regulatory, and manufacturing ecosystems capable of producing tomorrow's innovations on a sustained basis.

This broader perspective also changes how foreign ownership should be evaluated. Ownership of manufacturing facilities represents one component of a much larger system. Equally important are the movement of talent, the location of clinical development, the accumulation of manufacturing expertise, the governance of biological and clinical data, participation in standards development, and long-term investments in research, infrastructure, and workforce development. Viewed individually, these activities may appear unrelated. Viewed collectively, they determine where future biotechnology leadership will reside.

Accordingly, the strategic question extends beyond where medicines are manufactured today. It includes whether the United States will continue to possess the integrated scientific, manufacturing, regulatory, industrial, and educational ecosystem necessary to discover, develop, manufacture, and continuously improve the medicines upon which future generations will depend.

The ecosystem—not the label—is increasingly the strategic signal.

III. The Bioeconomy: From Economic Sector to Strategic Infrastructure

Understanding what lies beyond the pharmaceutical label requires recognizing a broader structural transformation occurring within biotechnology itself.

For much of the past half-century, biotechnology has appropriately been viewed as a distinct scientific discipline and an important sector of the economy. Public discussion has traditionally focused on pharmaceuticals, vaccines, medical research, agricultural biotechnology, and more recently synthetic biology. While these remain essential components of the biotechnology enterprise, they no longer fully describe biotechnology's strategic significance.

Biotechnology increasingly functions as an enabling capability supporting multiple sectors of critical national infrastructure simultaneously.

Healthcare, agriculture, advanced manufacturing, and artificial intelligence increasingly depend upon advances in biotechnology. Sectors once viewed largely independently are becoming interconnected through shared biological capabilities, data, manufacturing platforms, and innovation ecosystems.

This convergence fundamentally changes how biotechnology should be understood. Earlier generations witnessed similar transformations as electricity evolved from an emerging technology into essential infrastructure supporting virtually every sector of modern society. Likewise, the internet evolved from a communications network into foundational infrastructure enabling commerce, finance, education, healthcare, manufacturing, and government. The strategic importance of these technologies ultimately resided less in the products they created than in the systems they enabled.

Biotechnology is undergoing a comparable transition. Its strategic value no longer resides solely in what it produces, but increasingly in what it enables across multiple sectors of critical national infrastructure.

This distinction carries important implications for public policy. Decisions affecting healthcare increasingly influence agriculture. Agricultural policy increasingly influences manufacturing. Manufacturing increasingly depends upon artificial intelligence, biological data, workforce development, and resilient supply chains. Sectors that have historically been considered independently are becoming increasingly interconnected through the expanding capabilities of biotechnology.

The bioeconomy should therefore be viewed not simply as another sector of the economy, but as strategic infrastructure supporting national resilience, economic competitiveness, scientific leadership, and long-term prosperity.

Recognizing this transformation provides a more useful framework for understanding the increasingly global competition now taking shape around biotechnology.

IV. Global Biotech Competition: Building Innovation Ecosystems

Recognizing the bioeconomy as strategic infrastructure also changes how global competition should be understood.

For much of the twentieth century, technological competition was often measured by individual achievements. The Space Race, for example, was symbolized by satellite launches, lunar exploration, and advances in aerospace engineering. Those accomplishments were never solely about rockets. They reflected national investments in education, research institutions, manufacturing, engineering, supply chains, and scientific talent. The visible achievements were manifestations of a much broader innovation ecosystem.

Increasingly, nations are not competing simply to develop the next breakthrough therapy or medical device. They are competing to establish the scientific, industrial, manufacturing, regulatory, educational, and financial ecosystems capable of producing successive generations of innovation. Long-term competitiveness is becoming less dependent upon individual discoveries than upon the capacity to repeatedly generate, scale, and continuously improve biological technologies.

This broader perspective provides a more useful framework for understanding China's biotechnology strategy.

China's biotechnology initiatives are often discussed individually through programs such as **Healthy China 2030**[1], the **14th and emerging 15th Five-Year Plans**[2], **China Standards 2035**[3], precision agriculture, industrial biotechnology, artificial intelligence, and biomanufacturing. Viewed independently, these appear to represent separate policy initiatives. Viewed collectively, they reflect a coordinated effort to strengthen the enabling infrastructure supporting long-term biotechnology leadership.

Importantly, this observation should not be interpreted solely through the lens of geopolitical competition. China's biotechnology strategy reflects recognition of a series of real and interconnected national challenges, including an aging population, declining workforce demographics, rising healthcare demands, food security, environmental sustainability, and the need to sustain long-term economic growth. Biotechnology is increasingly viewed as an enabling capability capable of addressing these domestic challenges while simultaneously strengthening industrial capacity, technological leadership, and long-term national resilience.

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[1] *Healthy China 2030 Planning Outline, State Council of the People's Republic of China (2016).*
[2] *The Fourteenth Five-Year Plan for National Economic and Social Development of the People's Republic of China and the Outline of Vision 2035* (2021).
[3] *China Standards 2035 (战略性新兴产业标准化发展规划/ associated national standardization policy initiatives).*

At the same time, these investments extend well beyond domestic policy objectives. Leadership in biotechnology increasingly creates opportunities to shape international standards, expand manufacturing capacity, strengthen supply chain relationships, influence global markets, and deepen scientific and commercial partnerships. The same biotechnology ecosystem that supports domestic resilience also strengthens a nation's ability to expand economic influence and exercise long-term strategic leadership within the global bioeconomy.

Viewed collectively, China's biotechnology initiatives should therefore be understood not as isolated sector-specific programs, but as mutually reinforcing investments in an integrated national strategy. The principal lesson for the United States is not that China has adopted this approach. It is that biotechnology has evolved into a strategic capability capable of simultaneously advancing healthcare, agriculture, manufacturing, economic prosperity, and international influence.

The strategic implication extends beyond any single country. As biotechnology assumes greater importance across healthcare, agriculture, manufacturing, and national security, more nations are likely to pursue similar ecosystem-based strategies. The principal question for the United States is therefore not whether others will invest in biotechnology. It is whether America will continue strengthening the innovation ecosystem that has historically made it the global leader in scientific discovery, entrepreneurship, and technological advancement.

Strategic competition within the biological century will increasingly be measured not by isolated breakthroughs, but by the resilience, adaptability, and productivity of the ecosystems that produce them.

V. Advanced Therapeutics: Learning as a Strategic Asset

Advanced therapeutics provide a useful illustration of how strategic competition within the bioeconomy is evolving.

Historically, competitive advantage was often evaluated by where a therapy was discovered or manufactured. Increasingly, however, the strategic value of advanced therapeutics extends well beyond the physical product itself. Every stage of research, clinical development, manufacturing, regulatory review, and patient care generates new information that contributes to future innovation.

Clinical trials generate evidence regarding safety, efficacy, patient selection, treatment response, and long-term outcomes. Manufacturing operations generate process knowledge, quality improvements, operational efficiencies, and production experience. Regulatory interactions refine scientific understanding while improving future product development. Collectively, these activities produce continuous learning that extends well beyond any single therapeutic product. Unlike traditional manufacturing, advanced therapeutics become more valuable over time

because every patient, every manufacturing campaign, and every regulatory interaction contributes to a continuously expanding body of knowledge that improves future therapies.

Figure 1 illustrates the increasingly global distribution of innovative drug development. While the United States remains the world's leading biotechnology innovator, scientific capability, clinical development, and manufacturing capacity are expanding internationally. This evolution reflects the emergence of a more globally distributed biotechnology ecosystem rather than a single geographic center of innovation.

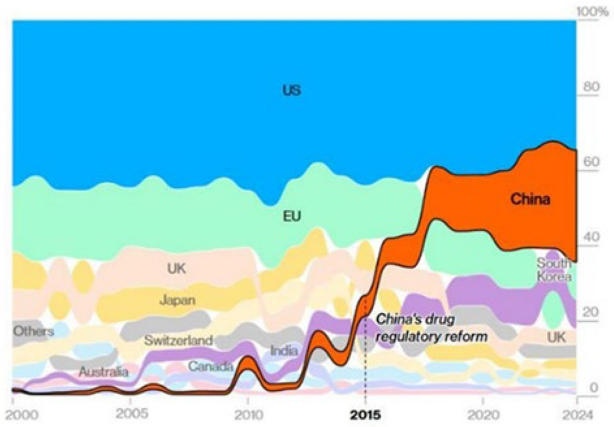


Figure 1. Share of innovative drugs entering development by country over time.

Source: Adapted from publicly available industry analyses (e.g., IQVIA Institute for Human Data Science).

The implications become even more apparent when examining advanced cell therapies. Figure 2 illustrates the development pathway for allogeneic CAR-T cell therapies. Although attention often focuses on where therapies are manufactured or where clinical trials occur, the more consequential observation concerns the movement of knowledge throughout the development process. Clinical data, manufacturing experience, process optimization, regulatory interactions, and operational expertise continuously accumulate as therapies progress from laboratory research through commercial development.



Figure 2. Illustrative Movement of Clinical Development, Manufacturing Experience, and Learning within Global Allogeneic CAR-T Development

Source: Author's illustration based on publicly available clinical trial data and industry analyses.

The directional flow illustrated in Figure 2 represents more than the movement of a therapeutic product. It also reflects the movement of scientific understanding, manufacturing capability, clinical experience, and operational learning. These intangible assets increasingly determine future innovation capacity.

This broader perspective suggests that clinical data should not be viewed solely as evidence supporting regulatory approval. Clinical, manufacturing, and operational data increasingly represent strategic national assets that contribute to future scientific discovery, improved manufacturing processes, artificial intelligence applications, and the development of subsequent generations of biotechnology.

The strategic question is therefore evolving. It is no longer limited to where a therapy was invented or manufactured. It increasingly encompasses where the learning generated by that therapy ultimately resides.

VI. Farm to Pharma: Agriculture, Biomanufacturing, and National Resilience

The evolution of biotechnology extends well beyond healthcare.

Many of these agricultural systems are sustained by family farms operated by older Americans whose stewardship of the land continues to underpin the Nation's food security, renewable feedstocks, and growing bioeconomy.

Agriculture has historically been viewed primarily through the lens of food production. Increasingly, however, agricultural systems support a far broader range of strategic objectives. Biological feedstocks now contribute to food, renewable fuels, industrial materials, specialty chemicals, biomaterials, precision fermentation, and biopharmaceutical manufacturing. The traditional concept of "Farm to Fork" is expanding to include **Farm to Fiber, Farm to Fuel, and Farm to Pharma.**

This broader perspective illustrates the interconnected nature of the bioeconomy. Agricultural production provides the biological feedstocks supporting industrial fermentation and advanced biomanufacturing. Those manufacturing capabilities produce pharmaceuticals, biologics, renewable products, industrial enzymes, advanced therapeutics, and numerous other products supporting healthcare, manufacturing, and economic resilience. Investments in agricultural productivity therefore reinforce manufacturing capacity, which in turn strengthens healthcare resilience and national competitiveness.

The COVID-19 pandemic demonstrated that scientific discovery alone is insufficient to ensure national resilience. Operation Warp Speed successfully accelerated vaccine development while simultaneously revealing the importance of flexible domestic manufacturing capacity capable of translating scientific breakthroughs into scalable production. Discovery and manufacturing are complementary components of the same innovation ecosystem.

Biofoundries represent an increasingly important element of that ecosystem. Rather than functioning solely as research laboratories or emergency production facilities, biofoundries integrate automation, synthetic biology, engineering, advanced analytics, and biomanufacturing into flexible platforms capable of supporting continuous innovation. Their strategic value extends beyond the products they manufacture. They cultivate workforce expertise, process optimization, technology maturation, and operational experience while remaining available to support national priorities during future emergencies.

This capability should be viewed as living infrastructure rather than contingency infrastructure. Biological manufacturing capacity cannot simply be activated during periods of crisis. Skilled personnel, validated manufacturing processes, quality systems, regulatory expertise, and operational knowledge require continuous development. Sustained investment in distributed biomanufacturing therefore strengthens both routine innovation and emergency preparedness.

Viewed through the broader framework of the bioeconomy, agriculture, manufacturing, healthcare, and national resilience no longer represent separate policy domains. They constitute interconnected components of a single strategic ecosystem whose collective performance increasingly influences America's long-term competitiveness.

VII. Governance, Licensing, and Strategic Influence

As biotechnology increasingly functions as strategic infrastructure, competition extends beyond scientific discovery and manufacturing. It also encompasses the governance frameworks, licensing practices, and technical standards that influence how innovation is developed, validated, commercialized, and ultimately adopted throughout the global economy. As biological innovation becomes increasingly global, governance becomes as important as technology itself. Scientific breakthroughs create new possibilities, but governance frameworks determine how those breakthroughs are trusted, adopted, integrated into society, and translated into long-term strategic advantage.

Licensing has traditionally been viewed as a commercial mechanism for transferring intellectual property. Increasingly, however, licensing transfers far more than legal rights. It often transfers manufacturing expertise, process optimization, regulatory experience, workforce development, and opportunities for continued scientific collaboration. As a result, licensing increasingly influences where scientific capability matures and where innovation ecosystems develop over time.

Technical standards perform an equally important strategic function. Standards are frequently viewed as technical specifications governing interoperability, manufacturing processes, quality systems, or regulatory expectations. In practice, they shape much more than technical performance. Standards influence product design, data exchange, manufacturing systems, regulatory pathways, supply chain interoperability, and ultimately market access. They establish the common framework through which industries operate and technologies are adopted.

If manufacturing determines where products are made, standards increasingly determine where industries grow.

This strategic reality is reflected in China's **China Standards 2035** initiative. Rather than focusing solely on traditional manufacturing sectors, the initiative prioritizes emerging technologies expected to shape future economic competitiveness, including artificial intelligence, quantum technologies, and biotechnology. These technologies were not selected independently. Together, they represent converging capabilities expected to influence future industries, global supply chains, and technological leadership.

The strategic significance extends well beyond technical specifications. Standards influence investment decisions, product design, regulatory acceptance, workforce training, software development, procurement requirements, and international market access. In many respects, standards become the operating architecture upon which future industries are built. Nations and organizations that help establish widely adopted standards are often positioned to influence the direction of research, manufacturing, and global markets long after individual technologies have evolved.

This principle extends across the broader bioeconomy. As biotechnology converges with artificial intelligence, advanced manufacturing, precision agriculture, and digital infrastructure, leadership in standards development will increasingly influence how biological data are governed, how manufacturing systems communicate, how artificial intelligence models are

validated, and how future biotechnology products gain acceptance in domestic and international markets.

For the United States, continued leadership will depend not only upon scientific excellence, but also upon sustained participation in the international institutions that shape governance, standards development, and trusted scientific collaboration. Leadership in the biological century will increasingly be measured not only by who develops the next breakthrough, but also by who helps establish the frameworks through which future breakthroughs are evaluated, manufactured, trusted, and adopted throughout the world.

The strategic challenge confronting the United States is therefore larger than strengthening an individual supply chain or protecting a single technology. It is whether America will continue to cultivate the scientific institutions, manufacturing capacity, agricultural productivity, workforce, governance, and innovation ecosystem necessary to lead the biological century. Success will increasingly depend not upon optimizing individual components, but upon strengthening the resilience and competitiveness of the bioeconomy as an integrated national capability.

VIII. Recommendations

The observations presented throughout this testimony suggest that strengthening America's pharmaceutical resilience requires a broader strategic approach than securing individual supply chains alone. The following recommendations are offered as strategic considerations for Congress.

Recognize the Bioeconomy as Strategic Infrastructure. Biotechnology should increasingly be evaluated as enabling infrastructure supporting healthcare, agriculture, manufacturing, artificial intelligence, energy, and national competitiveness. This broader perspective provides a more effective framework for evaluating long-term resilience than examining individual sectors independently.

Continue Advancing the National Security Commission on Emerging Biotechnology's Vision[4]. The National Security Commission on Emerging Biotechnology has provided Congress with one of the most comprehensive roadmaps for strengthening America's biotechnology enterprise. Its work successfully translated highly technical scientific developments into practical policy considerations spanning research, workforce development, manufacturing, infrastructure, standards, investment, and national security. As the Commission concludes its statutory mission, its contributions warrant continued implementation. Equally important, Congress should ensure that future mechanisms exist to provide similarly independent, multidisciplinary technical

[4] National Security Commission on Emerging Biotechnology, Charting the Future of Biotechnology (Final Report, 2025).

assessments as biotechnology continues to evolve. The need for trusted scientific and strategic translation will only increase in the years ahead.

Strengthen the Nation's Ability to Assess the Global Bioeconomy. Effective policy depends upon effective situational awareness. Biotechnology should increasingly be assessed not solely as a biosecurity issue, but as a driver of strategic competition, industrial capability, economic competitiveness, healthcare innovation, agricultural resilience, and geopolitical influence. The Intelligence Community should continue strengthening its capacity to assess these developments while expanding support to departments and agencies responsible for implementing national bioeconomy policy, including the Departments of Health and Human Services, Agriculture, Commerce, and Energy. The ability to continuously understand developments across the global bioeconomy should itself be viewed as a strategic national capability. Assessments of the bioeconomy should routinely integrate expertise from the life sciences, engineering, agriculture, manufacturing, artificial intelligence, economics, and national security to better identify emerging opportunities, strategic dependencies, and risks before they become national vulnerabilities.

Protect America's Learning Ecosystems. Clinical data, manufacturing expertise, regulatory science, operational knowledge, and workforce experience increasingly represent strategic national assets. Policies that responsibly steward these learning ecosystems while preserving scientific collaboration will strengthen America's long-term biotechnology leadership.

Invest in Resilient Biomanufacturing Capacity. Distributed biomanufacturing, biofoundries, workforce development, and resilient agricultural feedstock supply chains should be viewed as long-term investments in national capability. These assets strengthen innovation during normal operations while enhancing national resilience during future emergencies.

IX. Conclusion

The issues examined throughout this testimony extend well beyond foreign ownership of America's pharmaceutical supply chain. They encompass healthcare, agriculture, manufacturing, artificial intelligence, energy, scientific research, workforce development, economic competitiveness, and national security. The strategic implications therefore extend well beyond the jurisdiction of any single committee or department.

That broader perspective is particularly appropriate for the Senate Special Committee on Aging. The generations represented by this Committee made extraordinary sacrifices to build the Nation we have inherited. They cultivated America's farms, strengthened its industries, built its universities, advanced its scientific enterprise, expanded its healthcare system, and created opportunities that many of us have been privileged to enjoy. The biotechnology innovations discussed throughout this testimony rest upon foundations that they helped build over decades of hard work, service, perseverance, and sacrifice.

The most meaningful way we can honor those contributions is not simply by expressing our gratitude, but through responsible stewardship.

Stewardship means preserving what they built, strengthening it where necessary, and preparing it for challenges they could not have anticipated. It means recognizing that the bioeconomy is not simply another sector of the economy, but a strategic foundation upon which the health, resilience, prosperity, and security of future generations will increasingly depend.

Ultimately, looking beyond the pharmaceutical label reveals a much larger national responsibility. The question before Congress is not simply how to secure today's medicines. It is how to ensure that America continues to lead in scientific discovery, agricultural innovation, advanced manufacturing, and biotechnology so that future generations inherit a Nation that is healthier, stronger, and more resilient than the one entrusted to us.

Every parent makes an unspoken promise to the next generation: not simply to leave behind a better world, but to create opportunities for their children to achieve even more than they themselves were able to achieve.

As a Nation, we inherit that same responsibility.

The strategic imperative of the bioeconomy is ultimately not about biology. It is about fulfilling that enduring promise by honoring the sacrifices of those who came before us and ensuring that the generations who follow inherit an America whose greatest achievements still lie ahead.

If looking behind the label helps secure today's medicines, then looking beyond the label will help ensure that future generations inherit a Nation capable of discovering, producing, and continuously advancing the innovations upon which their health, prosperity, and security will depend.

That is the enduring responsibility before us.

COUNCIL on FOREIGN RELATIONS

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SFS | GEORGETOWN UNIVERSITY Walsh School of Foreign Service

Prepared Statement: For the Hearing "Behind the Label: Foreign Ownership and Control in America's Drug Supply Chain"

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Chairman Scott, Ranking Member Gillibrand, distinguished members of the Committee, thank you very much for the opportunity to testify at today's hearing.

The United States must confront two hard truths. The first is that the United States has a "rare earths" problem in medicine, and that it is partly self-inflicted. We allowed our pharmaceutical supply chain to migrate offshore. We became dependent on China for our essential medicines. And we are now repeating that error in biotechnology — an industry that supports millions of American jobs and trillions of dollars in economic activity, and one that might disappear if we do not act.[1]

The second is that China has become genuinely innovative in this sector, and that the United States cannot simply wall itself off from that dynamism. China is now the second-largest developer of new therapeutics in the world, and some of the medicines emerging from its system will have significant positive impact.

The task before us is to find a path between these two realities — one that preserves American patients' access to genuine innovation while avoiding dependency on a strategic competitor and retaining the industry that has long been among our greatest sources of innovation, employment, and economic activity. A policy that ignores the first truth invites coercion. A policy that ignores the second makes medicine scarcer, costlier, and slower for Americans.

To that end, my testimony today draws in part from a report we published last month at the Council on Foreign Relations with my co-authors Tom Bollyky, Prashant Yadav, Olivia Kosloff, and Elena Every after a year-long, twenty-person study.[2]

The Council on Foreign Relations takes no institutional positions on policy issues and has no affiliation with the U.S. government. All statements of fact and expressions of opinion contained herein are the sole responsibility of the author.

I will structure it around two broad questions: First, how dependent is the United States on China for small-molecule drugs and what can we do about it? Second, why are we at risk of losing our biotechnology industry to China, and how can we turn the situation around?

I. Dependency on China for Small-Molecule Drugs

Most pharmaceuticals are built in stages. A key starting material (KSM) — the basic chemical building block — is converted into an active pharmaceutical ingredient (API), the compound that produces the therapeutic effect. Only then is it made into a finished dosage form (FDF), such as a pill or a vial, and labeled. The label often reflects that last stage alone. It discloses nothing about the first two, and it is in the first two that our dependence on China is concentrated.

Our team analyzed U.S. trade and ingredient-sourcing data to map this chain tier by tier. We did so because conventional estimates rely on the location of the label holder, which is precisely what obscures the risk. What we found is a consistent pattern: the finished dose appears diversified, and one step upstream the diversification disappears.[3]

Amoxicillin is illustrative. American physicians write approximately sixty million prescriptions for it each year, and at first glance its supply looks well distributed — active ingredients are manufactured in Austria, China, and India; finished doses produced in India, the European Union, and occasionally the United States. But its synthesis depends on materials produced almost entirely in China. China controls roughly 94 percent of global supply of the most critical of them, 6-aminopenicillanic acid, and five Chinese firms control more than four-fifths of world production. India, which manufactures the majority of the world's finished amoxicillin, buys its intermediates from China as well.[4]

Heparin follows the same pattern. More than twelve million hospitalized Americans receive it each year, and roughly 80 percent of the world's crude supply originates in China. The consequences of that concentration are not hypothetical: contaminated Chinese heparin killed eighty-one Americans in 2007 and 2008.[5]

These are not isolated cases. China is the sole source of at least one key starting material for nearly seven hundred active ingredients approved for use in the United States. Forty-one percent of the KSM found U.S. API are produced only in China, more than twice the share of the next-largest sole supplier.[6]

And a growing number of finished medicines are imported directly from China with no ready substitute, including the immunosuppressants that prevent rejection of a transplanted organ, a frontline hospital antibiotic, and a drug used in the treatment of heart failure, among others.[7]

How did this happen? We built a procurement system in which the U.S. government, wholesalers, distributors, and supply chain intermediaries purchased their volumes from the lowest-cost manufacturer, sometimes at the expense of quality and resilience. That was a structure that inadvertently benefited China. We made domestic manufacturing more difficult and more expensive, while permitting Chinese producers to export into our market tariff-free and permitting drug finishers and API makers to avoid disclosing their upstream China dependency. Beijing, for its part, ran the same play it ran in rare earths: it subsidized capacity, discounted energy and inputs, tolerated pollution that Western regulators would not accept, and priced below cost to deter entry — thereby locking in a durable monopoly position. As in rare earths, it is now working to defend that position, flooding markets with below-cost exports in order to harm alternative suppliers in India and elsewhere.[8]

The transition was rapid. American amoxicillin production fell from one hundred percent of the domestic market to zero in twelve years.[9]

We were also slow to see it coming, because the supply chain is not transparent. A drug's label may indicate where the product was finished, but it says nothing about a dependency two tiers upstream. Transshipment and repackaging compound the problem: a 2023 Department of Defense review found that fifty-four percent of the medicines it purchased under domestic-sourcing rules in fact originated in China, India, or sources unknown.[10]

What, then, should the United States do to reduce these dependencies? I would offer five recommendations.

First, we need transparency. Congress should mandate country-of-origin disclosure at the finished dose, active ingredient, and key starting material levels, through legislation such as the CLEAR LABELS Act. Without visibility into the upstream tiers, transshipment and repackaging make it difficult to avoid dependency.[11]

Second, we need to realign trade incentives. Tariffs should be tied to upstream inputs rather than to the finished drug alone. That may mean raising them, gradually over time to avoid supply shocks, on finished medicines that depend on Chinese starting materials, and reducing them on goods with inputs from trusted allied suppliers. We cannot return all key starting material and active ingredient production to the United States, nor should we attempt to. We should instead divide these chokepoints among allies rather than go it alone — which will require shared inventories, mutual recognition of inspections, and binding purchase commitments, not another consultative forum.[12]

Third, we need to realign procurement incentives. Federal purchasers — Medicare, the Department of Veterans Affairs, and the Department of Defense — should reward supply reliability rather than price alone, and should favor non-Chinese sources of supply.

Fourth, we should stockpile. Congress should fund reserves of finished doses, active ingredients, and key starting materials, and should pair those reserves with the fill-and-finish capacity required to convert stockpiled ingredients into administrable medicine. That means filling the new Strategic API Reserve (SAPIR).[13]

Fifth, we should build capacity. That means funding leapfrog innovation — continuous manufacturing, enzymatic and cell-free synthesis, green chemistry — that breaks our reliance on cheap and polluting overseas chemistry altogether. And it means extending low-cost capital to manufacturers here and among our allies. A single fifty-million-euro grant made an Austrian plant cost-competitive with Chinese penicillin chemistry.[14]

II. Displacement of the U.S. Biotechnology Industry

In biotechnology, the challenge is different. The risk is not a single upstream chokepoint but competitive displacement across the entire value chain — discovery, clinical development, and manufacturing. And in significant measure, the United States is financing that displacement itself.

Consider first what is happening in drug discovery. American pharmaceutical companies confront the expiration of patents on products generating as much as two hundred billion dollars in annual revenue by 2030. They need new assets, and increasingly they are licensing them from China rather than acquiring them from American startups.[15]

Chinese firms completed 186 cross-border out-licensing transactions in 2025, with a total potential value of $137.7 billion — nearly a tenfold increase over 2021, when the comparable figure was $13.9 billion across sixty-five deals.[16] By one estimate, roughly one-third of the pharmaceutical industry's global licensing spending in 2025 involved assets originating in China.[17] This is effectively a reallocation of the early-stage pipeline away from U.S. startups that risks hollowing out the American innovation ecosystem.

Part of the explanation is regulatory. Alongside its reformed drug approval track, China permits a faster and considerably more permissive pathway: investigator-initiated trials (now also called industry-initiated trials after China's recent reforms) conducted at hospitals can occur without approval from the central regulator or an IND.

These require only local ethics-board approval, and under State Council Order 818, a qualifying hospital may even charge patients for an unapproved therapy while the trial proceeds.[18] Data generated this way will not, standing alone, satisfy the FDA. But it establishes human proof of concept quickly and cheaply — and that is precisely what attracts a licensing deal.

Even within the formal regulatory track, China is faster and cheaper. Its regulator clears a clinical trial application in a fraction of the time while the American investigational new drug process takes twenty-four to thirty-six months. Trials in China have been estimated to cost fifty to sixty percent less than in the United States, with early-phase studies running substantially faster.[19] And because China joined the International Council for Harmonisation (ICH) in 2017, data from that formal track can support filings with the FDA, though it is not enough on its own. Accordingly, China's share of global clinical trial starts rose from one percent in 2009 to roughly thirty percent in 2024.[20]

China's system is more flexible than Western systems. Some of its speed advantage is purchased through weaker protections for patients rather than through better process. When American firms license assets de-risked in that system, there is at times an element of arbitrage, especially for biologics that are fast-following U.S. approaches and competing largely on the ability to achieve faster pre-IND human proof-of-concept or to demonstrate results on Phase 1 and Phase 2 clinical trials. Australia offers the instructive contrast. Australia is also fast and even decentralized, but it achieved its speed by removing administrative delay while adhering fully to international standards, and its investigator-initiated studies remain strictly non-commercial. That is why the FDA accepts Australian data as a matter of course.[21]

At the same time, the United States has acquired a new dependence in biomanufacturing. The BIOSECURE Act was intended to address this problem, but it was significantly narrowed before enactment. Roughly eighty percent of American biopharmaceutical companies now have a product or a contract with a Chinese contract manufacturer, with dependence growing.[22] This integrated contract-manufacturing model captures a molecule at the discovery stage and carries it through commercial production, so that switching costs are high. Departing requires revalidating a manufacturing process at a new site, which can take years, creating lock-in. As U.S. dependence grows, China is reducing its own exposure, developing domestic substitutes for the bioreactor bags, filters, and cell culture media it once purchased from us.[23]

How did China gain significant advantages in discovery, clinical development, and biomanufacturing relative to the United States? In part, this occurred because the United States grew complacent. In striving for the very highest standards on safety and efficacy, we ended up making our clinical trials slower and more costly, made licensing foreign assets comparatively easy, and drastically cut federal support for the basic research on which everything downstream depends. China, meanwhile, ran faster. After a 2015 audit found that roughly eighty percent of its pending clinical trial data was unreliable, Beijing criminalized data fraud, required verification against original patient records, funded its reviewers, adopted a sixty-day implicit approval standard, and joined the International Council for Harmonisation. China made biotechnology a Made in China 2025 priority and heavily subsidized research and biomanufacturing.[24] There are questions about patient protection in its system, but there is no doubt that over the last ten years they have sprinted to build a system that will benefit their biotechnology industry. Today, China does innovate first-in-class therapeutics, but many of the major licensing deals we have seen involve a focus on targets long identified by Western biopharmaceutical companies, and are, in this sense, a kind of fast-follow approach based on already validated science.

What, then, should we do?

First, we need to make our own system better. That means clinical trial reform that allows American researchers to move faster, including a new pathway for first-in-human trials, modeled on Australia's, that is fast, fully compliant

with international standards, and that ensures the FDA retains full authority to intervene.[25] It means restoring federal funding for basic research and reversing cuts under the Trump administration. It means industrial policy support for biomanufacturing, including low-cost capital. And it means investing in the automation and artificial intelligence that would allow American scientists to compete against cheaper scientific labor abroad, including using procurement to incentivize adoption of advanced biologics manufacturing technologies.

Second, we need a middle course on the licensing of Chinese biotechnology assets that sits between an outright prohibition, which would deny American patients access to genuinely novel therapies, and the current absence of scrutiny, which hollows out our own sector and sometimes rewards arbitrage rather than innovation. Adding biotechnology as a covered sector for outbound investment screening is a sensible first step, as is treating licensing transactions as covered.[26] But the substance will lie in the regulations, which must balance patient access against the health of our innovation ecosystem. The FDA should decline clinical data — wherever generated — that cannot meet our standards for informed consent, adequate control arms, and source verification. And we should repair a patent system that permits fast-followers to design around American breakthroughs, outpace them in China's clinical trial system, and then sign large licensing deals with U.S. pharmaceutical companies.

Third, we need to reduce reliance on Chinese contract biomanufacturers without forcing a rupture that would strand patients mid-trial. The BIOSECURE Act is an important defensive step. But in addition, federal funders — the National Institutes of Health, BARDA, and the Department of Defense — should require China-risk plans as a condition of support. That might mean specifying a qualified alternate manufacturer in the United States or an allied country before a program reaches a defined milestone, with technology-transfer rights and portable process data. And firms need somewhere else to go other than China's contract manufacturers, which means financing trusted contract manufacturers in allied countries. Building a national center for advanced biologics manufacturing could be a useful next step.[27]

Finally, we should attend to the inputs and the data. On the input side, we should require trial sponsors and manufacturers of biologic assets to disclose critical supplier risk beyond the first tier of supply chains, including cell banks, single-use bags and tubing, and other key inputs. Synthetic DNA and genomic information are the raw materials of this industry, and we should ensure that the sequences we order and the biological data we generate are not routed through, or harvested by, entities answerable to a foreign intelligence service.[28]

American purchasers — and above all American taxpayers — account for roughly seventy percent of global pharmaceutical profits. We are the market that makes pharmaceutical innovation commercially viable worldwide. That spending should be used to finance supply chain security, a healthy innovation ecosystem, and domestic manufacturing capability that delivers for patients.

Thank you for your time, and I look forward to your questions.

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The Pharma Choke Point

How to Reduce U.S. Dependence on Chinese Pharmaceutical and Biotechnology Supply Chains

By Thomas J. Bollyky, Rush Doshi, Olivia Kosloff, Prashant Yadav, and Elena Every

June 2026

The mission of the Council on Foreign Relations is to inform U.S. engagement with the world. Founded in 1921, CFR is a nonpartisan, independent national membership organization, think tank, educator, and publisher, including of *Foreign Affairs*. It generates policy-relevant ideas and analysis, convenes experts and policymakers, and promotes informed public discussion—all to have impact on the most consequential issues facing the United States and the world.

This report represents the efforts of a year-long study group convened by CFR's Global Health Program and the China Strategy Initiative's China Policy Accelerator. The Council on Foreign Relations takes no institutional positions on policy issues and has no affiliation with the U.S. government. All views expressed in its publications and on its website are the sole responsibility of the author or authors.

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EXECUTIVE SUMMARY

U.S. dependence on China for essential medicines is structural—deeper, broader, and more consequential than conventional market analyses suggest. That dependence began with generic medicines and their ingredients but is now growing in biologics manufacturing, first-in-human trials, and synthetic DNA. That dependence is not simply the result of market conditions but rather decades of Chinese state investment.

The United States (and just about every other nation) faces a growing risk that China will deliberately withhold essential pharmaceutical inputs as a tool of economic or political coercion outside of a military conflict, public health emergency, or natural disaster, as China has done with rare-earth critical minerals. Those risks are greatest for the subset of essential medicines and inputs that China exports directly, which include medications to prevent organ transplant rejections, broad-spectrum hospital antibiotics, and a powerful blood thinner. China also dominates upstream inputs for many other critical medicines, such as the antibiotic amoxicillin and the circulatory stimulant norepinephrine, but those inputs are not exported directly to the United States. China would need to restrict supplies or their use in a third country—typically India—to prevent those inputs from being made into active pharmaceutical ingredients (APIs, the chemical compounds in a drug responsible for its effect) or finished dosage forms (FDFs, the final, consumer-ready version of the drug) and exported to the United States. But it has the means, clandestinely if desired, to do so. And if Chinese authorities choose to act, the adverse consequences of cutting off the supply of key starting materials (KSMs), the building blocks that typically feed multiple API and FDF manufacturers, would reverberate throughout multiple pharmaceutical supply chains.

This analysis aims to provide a replicable framework—an archetype model—for policymakers and researchers they can apply to other products that share the same root causes of dependence on China. We identify three archetypes of pharmaceutical supply chain dependence:

Archetype One: Reliance on China for Raw Materials and Upstream Supplies for Generic Drugs

For many essential small-molecule generic medicines—chemically manufactured drugs, simple in structure, easy to replicate, and primarily taken as a pill—the defining vulnerability is a choke point at the raw material or key starting materials stage that makes downstream diversification illusory. China controls the raw or key starting materials for 94 percent of amoxicillin, 74 percent of heparin, and 70 percent of acetaminophen, ensuring that diversification at a later stage provides no meaningful protection. Transshipment and repackaging of APIs and KSMs thwart federal "Buy America" initiatives.

Ensuring access to products in this category requires multiple steps. The United States needs to create a strategic reserve of critical medicines and build allied partnerships to manage near-term acute risks. It also needs to undertake a mix of longer-term supply and demand interventions to make domestic or allied production of KSMs, APIs, and other upstream inputs economically viable.

Archetype Two: Erosion of U.S. Biopharmaceutical Manufacturing and Clinical Trial Capacity to China

For innovative biologics—medicines made from living cells—such as monoclonal antibodies, the risk is not a single upstream choke point but competitive displacement across every stage of the value chain: discovery, clinical development, contract manufacturing, and market access. Chinese firms now hold approximately thirty-two of fifty-five late-stage monoclonal antibody programs globally. The Chinese firm WuXi Biologics is engaged in nearly half of U.S. clients' drug development programs. China biotech licensing reached $137.7 billion in 2025, a tenfold increase from 2021.

Reducing dependence in this archetype requires taking a number of steps: accelerating first-in-human clinical trials in the United States, funding and incentivizing the adoption of advanced biologics manufacturing technologies, building contract research alternatives in allied countries, bolstering the U.S. biomanufacturing workforce, and creating a system to secure artificial intelligence (AI)–ready biodata and digital chemistry, manufacturing, and controls.

Archetype Three: Dependence on China for the R&D Infrastructure for Sensitive Biotechnology

For DNA synthesis—the process for producing DNA from individual nucleotides in the laboratory—the vulnerability is not disruption in the supply of an existing product, but Chinese control over the research-and-development (R&D) infrastructure underlying future pharmaceutical innovation. One of the three firms accounting for 86 percent of the supply of global synthetic DNA is Chinese, and the other two have a significant presence in China. As AI accelerates the design of novel therapeutics, control over synthetic DNA inputs becomes inseparable from control over the trajectory of U.S. biotechnology broadly. As it stands, the offshoring dynamic that hollowed out small-molecule API manufacturing is set to repeat itself in synthetic biology.

Solutions include improving DNA supply chain security, enhancing transparency and disclosing provenance, increasing federal investment in next-generation DNA synthesis technologies, and bolstering allied cooperation on standard-setting and procurement to encourage the adoption of these technologies.

Common Challenges

Cross-cutting themes apply across the three archetypes. Continuity in federal oversight, funding, and dedicated White House–level coordination is essential to overcoming two decades of government inertia. U.S. pharmaceutical supply chain vulnerabilities were visible in trade and regulatory data for years before reaching crisis levels. Monitoring upstream inputs in critical supply chains can help identify and raise the alarm on an imminent shortage before it happens.[1] Allied partnerships, such as the Biopharmaceutical Alliance and European Union Critical Medicines Act, are powerful on paper, but without shared inventories, inspection recognition, and purchase commitments, they serve merely as consultative forums, not meaningful guarantees of critical supplies.

A core challenge is incentivizing the commercial adoption of advanced manufacturing technologies. Every industrial policy tool carries risks of unintended consequences—higher costs, reciprocal retaliation, lock-in of obsolete capacity, or accelerated Chinese substitution. These risks need to be anticipated and mitigated.

China has both the tools and demonstrated willingness to weaponize U.S. pharmaceutical dependence: the structural conditions enabling it run through nearly every tier of the pharmaceutical supply. The question is not whether to act, but if the United States will manage to do so before a crisis makes the cost of decades of inaction unavoidable.

INTRODUCTION

For decades the United States has allowed its pharmaceutical supply chain to migrate offshore in pursuit of lower business costs, a process accelerated by regulatory inertia and inadequate public investment. The People's Republic of China (PRC) and India have been the primary beneficiaries. Today, Chinese manufacturers supply most of the world's key starting materials (KSMs) and active pharmaceutical ingredients (APIs) for critical medicines Americans depend upon. These range from common antibiotics to blood thinners to emergency room drugs such as heparin.

Over the last decade, China has also surged up the innovation ladder to become a major force in the biotechnology sector, displacing the United States as the go-to setting for critical first-in-human (FIH) drug trials and rivaling the United States in developing and producing innovative and promising new medicines. China has pursued a deliberate industrial strategy to achieve this status: it has subsidized manufacturing capacity, undercut competitors on price, and gradually made itself indispensable to the global pharmaceutical system. The result is a structural dependence that now runs through nearly every part of the U.S. medicine supply chain.

This dependence leaves the United States at risk of calibrated coercion by China. Beijing has already demonstrated across rare-earth elements (REEs), critical minerals, and agricultural products that it will weaponize its control of critical supply chain components in response to diplomatic disputes, trade disputes, and geopolitical pressure. The U.S. pharmaceutical supply chain faces a similar risk. "China is the world's largest exporter of vitamins and antibiotic raw materials," the Chinese economist Li Daokui stated in a March 2019 general meeting of the Chinese People's Political Consultative Conference, a top PRC political advisory group. "Once the export is reduced, the medical systems of some developed countries will not work."[2]

Beijing does not need to cut off medicine exports entirely to cause serious harm; it can simply restrict licensing, allow quality to erode, and slow shipments through regulatory friction. All those levers are available today, and none requires a formal declaration or a military provocation to deploy.

At times, shortages of the antibiotic amoxicillin, the anti-coagulant heparin, and the circulatory stimulant norepinephrine have already forced American hospitals to ration care, delay surgeries, and substitute less effective treatments. Such examples highlight the vulnerabilities in the supply chain. Few people understand just how this critical vulnerability came to be, how it could be weaponized by China, and what it would take to reverse it.

Scope and Methodology

The U.S. pharmaceutical supply chain faces a threat equal to the "rare-earths" challenge already posed by China's exploitation of its dominance of those critical minerals. This is due to the structural dependence on China that exists across the entire production of the critical medicines on which Americans rely and the ways in which China could feasibly weaponize that dependence to create economic, strategic, and political leverage. In this report, we

- assess where the dependence on China currently exists or is likely to emerge in the next five to ten years;
- identify the pathways by which China could exploit that dependence and carry out a weaponization program against the United States;
- outline the strategic, public health, and geopolitical risks of dependence; and
- develop a menu of targeted industrial policy options for mitigating and reducing U.S. dependencies in this sector.

In accomplishing these tasks, this report breaks new ground in several ways.

First, this report focuses on **"peacetime weaponization"**: the deliberate withholding of pharmaceutical inputs as a tool of economic or political coercion outside of a military conflict, a public health emergency, or other kinetic events. Previous analyses have concentrated on how China might weaponize its dominant market share in aspects of the U.S. pharmaceutical supply chain during a pandemic or a military attack.[3] China's coercive episodes, however, have followed a different pattern: they are triggered by political grievances amid ongoing global strategic competition, target civilian industries with no direct involvement in the dispute, are implemented through informal means to maintain deniability, and escalate over time.[4] This report focuses on the risks of this type of weaponization, which may harm access to different critical medicines and require different policy solutions than those available in a military or public health crisis.

Second, this report's findings, wherever possible, are grounded in **original data analysis**. To assess the scope of dependence on China for critical medicines, we examined U.S. import trade data by looking at harmonized tariff schedule codes and United States Pharmacopeia (USP) ingredient sourcing records, and mapped the supply chain tier by tier, from raw feedstocks and KSMs through APIs to finished dosage form (FDF) pharmaceutical products. Where transshipment has obscured the true origin of inputs, bilateral trade comparisons have been used to expose the gap between the nominal country of origin and the actual one.

Third, this report focuses on case studies, representing the distinct **archetypes of dependence** on China that exist in critical U.S. pharmaceutical supply chains. Overcoming the origins of U.S. pharmaceutical dependence on China requires understanding why some essential medicines and ingredients are no longer produced in the United States and why that same shift could happen to others. Rather than attempting an exhaustive audit of every vulnerable medicine and the entire U.S. pharmaceutical landscape, the report aims to create a replicable analytical framework—the archetype model—for policymakers, agencies, and researchers to apply to additional product classes. The three structural archetypes identified, explained in detail below, are each represented by case studies, chosen for their presence on critical medicines lists, documented history of shortages, and analytical usefulness across product classes. The six case studies are: amoxicillin, heparin, norepinephrine, acetaminophen, monoclonal antibodies, and synthetic DNA.

Fourth, this report provides granular, **realistic policy options** for addressing the root causes of these problems. These policy options are intended to be bipartisan in nature and politically feasible. These recommendations and our underlying analysis benefited immensely from the inputs and insights of a bipartisan CFR study group, with a cross-disciplinary scope that spans China policy, biosecurity, manufacturing, regulation, supply chains, trade, and industrial policy. The group met eight times between June 2025 and May 2026, and its members are listed in the appendix of this report.

A BRIEF HISTORY OF CHINA WEAPONIZING SUPPLY CHAIN CONCENTRATION

Over the last fifteen years, Beijing has purposefully used supply chain concentration as an instrument of statecraft and as a dimension of its national security strategy. As noted in China's signature *Made in China 2025* document, "building an internationally competitive manufacturing industry is the only way China can enhance its comprehensive national strength, ensure national security, and build itself into a world power."[5] China has deployed the centralization and concentration of supply chains as a coercive tool in response to diplomatic disputes, market access demands, and Taiwan-related scenarios, and wielded its powers with enough deniability that attribution is often contested long after the damage is done.

China pioneered its supply chain playbook in rare-earth elements. Beijing controls roughly 70 percent of global extraction and 90 percent of global processing of these materials. The focus on critical minerals may have entered the zeitgeist fairly recently in Washington, but Beijing began leveraging its market dominance as early as 2010. That fall, following a Chinese fishing boat's collision with two Japanese vessels near the Senkaku/Diaoyu Islands, Beijing halted REE shipments to Japan without formal announcement, allowing the embargo to operate quietly while creating plausible deniability.[6]

This pattern of unofficial, deniable restriction is a recurring feature of China's supply chain statecraft. Rather than issue formal export bans, Beijing slows shipments, delays licenses, and multiplies inspections. This pattern of behavior allows the PRC to benefit from the coercive effect of an export ban while avoiding the potential legal consequences of a declared embargo. More recently, in April 2025, Beijing imposed formal controls on seven heavy REEs and radically curtailed licensing approvals, triggering sharp price surges, factory closures across Western allied nations, and the temporary shutdown of a Ford plant in Chicago.[7] Those examples offer a preview

of the cascading industrial disruption that pharmaceutical supply chain coercion could replicate at an even more consequential scale.

This model of supply chain weaponization has been extended to other industrial inputs and trading partners. China imposed import restrictions on Australian goods after Canberra called for an independent investigation into COVID-19's origins. Beijing embargoed Lithuania after Vilnius permitted a Taiwanese representative office to open. At least fifteen countries have experienced a form of Chinese supply chain coercion, a pattern that reflects not isolated episodes but a consistent strategy.[8]

U.S. dependence on China for critical pharmaceutical inputs is mirrored across many low- and middle-income countries, and it is increasing. As part of the Belt and Road Initiative (BRI), China is financing pharmaceutical manufacturing abroad while providing the technical expertise needed to operate it. By embedding Chinese-origin APIs, key starting materials, equipment, financing, and technical standards into pharmaceutical manufacturing across developing countries, the BRI extends China's sway globally and creates third-country leverage channels even where direct exports to the United States are limited. In a future crisis, such as a major disease outbreak in Africa, countries with nominal local production capacity could be constrained by losing critical Chinese-controlled inputs. That could compromise that outbreak response, threatening global health security and U.S. interests. This strategy, which provides China with a powerful political and economic tool, extends beyond pharmaceuticals into adjacent sectors such as genomic sequencing and biomedical research infrastructure, where Chinese firms and state-backed initiatives are expanding their global footprint as well.[9]

Any tier of a supply chain in which China has achieved concentration serves as a potential point of leverage which can be exercised formally or informally, announced or deniable, in response to geopolitical flash points or market access disputes. The pharmaceutical supply chain is not exempt from this dynamic. It is, increasingly, its next frontier.

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PATHWAYS FOR WEAPONIZATION AND IMPACT PROPAGATION IN THE SUPPLY CHAIN

An Anatomy of Medicine and Its Production

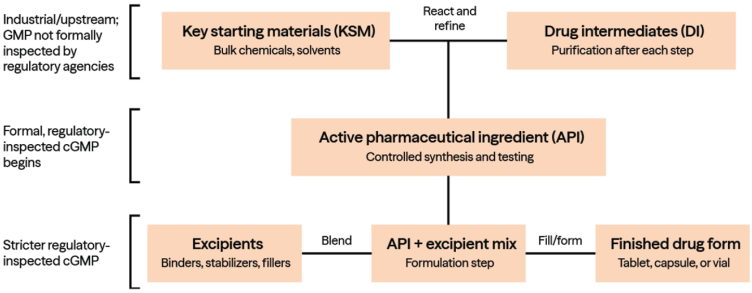
Medicines are produced through a multistep process that begins with basic chemical inputs (key starting materials) that undergo transformation into drug intermediates and ultimately into active pharmaceutical ingredients.

For small-molecule drugs, the production is usually a chemical synthesis pathway, involving stepwise chemical synthesis and purification after each step. The upstream production of KSMs and drug intermediates often looks more like industrial chemical-plant manufacturing. It can involve bulk chemical reactions, solvents, reagents, commodity inputs, and large-scale purification before the material enters the more tightly controlled pharmaceutical supply chain. Regulatory standards become progressively stricter as the process moves downstream, and production stages from APIs to FDFs are under strict good manufacturing practice (GMP).

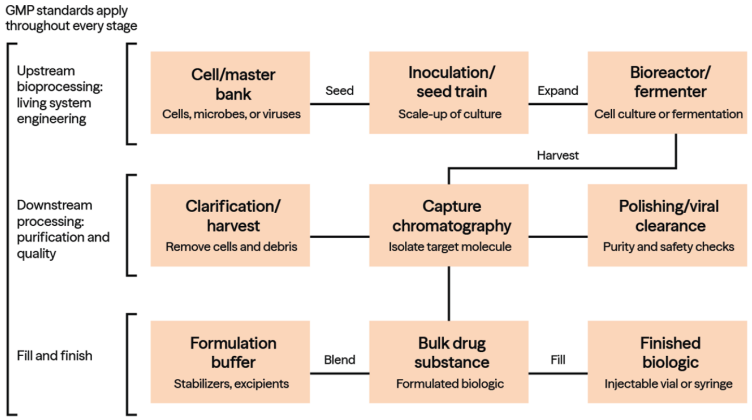
APIs are combined with excipients to create the finished product. Excipients are ingredients such as colorings, emulsifiers, flavorings, lubricants, preservatives, solvents, binders, stabilizers, and release-control agents. Excipients do not have a role in the intended therapeutic effect of the drug, but they are essential for manufacturability, stability, delivery, appearance, and patient usability. After mixing with the excipients, APIs are finished in the form of a tablet or capsule or filled in a vial.

In contrast to small molecules, biologics are made from or with living systems such as microorganisms, cells, proteins, sugars, nucleic acids, tissues, or complex combinations of these. Their manufacturing relies more on cell culture, fermentation, expression systems, and purification than on traditional stepwise chemical synthesis. This sequence requires more tightly controlled processes and quality checks.

Small-Molecule Manufacturing



Biologics Manufacturing



The Origins of U.S. Dependence on China for Pharmaceutical Supplies[10]

U.S. pharmaceutical manufacturing emerged from the dye and chemical industry in the 1930s and expanded dramatically with the increased production of antibiotics in World War II. Because drug and vaccine manufacturing is capital intensive, and the quality, safety, and efficacy of medicines are regulated, it was initially less susceptible to the low-cost locales that lured the garment, consumer electronics, and other labor-intensive industries offshore. Well into the late 1990s, the United States, Europe, and Japan dominated the global market for medicines and their key ingredients.

Change began with the widespread production of low-cost generic medicines—off-patent and unbranded—in the United States. The Drug Price Competition and Patent Term Restoration Act of 1984 established the generic drug industry in the United States by making it easier for pharmaceutical manufacturers to receive approval for a generic drug without having to redo all the expensive clinical trials that supported the original drug's approval.[11] Once a generic drug is deemed bioequivalent to a patented drug listed in the Orange Book, run by the U.S. Food and Drug Administration (FDA), it becomes officially substitutable.[12] Because generics are often cheaper than patented medications, many state legislatures have created rules allowing or mandating substitution by pharmacies. Pharmaceutical benefit managers, Medicaid programs, and insurers have done the same, encouraging patients to use the cheapest available FDA-approved generic version by implementing strong financial incentives.[13]

Consolidation, particularly among pharmaceutical wholesalers, has spurred ruthless generic price competition, in which wholesalers solicit daily tenders and choose the lowest price on offer.[14] The wholesalers then compete for customers—hospitals, health systems, retail pharmaceutical chains, and other providers—on price rather than quality, availability, or manufacturing resiliency.[15]

This combination of a business opportunity to sell ever-cheaper versions of generic drugs and more conducive U.S. laws and policies opened the door to cheap imports from abroad. Shifts in trade policy kicked that door open wider, with the United States entering into a 1994 World Trade Organization agreement exempting pharmaceuticals from tariffs and normalizing trade with China in 2000.[16] Environmental concerns played a role as well in shifting manufacturing abroad for the ingredients in many common antibiotics and everyday cardiovascular drugs such as statins. Public alarm

over the discovery of hormones in pharmaceutical manufacturing runoff feminizing fish in streams, as well as concern over high concentrations of antibiotics in riverbeds and sewage, prompted new U.S. and European environmental risk assessments and regulations.[17] API and KSM production often involves chemical reactions with toxic byproducts, which began to get greater scrutiny from Western regulators and media.

China offered more lax environmental laws, discounted water and power inputs, and, as more API and KSM manufacturing became sourced in that nation, enormous economies of scale. Large plants for manufacturing antibiotics and other pharmaceuticals and their ingredients emerged in China, supported by well-integrated material supply chains that reduced material, shipping, and transaction costs to go along with already low labor-cost advantages. In certain cases, the country pursued predatory industrial policy measures that drove U.S.-based manufacturers out of business, such as when China flooded the global market with low-priced penicillin and vitamin C in the early 2000s.[18]

In 2021, China's antibiotic exports constituted one-fifth of global antibiotic exports and nearly half of global antibiotic ingredients exports. The country's production capacity reached fourteen thousand tons—nearly three times that of India—for amoxicillin, a broad-spectrum penicillin antibiotic used to treat several bacterial infections, including ear, throat, sinus, respiratory, and urinary tract infections, especially in children. In the United States, physicians write nearly sixty million amoxicillin prescriptions a year. Although the medicine is sourced from generic manufacturers in Europe, India, Israel, Jordan, and a small Tennessee facility, most of them rely on APIs made in China, which are primarily produced in Jiangsu, Shanghai, and Zhejiang. If China withheld amoxicillin API supplies for geopolitical reasons, as it has with rare-earth elements, or a natural disaster struck those areas, every U.S. hospital, pharmacy, and pediatric practice would feel the effects within weeks.

U.S. Pharmacopeia estimates that nearly seven hundred medicines approved for use in the United States depend on at least one chemical produced solely in China, with KSMs for drugs for statins, antibiotics, seizures, cancer, and HIV.[19] Unless required to do so, companies are not likely to buy U.S.-made chemicals (or those from other markets) unless they are sold at China-like prices and scale. In 2023, a U.S. Department of Defense official testified that the national security risks of Chinese dominance of the global market for APIs "cannot be overstated . . . should China decide to limit or restrict the delivery of APIs to the United States, it would have

a debilitating effect on U.S. domestic production and could result in severe shortages of pharmaceuticals for both domestic and military uses."[20]

Over the last decade China has also surged up the innovation ladder to become a major force in the biotechnology sector via a coordinated statewide campaign that has incorporated regulatory overhaul, subsidies, dedicated biotech hubs, and other forms of government support on a scale few other nations can match.[21] The campaign began with regulatory reforms undertaken in response to a series of scandals involving corruption at China's food and drug authority in 2007, contaminated Chinese-made heparin in 2008, and substandard rabies and diphtheria vaccines in 2018. These reforms improved the enforcement of bioequivalence for Chinese APIs and inputs and dramatically cut the approval time for clinical trial applications and new drug products, supporting China's contract research industry that now conducts many of the early-stage development and first-in-human trials for multinational firms.[22]

It is a strategy that has capitalized on cumbersome FDA approval processes for early-stage clinical research, which shifted many phase I clinical trials abroad, mostly to China.[23] China has also used joint venture requirements and conditioned marketing approval of drugs to compel foreign pharmaceutical firms to share their drug formulations, manufacturing processes, or research data with local firms and regulators. Heavy government support is helping BioMap, Baidu's life sciences arm, and WuXi App Tec, China's leading biomanufacturer, emerge as advanced biotech powers. In the first half of 2025 alone, U.S. pharmaceutical firms signed fourteen licensing agreements potentially worth $18.3 billion to restock their innovation pipelines with drug and vaccine candidates from Chinese biotech firms. Those agreements stand in contrast to just two such deals in the same period the year prior.[24]

Chinese Firms Targeted U.S. Pharma Assets Across the Entire Value Chain

Selected acquisitions in generics, biologics, R&D tools, and genomics, 2008–20

Country	Target	Acquirer	Year	Deal size	Implications
GENERICS					
U.S.	Epic Pharma	Humanwell Healthcare / PuraCap	2016	100%, $550M	FDA/DEA-approved U.S. manufacturing and ANDAs
India	Gland Pharma	Shanghai Fosun Pharmaceutical	2017	~74%, up to $1.09B	Global injectables platform including heparin
U.S.	Scientific Protein Labs	Shenzhen Hepalink Pharmaceutical	2014	$337.5M + contingent	Heparin value-chain control
MONOCLONALS AND BIOLOGICS					
U.S.	Dendreon	Sanpower Group	2017	100%, $819.9M	Access to a U.S. cell therapy asset
U.S.	AppTec Laboratory Services	WuXi PharmaTech	2008	~$163M incl. debt	U.S. biologics CDMO and testing footprint
U.S.	Cytovance Biologics	Hepalink USA / Shenzhen Hepalink	2015	$205.7M	Biologics CDMO diversification beyond APIs
R&D TOOLS AND CRITICAL EQUIPMENT					
U.S.	Absorption Systems	Pharmaron Beijing	2020	100%, up to $137.5M	End-to-end CRO expansion; U.S. client access
U.S. / China	XenoBiotic Laboratories	WuXi PharmaTech	2014	Undisclosed	North American DMPK/bioanalysis capacity
GENOMICS					
U.S.	Complete Genomics	BGI-Shenzhen	2013	$3.15/share (tender)	U.S. sequencing platform; global genomics scale
U.S. / Iceland	NextCODE Health	WuXi PharmaTech	2015	$65M	Genomic medicine and diagnostics entry

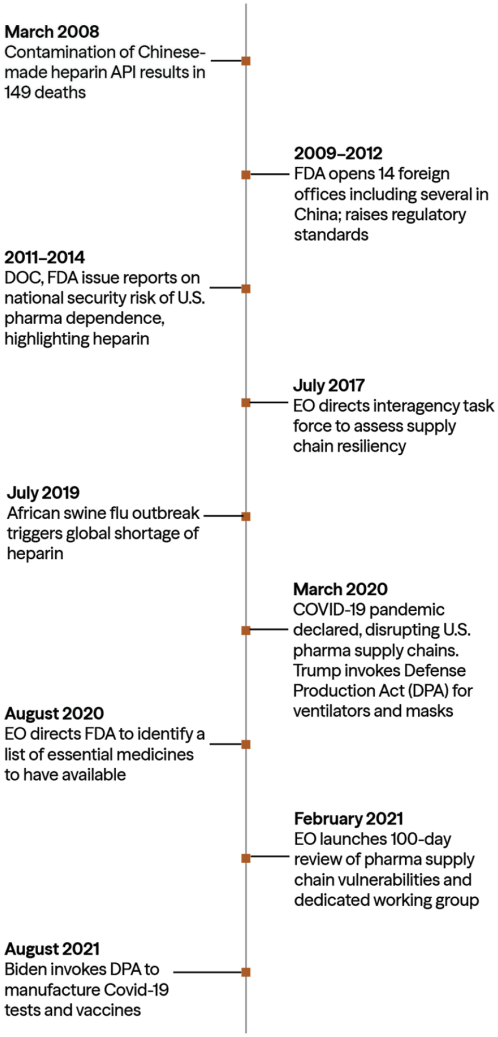
Sources: PRNewswire, SEC filings, Fosun Pharma, Fierce Pharma, PRWeb, BioSpace, Pharmaron. Deal sizes reflect announced terms; some subject to adjustments.

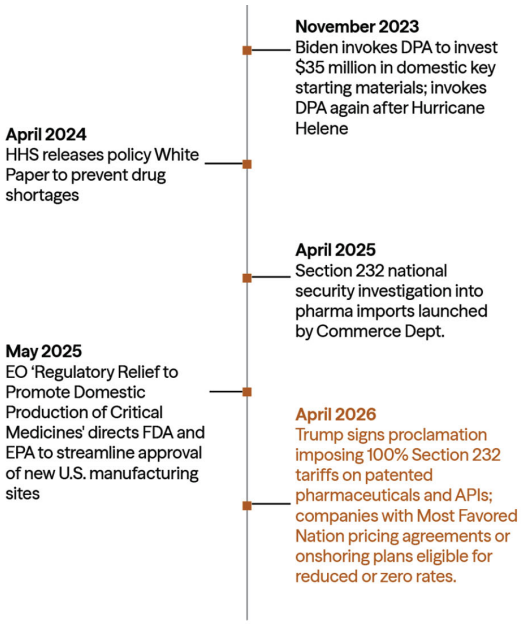
A BRIEF HISTORY OF THE U.S. RESPONSE TO PHARMACEUTICAL DEPENDENCE ON CHINA

U.S. policymakers have been concerned for nearly two decades about U.S. dependence on China for active pharmaceutical ingredients and key starting materials for many critical medicines. Although the United States has changed its perception of the problem from a regulatory to a national security challenge, it continues to struggle to rectify the problem in any meaningful way. The figure below highlights certain milestones along that journey to date.

U.S. Pharmaceutical Supply Chain Timeline

Major supply chain disruptions and federal policy responses, 2008–26





Source: Food and Drug Administration; Department of Health and Human Services; White House; Department of Commerce Bureau of Industry and Security; Government Accountability Office

PATHWAYS FOR WEAPONIZATION

Choke points in critical supply chains share three characteristics.[25] First, a nation or coalition of allies has a dominant, concentrated market share in a critical input or production stage. Second, substitutes are not immediately available. Third, that country has a practical means of weaponizing its position in ways that create asymmetric leverage, inflicting substantial pain on the target while suffering minimal harm itself.

Pharmaceutical supply chains are particularly susceptible to choke points because both supply and demand for essential medicine inputs and production processes often do not readily respond to changes in price. That may be the case for the demand for an essential medicine if it is a medical necessity to patients and no good therapeutic substitute exists. The supply of an essential drug is similarly constrained, especially in the short term, because existing suppliers must obtain FDA approval for new manufacturing facilities or production lines needed to meet the shortfall. New entrants face similar regulatory obstacles and have to offer lower prices than existing producers to gain market share, while innovative production technologies often struggle to gain traction in a highly regulated sector that is understandably path-dependent and conservative.

Older U.S. generics are particularly susceptible to shortages because margins are low. A 2025 study found that once U.S. drug shortages occur, they tend to persist, lasting three years on average (up from two years in 2020).[26] Shortages affect both purchasers—spurring hoarding and higher healthcare costs—and patients, delaying surgeries and leading to less effective or less safe alternatives, medication errors, and avoidable deaths.[27]

In 2019, Chinese President Xi Jinping announced a "whole nation" effort to advance the biotechnology and pharmaceutical sector, deploying the full weight of the authoritarian state across central ministries, provincial governments, academia, and industry to pursue the nation's strategic priorities in this sector.[28] This broad authority empowers China with a wide range of options to exercise leverage over U.S. pharmaceutical supply chains.

China could weaponize supply cuts by imposing direct or indirect export restrictions. China has previously exercised its authority to require that

exports of medical products—including COVID-19 testing kits, medical face masks and protective suits, ventilators, and infrared thermometers—be accompanied by proof of registration with the National Medical Products Administration. Alternatively, China could resort to more indirect, subtle regulatory measures that delay shipments or temporarily halt production at a critical facility, accomplishing the same practical effect of choking off needed supplies to U.S. patients and purchasers.

China can—and does—cut prices to disable competing supply chains. For generics, producers all along the global supply chain operate on thin margins due to robust price competition, reimbursement limits, or fixed contracts. Chinese producers recently flooded the market with below-cost exports of APIs and KSMs to cripple alternative suppliers in India that were supported under India's Production-Linked Incentive scheme.[29]

A further risk is China weaponizing information. China need not impose a physical export restriction to create downstream stress; threatening restrictions or amplifying rumors via channels like TikTok can trigger anticipatory hoarding and panic-buying by consumers, hospitals, group purchasing organizations (GPOs), wholesalers, and manufacturers. In a buffered multitier supply chain, this behavior converts perceived scarcity into real scarcity by pulling forward demand, distorting order signals, and exhausting inventories faster than normal consumption would. The 2022 infant formula crisis illustrated how media attention and panic buying can intensify shortages beyond the underlying physical disruption. Similar behavior was observed during the COVID-19 pandemic, when hospitals and buyers over-ordered critical products in anticipation of future scarcity.

China could also pursue subtler forms of coercion by weaponizing quality, with Beijing's manufacturers adulterating inputs or allowing manufacturing standards to quietly erode. Weaponization of quality—whether through deliberate adulteration or because of inadequate standards—represents a form of supply chain disruption particularly difficult to attribute and counter. The 2007–08 contamination of Chinese-manufactured heparin, which killed eighty-one Americans, illustrated that harm can propagate through supply chains even without formal export restrictions. While that particular episode may not have been deliberate, the possibility that it could be repeated intentionally is a form of risk that cannot easily be deterred. As pharmaceutical inputs become more complex and AI-driven synthesis makes their origins harder to trace, quality becomes an increasingly viable instrument of quiet pressure. Quality problems create plausible deniability, enabling a pathway for weaponization that is not always straightforward and may remain deliberately obscured.

Thus, assessing the risk of China weaponizing the U.S. pharmaceutical supply chain usually boils down to situations where China has dominant, concentrated market share and where pathways exist through which China could practically leverage that dependence in a manner that adversely affects the United States. Four such scenarios exist.

SCENARIO 1: CHINA RESTRICTS ACCESS TO RAW MATERIALS, KSMS, APIS, OR FDFS THAT GO FROM CHINA DIRECTLY TO THE UNITED STATES.

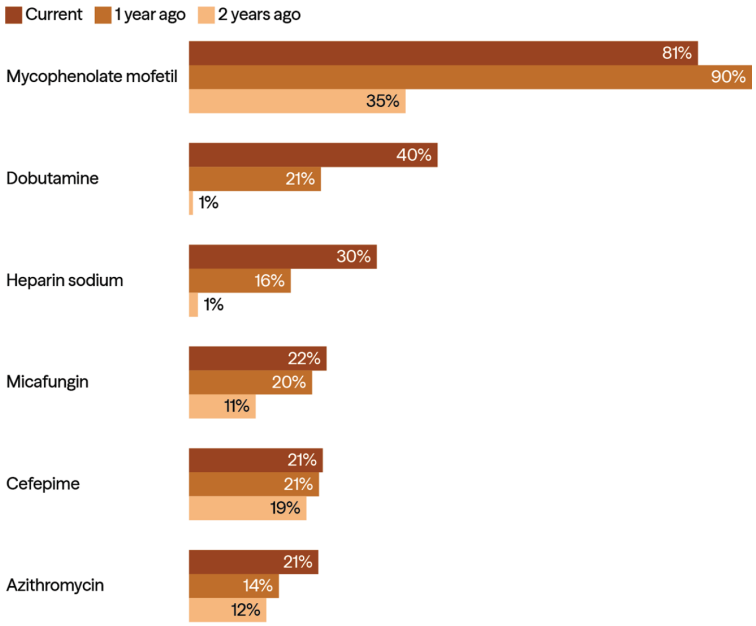
China's influence over U.S. pharmaceutical supply chains runs through two parallel paths: the inputs—raw materials, KSMs, and APIs—that provide the foundation for global manufacturing and finished dosage forms exported directly to U.S. patients. Currently, a relatively small percentage (an estimated 13 percent) of U.S. generic drugs and their inputs are imported directly from China, but this figure underplays the risk in certain vulnerable drugs that are highly dependent on Chinese manufacturers for finished dosage forms sold in the U.S. market.[30]

The oral solid products are dominated by antihypertensive medications—drugs taken daily by over fifty-five million Americans.[31] Although they would not necessarily lead to an immediate crisis, shortages of these drugs would result in serious public health consequences. As multiple drugs in the same therapeutic class are included in this list from the same manufacturers, supply disruptions are unlikely to be isolated, leading to simultaneous shortages across related medications, thus limiting substitution options.

The U.S. injectable products imported directly from China include the immunosuppressant mycophenolate, which is critical for preventing organ transplant rejections; some broad-spectrum hospital antibiotics; and an acute heart failure agent. Again, the products are not easily substituted and represent the standard of care in some of the most common and serious conditions used in hospital settings. Mycophenolate is the standard of care in transplant surgery: a shortage would pressure clinicians toward alternative drugs with higher rejection rates and poorer graft outcomes.[32] Cefepime is one of the most commonly reported antimicrobials to fall into shortage, with hospitals often shifting to less suitable drugs that carry downstream consequences for antimicrobial resistance and patient outcomes.[33] Dobutamine is only one of two inotropes (drugs used in cases of cardiogenic shock and acute heart failure) accessible in the United States.[34]

China's Share of the U.S. Injectables Market Has Surged in Recent Years

Market share of select U.S. injectable products by Chinese manufacturers, percent of units

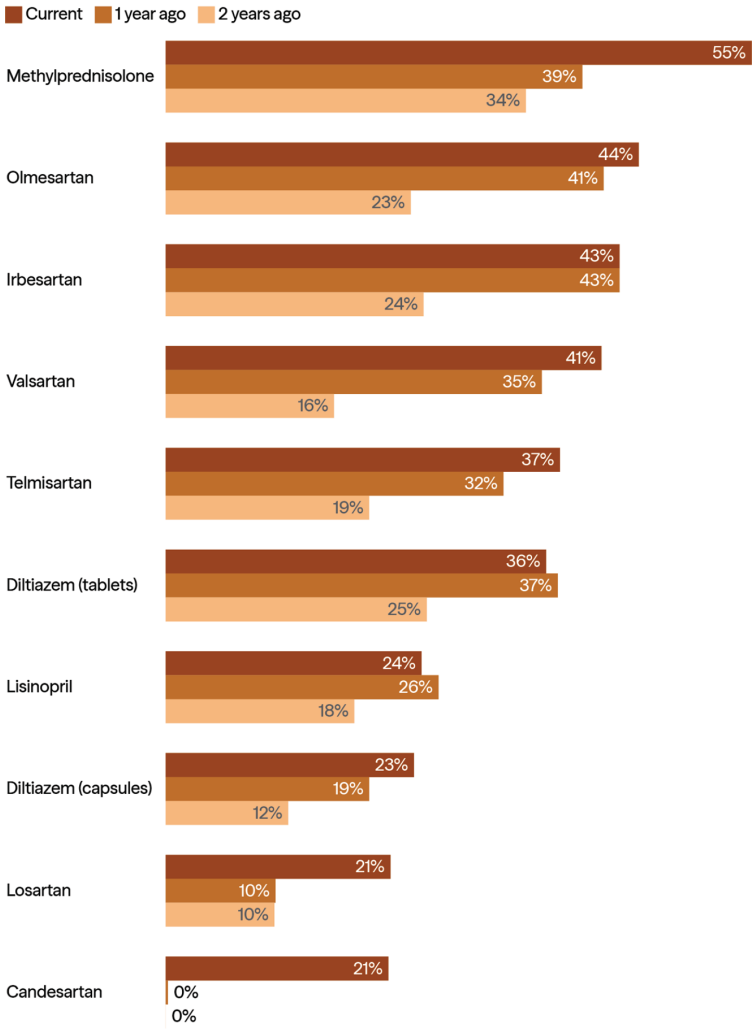


Source: U.S. Pharmacopeia Medicine Supply Map

Further, although the volume of direct U.S. imports from China in FDF is currently limited, it is poised to increase as China produces more innovative medicines on which the United States relies. Though the bulk of Chinese exports to the United States are in the form of KSMs and APIs, including indirect dependence from foreign manufacturers who source from China, the Chinese manufacturer is in many cases not the entity visible in the U.S. market. Rather, a U.S.-based company holds the drug label and distributes the product domestically but sources the API or the finished medication from a Chinese manufacturer under contract, sometimes without FDA authorization, such as with certain anti-obesity GLP-1 agonists. This

China's Share of the U.S. Oral Market Has Surged in Recent Years

Chinese manufacturer market share of select U.S. oral solid drugs, percent of units



Source: U.S. Pharmacopeia Medicine Supply Map

structure can obscure the true origin of manufacturing when supply chain analyses rely on label holders' market share rather than underlying producers. The FDA recognizes and inspects the underlying manufacturer as part of its oversight, but the arrangement means that the concentration of foreign manufacturing risk could be significantly understated in conventional market estimates.

SCENARIO 2: CHINA RESTRICTS ACCESS TO RAW MATERIALS AND KSMS TO A THIRD COUNTRY ON WHICH THE UNITED STATES RELIES FOR IMPORTS OF APIS OR FDFS, AND THE UNITED STATES SUFFERS COLLATERAL DAMAGE.

Beyond direct imports, China's upstream dominance creates an additional, less visible, channel of risk: restrictions on raw materials or KSMs shipping to India or Europe could trigger U.S. shortages collaterally, even in the absence of direct trade disruption between the United States and China. Nearly 41 percent of KSMs used in U.S.-approved APIs come solely from China and 16 percent from India.[35] Accordingly, much of the supply of APIs and FDFs that the United States imports from India or Europe for antibiotics, analgesics, steroids, and other widely used essential medicines indirectly comes from China. If China were to leverage its market dominance in upstream supply against that third country, the United States would suffer shortages too. For instance, China recently imposed export controls against shipping dual-use products to Japan, after its prime minister gave public remarks on the Taiwan Strait.[36] That list of dual-use products includes chemicals that are also used in pharmaceutical manufacturing, including solvents, reagents, fluorinated compounds, and certain fermentation-derived intermediates. If China imposed such a policy against India, it could result in serious consequences for the United States.

Because this approach would affect numerous countries and, potentially, a variety of medicines that incorporate that KSM, it would be a blunt policy instrument unlikely to align with China's more targeted past behavior. Though some Chinese commentators have suggested leveraging the market share of Chinese API producers to serve Beijing's policy goals, even its rare-earth critical mineral restrictions, in practice, included limited carve-outs for medical uses.[37]

SCENARIO 3: CHINA RESTRICTS A THIRD COUNTRY FROM EXPORTING API OR FDF PRODUCTS TO THE UNITED STATES MADE WITH RAW MATERIALS OR KSMS FROM CHINA.

China could use global diplomatic pressure, regulatory measures, threats to cut off access to its market, and export controls to prevent companies and third countries from selling targeted KSMs, APIs, or FDFs to the United States. China has leveraged such export controls on critical minerals. The United States has deployed, with only limited success, related measures to prevent foreign government choke point suppliers and non-U.S. companies from exporting advanced chips and semiconductor manufacturing equipment to China. China could seek to do the same with pharmaceuticals, but it would require the cooperation of other producing governments and undoubtedly spur the same all-out push for alternative sources and self-sufficiency as those export measures in other sectors have.

SCENARIO 4: CHINA RESTRICTS ACCESS TO CRITICAL DATA OR R&D INFRASTRUCTURE TO U.S. DRUG DEVELOPERS AND PRODUCERS.

Increasingly, first-in-human clinical trial activity for promising medicines is shifting away from the United States and Europe to China, where those trials can be conducted faster and more cheaply. China's share of global trial starts rose from 1 percent in 2009 to 30 percent in 2024.[38] As China gains share in early stages trials and the resulting data grows, it creates a strategic dependence that could undermine U.S. leadership in translational science, and slowly choke off U.S. capacity to engage in preparedness and countermeasure development.

How China Weaponizing U.S. Pharmaceutical Dependence Could Play Out

The likely effect of a U.S. pharmaceutical supply disruption can be assessed across six dimensions: (1) how quickly the disruption reaches the market; (2) where the disruption occurs along the supply chain stages; (3) the average scale of shortages or cost increases; (4) the worst-case shortages at their peak once stockpiles are depleted and panic buying has amplified the problem; (5) the capacity to absorb the shock through

excess inventory, alternative suppliers, or substitution; and (6) the time required to recover through approvals for new suppliers, restarted production, or expedited imports.

The severity of a disruption from China choking off supplies would depend on where in the supply chain it occurred. Restrictions at central, highly upstream points are more dangerous than later-stage supply shocks because they affect all downstream production paths. Therapeutic substitutability can reduce patient impact but can also shift demand to other antibiotics, leading to new shortages and creating secondary effects. Substituting sources at any tier of the supply chains (KSM, API, FDF) requires the FDA to assess and validate new batches, stability data, regulatory filing updates, and inspection readiness; buyers cannot simply switch suppliers without FDA approval. A CFR-*New England Journal of Medicine* analysis shows temporary importation can mitigate certain generic shortages, but the FDA generally deploys it only after other options are exhausted, even after months of delay. In one benzathine penicillin G case, nearly nine months passed before FDA authorization.[39]

Excess inventory and time buffers could delay the impact of China-instigated supply chain disruptions but in turn create a false sense of stability and surprise effects. Contract rigidity affects whether a shock manifests as higher prices, margin compression, or allocation. Typical human behavior in a crisis—over-ordering, hoarding, inflated forecasts, rationing—further accelerates propagation.

Most scenarios short of complete supply shutoff usually manifest first as price increases rather than immediate shortages: upstream inputs become more expensive, scarce suppliers raise quotes, buyers bid up available volumes, and downstream firms draw down inventory while repricing. In generics, price sensitivity runs through the entire chain: API manufacturers, FDF manufacturers, wholesalers, pharmacies, hospitals, and payers often operate under competitive pricing, tendering, reimbursement limits, or fixed contracts. As a result, upstream cost inflation may not fully pass through, instead appearing as margin compression, delayed replenishment of supplies, or even the exit of manufacturers. For innovative medicines and biologics, product pricing is largely decoupled from cost of goods sold (driven by patent protection, market access, contracting, and payer dynamics), so upstream input shocks are more likely absorbed as margin impact or supply-risk management before becoming visible price changes.

China controls about 94 percent of 6-APA (the main KSM for amoxicillin); API manufacturing occurs in Austria, China, and India; FDF manufacturing occurs in the India, the European Union, and sometimes in the United States. A simultaneous Chinese restriction on both 6-APA and amoxicillin API hits two tiers at once: non-China API manufacturers lose KSM access while FDF manufacturers lose both direct Chinese API and, over time, non-Chinese API. Under a 25 percent restriction, effective global API availability falls to roughly 80 percent (around a 20 percent deficit); under a 50 percent restriction, availability falls to roughly 60 percent (around a 40 percent deficit); and under a full ban, availability falls to about 20 percent, essentially Austria plus a small residual (around a 79–80 percent deficit). Because API manufacturers normally hold six months of KSM inventory, FDF manufacturers hold three to six months of API inventory, wholesalers hold thirty days, and pharmacies hold roughly fifteen days, the first signals would be API price increases, allocation, delayed replenishment, and tender failures—not pharmacy-level shortages. Once buffers deplete, a threshold effect drives sudden acceleration: peak shortages would arrive roughly within 6 to 9 months after a 25 percent restriction, 5.5 to 8.5 months after a 50 percent restriction, and 4.5 to 7.5 months after a full ban, with hoarding and over-ordering capable of pulling all timelines forward.[40]

AN ARCHETYPE APPROACH TO UNDERSTANDING U.S. PHARMACEUTICAL DEPENDENCE

This report aims to create a replicable analytical policy framework—the archetype model—for policymakers, agencies, and researchers to apply to other product classes that share the same root causes of dependence on China. A one-size-fits-all approach won't work for redressing the "rare-earths problem" in the U.S. pharmaceutical supply chain. The root causes of dependence often differ by product class and can arise at different stages of the value chain. Policy solutions must target those particular differences to be effective. Upstream market concentration in KSMs would only be masked by downstream supply diversification. The perilously low margins for older generic pharmaceuticals create sterile manufacturing facility fragility that cannot be redressed by re-shoring or sixty-day stockpiles alone. Country-of-origin labeling (COOL) or Buy American approaches need to account for transshipment, domestic branding, and API repackaging. R&D infrastructure capture reflects a systemic competitive erosion via Chinese state-backed integration and coordination that can only be addressed in kind.

Archetype One: Reliance on China for Raw Materials and Upstream Supplies for Generic Drugs

The defining characteristic of this archetype is a choke point at the raw material or key starting material stage and at the intermediate level. This archetype is defined by the "N-1 problem": apparent diversification at one stage often masks near-total concentration at upstream inputs where true dependence has quietly shifted up one critical step, the "minus 1." When

all downstream suppliers depend on that same concentrated input, downstream diversification (at the level of APIs or FDFs) provides no protection. It is an end-to-end supply chain challenge, and policy responses need to treat it as such, by mapping upstream tiers and arranging geographic diversification of starting material sourcing with allies.

Most medicines in the first archetype share a structural vulnerability. As low-cost but essential generics, these medicines no longer generate sufficient economic returns to justify domestic vertical integration. U.S. producers face structural cost disadvantages from environmental compliance, while GPOs concentrate buying power and drive a race to the bottom on price—functioning as embedded subsidies for foreign production. Partial investments at the API or FDF level, without corresponding KSM capacity, leave the core vulnerability intact. Total independence from foreign sources would require an end-to-end domestic supply chain: a solution demanding high capital, lead times of five to ten years, and sustained policy commitment that market forces alone cannot produce. This dynamic—low-margin generics, GPO price pressure, and shortage costs externalized onto patients rather than purchasers—recurs across our four case studies in Archetype One.

These case studies all reflect the broader trend of supply risk moving further upstream, where dependence on essential raw materials or intermediates has become a critical vulnerability. The nature of that upstream risk varies, however: certain inputs are synthetically produced, such as fermentation-derived materials, while others are naturally harvested, such as porcine mucosa (from which heparin is derived). The cases also differ in regulatory and manufacturing complexity, including whether they involve combination APIs under Drug Enforcement Administration (DEA) oversight and whether production depends on sterile injectable capabilities versus more flexible oral solid manufacturing.

Case Study: Amoxicillin

Amoxicillin is the most prescribed antibiotic in the United States, with nearly sixty million prescriptions per year, treating infections across hospitals, pharmacies, and clinics.[41] It is especially critical in pediatric care and for seniors over sixty-five, who use it at rates nearly 50 percent higher than younger Americans and depend on it for routine procedures such as hip replacements and cancer surgeries.[42]

Why This Product Is a National Security Concern

As recently as 2008, nearly all U.S.-administered amoxicillin was domestically manufactured.[43] Subsidized competition from Chinese and Indian generic manufacturers drove U.S. producers from 100 percent market share to 0 percent within twelve years.[44] Amoxicillin now sits on both the FDA and World Health Organization (WHO) emergency medicines lists, signifying that its uninterrupted supply is considered essential to basic health-care capacity.[45]

Without a reliable supply, cases as simple as minor wound infections can become life-threatening. The 2022 amoxicillin shortage—triggered by an ordinary demand surge in peacetime conditions—resulted in a 30.8 percent decrease in amoxicillin prescriptions in U.S. pediatric hospitals, accompanied by an increase in broader-spectrum antibiotics that accelerate antimicrobial resistance.[46] More broadly, the shortages led to documented cases of rationing, delayed surgeries, and substitution with less effective products. Those shortages offer a clear stress test: U.S. supply chains failed under everyday conditions, thus demonstrating that even minor disruptions can be devastating.

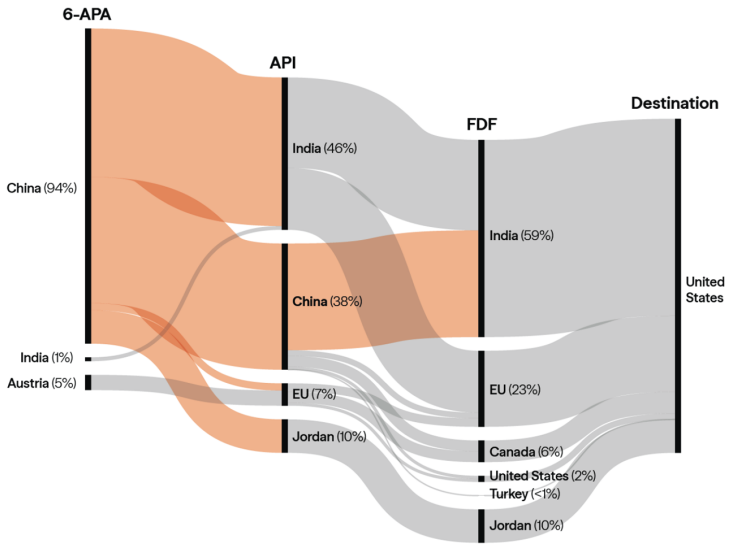
Structural Vulnerability

Although the API and FDF layers of the U.S. amoxicillin supply chain appear geographically distributed, they are all anchored to a single upstream choke point: penicillin G and its derivative 6-APA. Nearly all U.S. supplies of penicillin G originate in China, with near-zero Indian sourcing, making intermediate 6-APA stages dependent on this same base.[47] Five Chinese companies, including the state-owned North China Pharmaceutical Corporation, control over four-fifths of global 6-APA production. In parallel, our own analysis shows China supplying 94 percent of global amoxicillin starting materials; India, dominant in amoxicillin FDF manufacturing at 59 percent, sources its intermediates from China as well. The result is American pharmacy shelves stocked with the products of Chinese chemistry with Indian finishing—a supply so compressed that any upstream disruption propagates to American consumers within weeks. The starting materials of API manufacturers in Europe (Austria and Spain) and Jordan are also traced back to China, meaning even non-Chinese producers of amoxicillin are essentially reliant on

Chinese inputs. Diversification at the API and FDF stages therefore fails to provide meaningful protection against Chinese supply disruption—but it does create a dynamic in which China would need to leverage against the United States with the cooperation of another country, such as India, or as part of a larger effort against nations that rely on amoxicillin made with key starting materials from China.

Mapping Amoxicillin Ingredients to Finished Products

The majority of shipments for 6-APA, a key starting material for the antibiotic, originate in China.



Notes:

6-APA = 6-aminopenicillanic acid
API = active pharmaceutical ingredients
FDF = finished dosage form
USP = U.S. Pharmacopeia

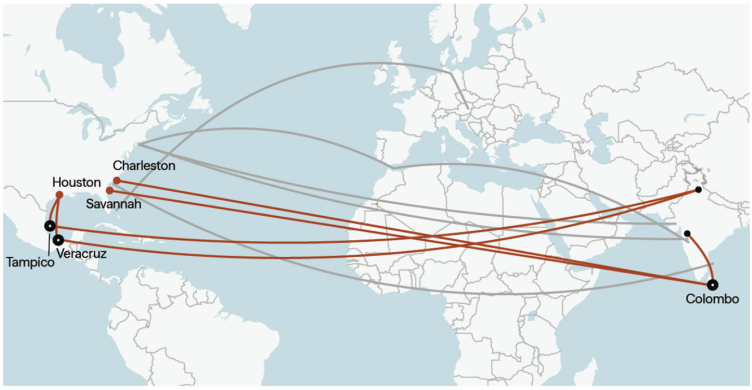
The chart shows approximate shipments from 6-APA suppliers to API suppliers to FDF suppliers that distribute products to the United States. 6-APA shares are allocated based on interviews and literature search about backward integration, PIB India data on 6-APA, and amoxicillin API from China. API data (manufactured units) and FDF data (standard units aggregated across dose and formulation types) are from the USP Medicine Supply Map. API supplier to FDF supplier mapping is based on Panjiva shipment transaction data. When data showed more than one API supplier for a given FDF manufacturer, FDF equivalent units were allocated based on weight and/or frequency of shipments. When a company had multiple sites and there are within-firm intersite shipments, some were collapsed into a single flow.

Sources: Panjiva; U.S. Pharmacopeia Medicine Supply Map

Trade and customs data reveal that certain Indian manufacturers route APIs through transshipment hubs in Mexico and Sri Lanka before entering U.S. ports, which obscures the true origin of the supplies and undermines country-of-origin enforcement. Those diversions disable current customs and regulatory oversight, blinding officials to the true supply chain concentration risks, while funneling multiple nominally independent supply lines through a handful of southeastern U.S. ports—creating a physical choke point mirroring the upstream chemical one.

API Transshipment Hubs

Some manufacturers ship amoxicillin APIs from India through Mexico and Sri Lanka



API = active pharmaceutical ingredients

Note: Map shows selected amoxicillin API shipping routes with additional routes shown in gray for comparison. Routes are approximate.

Source: Zauba

Case Study: Heparin

Heparin represents the clearest case where the choke point has shifted fully upstream to the starting material stage, presenting the strongest raw material concentration risk in this report. The drug is based on a biological input with sourcing overwhelmingly from China, no meaningful domestic alternative, and a recorded history of intentional contamination by Chinese producers.[48] For decades, heparin, a blood thinner, was made with bovine ingredients until the mad cow disease scare in the 1990s prompted manufacturers and regulators to adopt porcine alternatives instead.[49] With that change, China, the world's largest pork producer, also became the dominant supplier of crude heparin, now made only from pigs. Downstream diversification is irrelevant given global supply chains converge at the same biological input from China. Although the United States is the third-largest pork producer, it lacks the collection, processing, and transportation infrastructure needed to turn porcine mucosa, a byproduct, into a reliable domestic heparin input.[50] Because API and FDF manufacturers already have access to cheaper established sources in China, they have little market incentive to make the capital investments required to build this infrastructure.

Why This Product Is a National Security Concern

Heparin, like amoxicillin, is one of the backbones of modern medicine. Heparin is administered to more than 12 million hospitalized Americans per year, with approximately 265 million total doses provided annually.[51] Appearing on every critical medicines list of relevant agencies—the WHO, the Department of Health and Human Services (HHS), the FDA, and the Department of Defense (DOD)—its clinical span is unusually broad, spanning common surgeries, kidney dialysis, asthma treatment, battlefield injuries, and biological countermeasures.[52] Supply disruption would not just affect a single disease population but would degrade the operational capacity of hospitals nationwide. As of May 2025, the American Pharmacists Association lists heparin on its drug shortage list, with experts advising clinicians to begin rationing—a position reflecting baseline conditions, not a crisis scenario.[53]

Several times, the dependence on China for heparin has put the millions of U.S. patients who use the drug annually at risk. The 2019 African swine fever outbreak devastated China's pig population and triggered a global shortage of heparin. A 2008 contamination crisis, in which adulterated Chinese-manufactured heparin API triggered a massive FDA recall, resulted in numerous deaths worldwide—including eighty-one in the United States.[54] A supply disruption from 2017's Hurricane Maria produced a 152 percent increase in medication error rates and a 114 percent increase in error rates for its substitute drug, enoxaparin.[55]

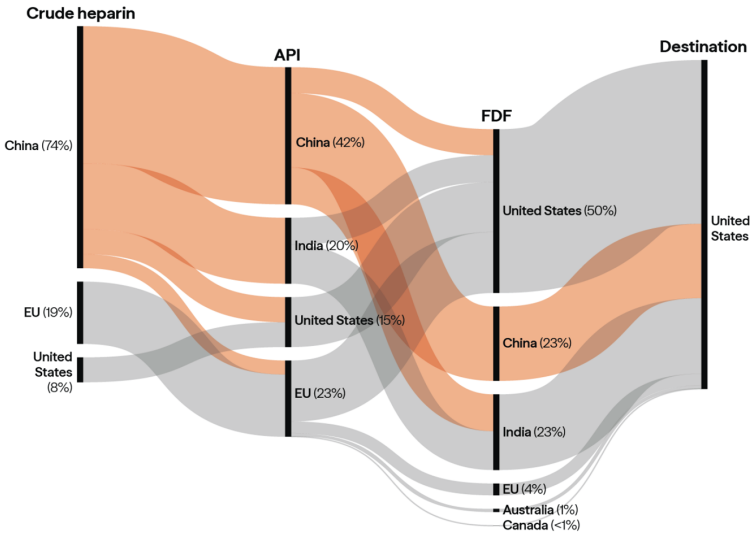
Structural Vulnerability

Heparin is derived from porcine intestinal mucosa, with 80 percent of the global supply and 74 percent of U.S. supply originating in China. Domestic collection accounts for less than 10 percent of global supply.[56] The United States is the third-largest pork producer, but it does not produce porcine mucosa at meaningful scale for pharmaceutical use.[57] Porcine mucosa is a slaughter byproduct that requires dedicated collection, segregation, preservation, and processing infrastructure to convert it into a pharmaceutical-grade heparin input. A regulatory decision made roughly twenty years ago prohibiting bovine-origin heparin over mad cow disease concerns foreclosed the primary pathway to geographic diversification.[58] The U.S. Strategic National Stockpile has limited heparin holdings; supply disruptions translate into immediate clinical impact with no buffer. Indian producers such as Dr. Reddy's Laboratories and multinational companies with significant Indian manufacturing, such as Mylan, source their API entirely from China. Hepalink—including its 2013 acquisition of Scientific Protein Laboratories in Wisconsin—has vertically integrated from mucosa collection through finished product, cementing Chinese control across the full value chain.[59]

Regulatory inertia and a lack of explicit incentives from FDA to switch to bovine heparin suggest that no private actor will invest in rebuilding domestic mucosa collection and bovine processing infrastructure. But Brazil's approach—establishing separate standards for porcine and bovine heparin in 2019—demonstrates that this is a manageable regulatory problem rather than an intractable market barrier.[60]

Mapping Heparin Ingredients to Finished Products

China supplies almost three-fourths of crude heparin used in U.S. products.



Notes:

API = active pharmaceutical ingredients
FDF = finished dosage form
USP = U.S. Pharmacopeia

The chart shows approximate shipments from crude heparin suppliers to API suppliers to FDF suppliers that distribute products to the United States. API data (manufactured units) and FDF data (standard units aggregated across dose and formulation types) are from the USP Medicine Supply Map. API supplier to FDF supplier mapping is based on Panjiva shipment transaction data. When data showed more than one API supplier for a given FDF manufacturer, FDF equivalent units were allocated based on weight and/or frequency of shipments. When a company had multiple sites and there are within-firm intersite shipments, some were collapsed into a single flow. Flows between EU countries were combined to mitigate tracking inconsistencies. When exact relationships between API manufacturer and FDF could not be established based on trade flow data, regulatory submission data, literature, and interviews were used.

Sources: Panjiva; U.S. Pharmacopeia Medicine Supply Map

Case Study: Norepinephrine

Norepinephrine is the foundation of resuscitation medicine, and shortages of it create a vulnerability that is simultaneously a civilian health-care crisis and a military readiness concern. Norepinephrine, which can treat life-threatening low blood pressure and sudden shock, is used in the vast majority of U.S. hospital trauma cases, is dependent on foreign API, and is constrained by aging domestic sterile injectable manufacturing. COVID-era shortages have already demonstrated system failure under stress without any adversarial trigger.[61]

Why This Product Is a National Security Concern

Norepinephrine is essential across military field care, civilian emergency rooms, intensive care units, and operating rooms, and is core to cardiac arrest algorithms. It is one of the most operationally critical hospital drugs, and supply disruption would simultaneously impact the broadest and most acute ends of the patient care spectrum. It appears on essential medicine lists from the DOD, the Administration for Strategic Preparedness and Response (ASPR), and the FDA.[62]

Shortages translate directly into preventable deaths: during the 2011 U.S. norepinephrine shortage, a study confirmed a 3.7 percent increase of in-hospital mortality among septic shock patients.[63] COVID-era shortages demonstrated how easily the supply chain fails under demand stress even without the prompting of an adversary, and instead can be strained by fragile just-in-time inventories and opaque global sourcing.

Structural Vulnerability

Norepinephrine's core vulnerability stems from two compounding factors that cannot be independently addressed: dependence on foreign API sources that, in turn, rely on KSMs from China, and domestic sterile injectable manufacturing capacity constraints. Resolving one without the other still leaves the supply chain exposed.

Sterile injectable production requires capital-intensive high-precision aseptic manufacturing, yet capable U.S. facilities for manufacturing this low-cost generic are aging and operating on margins too thin to support modernization or expansion. Robust competition keeps the prices

for norepinephrine low, creating no commercial incentive to invest in the quality or resilient supply beyond what is needed for FDA minimum standards. The just-in-time production and inventory model for norepinephrine is a structural consequence of margin pressure, not an operational choice that individual actors can unwind absent policy intervention. Minimal redundancy exists in the domestic manufacturing base, and even a single plant failure can collapse national availability.[64] Those manufacturing constraints are compounded upstream: heavy reliance on foreign APIs from regions vulnerable to coercion from China for their upstream KSM supplies means that even a functioning U.S. fill-finish operation remains exposed to input disruption.

Case Study: Acetaminophen

Acetaminophen, the most widely used analgesic in the United States, shares the upstream concentration risk of the cases above but has one important difference: separate over-the-counter (OTC) and prescription drug markets that together obscure the extent of U.S. dependence on China.

Why This Product Is a National Security Concern

Used by fifty-two million Americans every week and on the emergency medicines list for the HHS, FDA, and WHO, acetaminophen's scale of dependence has no true equal among the other products in this study.[65] Broad OTC access serves a preventative function—keeping patients with mild-to-moderate pain and fever out of emergency rooms—meaning supply disruption would generate downstream pressure on health-care infrastructure, not merely inconvenience consumers. It is consistently stocked in military field hospitals and deployed medical units, critical for troop readiness, and embedded in multimodal pain management protocols combining it with opioids across civilian and military surgical and trauma care.

Structural Vulnerability

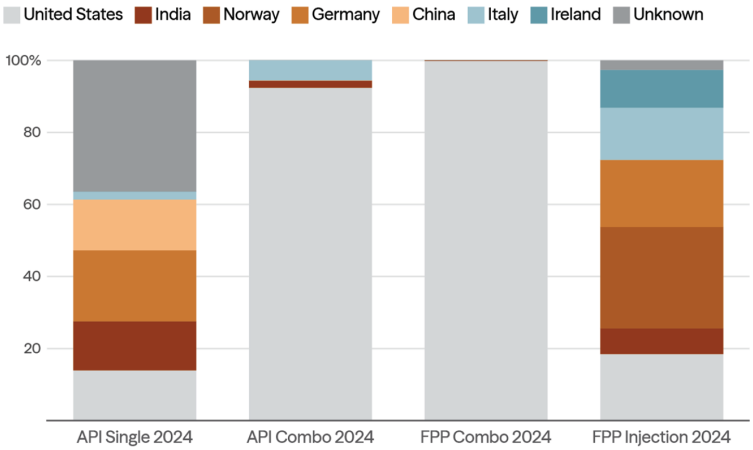
Although domestic finished-product manufacturing creates the appearance of resilience, 55 percent of global acetaminophen API comes from China and relies on a small number of primarily Indian FDF manufacturers.[66]

Meanwhile, the supplies for the higher-cost prescription version of acetaminophen are made domestically, again creating the perception of U.S. resilience. As acetaminophen is sold predominantly as an OTC product under domestic brand names, the fragility of its supply chain is masked by normal market mechanisms. Retailers see competitive prices, consumers see familiar labels, and the concentration risk remains unpriced and uncorrected. Like amoxicillin and norepinephrine, the OTC market structure provides no commercial incentive to correct this vulnerability: high-volume private-label demand from major retail chains, funneled through GPOs, suppresses margins throughout the supply chain.

In contrast, according to USP Medicine Supply Map data, the API market for higher-margin prescription opioid-combination formulations (e.g., acetaminophen/codeine) is almost entirely U.S.-based, as the figure below shows. This market segment, however, represents only a small fraction of total acetaminophen demand. Whether these domestic API suppliers could absorb broader market demand under a stress scenario remains unclear, creating a critical surge capacity gap with no clear corrective mechanism. Switching from one API supplier to another is not straightforward because the particle-size distribution for API for pediatric formulations is different than other versions.

U.S. Acetaminophen Finished Products Are Domestically Sourced; API Supply Is More Fragmented

Share of U.S. market by country, acetaminophen finished products and API, 2024



Notes: FPP market share data has some author approximations built in; FPP combo formulations include hydrocodone, oxycodone, codeine, butalbital, and tramadol combos; FPP OTC single-ingredient (oral) excluded due to unknown manufacturer origin. API data based on a nonstandard data source using U.S. import and Indian export data.

Source: U.S. Pharmacopeia Medicine Supply Map

An Industrial Policy for Archetype One: Near-Term Management of Acute Risks Combined With Longer-Term Market and Supply Creation

A credible Archetype One industrial policy—addressing choke points at the raw material or KSM level on which all downstream suppliers depend—needs to combine near-term risk management with integrated longer-term market and supply creation. The goal is targeted resilience: minimizing China's opportunity to extract strategic gains from weaponizing U.S. supply chains rather than reshoring all production or replicating the China model.

Without also addressing upstream KSM, excipients, and intermediates, onshoring API alone will not significantly reduce the China risk to Archetype One medicines like amoxicillin or heparin. Equally, securing upstream inputs will not prevent shortages absent excess aseptic fill-and-finish capacity to transform those inputs into sterile injectables such as norepinephrine. Eliminating the full end-to-end risk of a China shock requires coordination across KSMs, intermediates, API, and finished product—sustained by a multiyear industrial policy that outlasts election cycles.

Priority should go to essential medicines imported directly from China and where China holds concentrated market dominance, as those products and inputs are most susceptible to weaponization. Our analysis suggests, for example, that the United States depends on imports from China for mycophenolate mofetil, dobutamine, and cefepime, which appear on multiple U.S. essential medicines lists and the essential medicines list for the WHO.[67] Heparin also warrants priority: the U.S. imports nearly a quarter of its FDF supply from China and relies on China for 42 percent of its API and three-quarters of the crude heparin used in U.S. medicines.

Amoxicillin, acetaminophen, and norepinephrine are examples of medicines appearing on both U.S. and WHO essential medicine lists where China dominates upstream inputs, but whose supply is exported through a third country rather than directly to the United States.[68] Leveraging this exposure requires China to entice or compel that third country—typically India. This might occur when a supply shock in China restricts KSM and other inputs for essential medicines and the Indian government prioritizes its domestic population, as India did during COVID-19.[69]

Near-Term Management of Acute Risks

Over the next two years, the federal government should use the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR) or a similar strategic reserve mechanism to stockpile a minimum six-month supply of critical KSMs and APIs most at risk of weaponization from China. At the same time, the United States should enter into arrangements with FDA-approved allied (non-China) API suppliers for each of those medicines and have a clearly defined expedited pathway for temporary importation to improve buffer capacity. Finally, the United States should establish risk communication protocols for essential medicine shortages to reduce panic and hoarding by states, hospitals and other institutional purchasers, and patients.

Create a functional ecosystem for a strategic reserve of KSMs and APIs for priority critical medicines. Stockpiling has been explored by the United States at two stages of the pharmaceutical supply chain: FDF and API. FDF stockpiling, as practiced in the Strategic National Stockpile, enables immediate deployment during a crisis without downstream manufacturing, benefiting from preexisting regulatory approvals. Drawbacks are significant, however, including shorter shelf lives (one to five years), higher storage and cold-chain costs, limited formulation flexibility, and a design oriented toward health emergencies rather than weaponization scenarios.

SAPIR was launched in 2020 in response to the COVID-19 pandemic. It has promise: APIs and KSMs usually have longer shelf lives and lower storage costs than FDFs and can be converted into multiple FDFs when necessary. ASPR, which oversees the SAPIR, was intended to identify at-risk APIs and stockpile critical ingredients in U.S.-based GMP-compliant facilities. To convert those APIs into FDFs, it relied on a distributed network of sterile fill-and-finish facilities where FDFs were packaged for distribution. Instead, SAPIR languished largely unfilled and underfunded during the Biden administration.[70] The Trump administration is seeking to revitalize stockpiling active ingredients for some top priority medicines, but without a supporting ecosystem, this effort will fall well short of more expansive resilience goals.[71]

The SAPIR depends critically on an FDA-approved finished-dosage manufacturing network positioned to rapidly convert APIs into labeled medicines—with all regulatory approvals already in place. Certain manufacturers will also require liability protection before using stockpiled APIs and KSMs outside their control.

True resilience requires a layered approach: API reserves combined with formulation capacity and targeted FDF buffers. Stockpiling protects

against disruption but cannot resolve the underlying structural concentration that makes weaponization possible—only supply diversification can.

Congress should direct and appropriate funds for ASPR to purchase at least an eighteen-month supply of essential KSMs and APIs for the existing SAPIR facility under a dynamic life-cycle rotation program.[72] ASPR, working with the FDA and HHS, should then coordinate and fund a distributed network of aseptic filling sites—equipped with robotics, isolator technology, and single-use systems—capable of rapidly converting stockpiled APIs into finished drug products during shortages or emergencies.

Create allied coordination mechanisms for KSM production to distribute geographic risk, including regulatory cooperation. API manufacturing is largely offshore, and not just in China. The United States should leverage alliances to reduce shared pharmaceutical dependence on China—preventing shortages and limiting China's ability to weaponize supply chains through third countries. Allies should equally be able to rely on U.S. strategic posture as part of their own pharmaceutical supply chains.

The United States should facilitate and rely on cost-competitive allied API production rather than seeking to replicate China's full capacity domestically. Fortunately, some allied governments are already taking steps to reduce their dependence on China. The European Union, under the Critical Medicines Act, has expedited approvals for manufacturing certain medicines dependent on Chinese supply chains.[73] Japan is restarting and upgrading its production of critical antibiotics produced via fermentation.[74] India has recently launched incentive schemes to build domestic capacity for KSM, intermediates, and APIs.[75]

In February 2026, the Office of the U.S. Trade Representative (USTR) sought comments on a plurilateral critical minerals trade bloc offering preferential terms to partners and discriminating against Chinese-processed material. A similar arrangement, paired with mutual recognition agreements, could enable allied sharing and purchasing of critical KSM and API stockpiles.[76]

Finally, the FDA should more readily authorize temporary API importation from well-regulated allied markets. Although that is already permitted, the FDA only does so as a last resort after months or even years of delay. The agency should proactively identify and assess foreign sources for essential medicines where China holds a concentrated market dominance.

Risk communication plans are part of U.S. supply chain resilience. The ASPR, the Centers for Disease Control and Prevention (CDC), and state and

local public health agencies need pre-positioned plans for communicating essential drug shortages to the public, hospitals, and clinicians to prevent the panic buying and misinformation that may itself be China's coercive goal.[77] The National Academies' report on the 2022 infant formula shortage affirmed that communication and expectation setting are core components of supply chain resilience.

Longer-Term Demand-Side Interventions

The U.S. federal government has tools, such as the Department of Health and Human Services' (HHS) Defense Production Act (DPA) Title III Program, to subsidize the resiliency, diversity, and security of supply chains and to offer grants, tax incentives, loans, and loan guarantees for domestic manufacturing of many key pharmaceutical inputs. Some states have sought to go further and proposed directly manufacturing generic drugs.[78] But new or expanded capacity resulting from public investments may not continue long term as market demand for the product changes. For example, a company that received Title III funds to boost production of medical swabs for COVID-19 testing closed manufacturing sites in 2023 after a drop in demand.[79]

Over the next three to five years, policymakers should pursue a coordinated mix of longer-term demand and supply interventions—not just isolated fixes—to make domestic or allied production of KSM, API, and other upstream inputs economically viable and sustainable. The goal of those medium-term efforts should be to maintain at least 25 percent non-China KSM sourcing for essential medicines and inputs, such as amoxicillin (6-APA), heparin (crude mucosa), and norepinephrine API, and verify that sourcing through mandatory country-of-origin disclosure to FDA.

Require targeted API and KSM sourcing disclosure and labeling. The existing U.S. regulatory framework was not designed for upstream KSM or API transparency. The FDA requires only the name and place of business of the manufacturer, packer, or distributor on drug labels—not manufacturing locations—and officials acknowledge the agency cannot precisely determine China's actual API export volumes.[80]

U.S. agencies have even less information on KSM manufacturers. The Drug Supply Chain Security Act of 2013 focused on finished-dose traceability, not upstream sourcing. Trade data lacks the granularity of customs bills of materials, which have some of the proprietary information companies closely guard. Data sharing even among fellow HHS agencies on

drug sourcing and utilization is constrained. Defense Production Act surveys provide only point-in-time snapshots, not the dynamic visibility that supply chain management requires.[81]

Visibility into manufacturing locations is essential to supply chain risk management.[82] Without it, hospitals, clinics, and retail pharmacies cannot know if a drug is made in a flood-prone location, a country with a history of export restrictions, or a facility with previous FDA quality violations, limiting their ability to anticipate other supply vulnerabilities, not just the threat of Chinese coercion.

Numerous stakeholders have recommended mandatory COOL for APIs on retail and wholesale labels.[83] A new U.S. Customs and Border Protection (CBP) directive now requires pharmacy-repackaged drugs sold to retail customers to bear COOL markings and importers to certify they will notify pharmacies of their requirements.[84] Implementation, however, remains contested: pharmacy associations argue that dynamic API and KSM sourcing makes labeling impractical. Legislation pending in Congress would extend COOL requirements to all U.S.-sold pharmaceuticals—FDFs and APIs—across the full supply and distribution chain.[85]

Those barriers are not insurmountable. New Zealand maintains a functional public national pharmaceutical supply chain data system. A phased, tiered approach offers a workable path forward, beginning with confidential, product-specific mandatory disclosure to regulators for essential medicines and then building toward aggregate public reporting and labeling consistent with BIOSECURE Act compliance requirements.

Bolster KSM- and API-level domestic investment, with well-defined Buy America terms that account for transshipment. Buy America provisions through Veteran Affairs (VA), the DOD, and Medicaid could create stable baseline demand for domestic and trusted allied APIs and KSMs. Medicare Part B should help offset higher U.S. manufacturing costs through more generous hospital reimbursement rates for domestically sourced products. Medicare Part B offering a premium reimbursement for domestically sourced medicines and inputs could have broader impact, with commercial payers and insurers using Medicare as a benchmark in determining reimbursement standards. The Centers for Medicare and Medicaid Services (CMS) used this model for N95 respirators, with additional payments for domestically manufactured products approved by the National Institute for Occupational Safety and Health, although burdensome requirements undermined uptake. A version of that basic model should be adapted for KSMs and APIs.

Defining and verifying whether the output is "U.S.-manufactured" has been the central difficulty of using volume guarantees, Buy American provisions, and price premiums from the DOD, VA, and CMS to create predictable demand for domestically sourced APIs. A 2023 DOD report found that 54 percent of DOD-sourced national drug code (NDC) medicines were noncompliant with the Trade Agreement Act, actually derived from China, India, or unknown origins via transshipment and repackaging.[86] Policymakers must create clear standards for required shares of domestic API production and FDF manufacturing, with reliable CMS, hospital, and GPO tracking mechanisms to determine eligibility for additional payment. Extending preferences to trusted allied sources in well-regulated markets is also advisable, in part because shifting to an exclusively Buy America provision risks near-term shortages.

CMS could also preference Medicare Part B reimbursement of domestically sourced porcine or bovine API to offset import cost disadvantages. Expanding U.S. porcine mucosa collection would require USDA and FDA coordination on slaughterhouse practices, animal byproduct handling, traceability, and pharmaceutical-quality requirements, with subsidized capital for collection and preprocessing infrastructure. Funding from the Defense Advanced Research Projects Agency (DARPA), Biomedical Advanced Research and Development Authority (BARDA), Advanced Research Projects Agency for Health (ARPA-H), National Institutes of Health (NIH), National Science Foundation, and FDA could simultaneously accelerate new sources of synthetic and bovine heparin. In strategic cases, the federal government could consider equity purchases or direct investment in domestic heparin manufacturers.

Longer-Term Supply-Side Interventions

Target pharmaceutical tariffs on medicines containing APIs and KSMs from China. A tariff targeting products containing Chinese-sourced KSMs and APIs would be administratively difficult but would capture the actual points of dominance and national security risk, incentivizing production shifts to lower-cost allied sources.[87] In contrast, blanket tariffs on imports of generics would only worsen U.S. pharmaceutical insecurity, disrupting supplies of essential chemotherapy agents, penicillin, and sterile injectable medications that are low-margin, complex to make, and hard to reprice under Medicaid, Medicare, and long-term hospital contracts.

Support investment in advanced manufacturing technologies and U.S. production. KSM and API production will not sustainably attract private investment to the United States or trusted allies without cost competitiveness at scale and greater demand certainty. Advanced manufacturing technologies (AMTs)—including continuous flow manufacturing (which uses automated processes to cut down on production time) and green chemistry (which lowers environment costs by using biocatalysts)—already exist and can improve reliability, quality, and cost efficiency. Yet manufacturers resist adopting AMTs for low-margin generics because of their up-front cost and regulatory uncertainty. The U.S. government should deploy coordinated public R&D investment, tax credits, and push-pull regulatory incentives to spur that adoption, prioritizing projects with measurable improvements in yield, quality, and energy efficiency. NIH, BARDA, and ARPA-H funding can provide the needed support for scaling up capital-intensive fermentation. Novel precursors such as ARPA-H's WHEAT initiative have demonstrated the feasibility of this approach.[88] Public-private partnerships could help introduce AI-driven process optimization and predictive analytics to improve API and KSM production efficiency and identify potential quality issues proactively.

In 2022, Congress authorized an advanced manufacturing technology program, enabling the FDA to designate technologies outside product applications and provide expedited review incentives for adopters. Uptake, however, has been limited. The FDA should clarify how regulatory frameworks designed for conventional manufacturing should be applied to AMTs and update AMT designation guidance to expand incentives, reducing regulatory uncertainty as a push to adoption.

Extended market exclusivity is a pull incentive that improves long-term returns for higher-cost domestic manufacturing; that is, advance purchase commitments reduce demand uncertainty for fermentation-based facilities. The FDA's National Priority Voucher pilot, recently applied to Augmentin extended-release capsules for a U.S. manufacturer, offers a potential model, though its real-world impact remains to be assessed.[89]

Other risk-sharing mechanisms include multiyear tax credits for API and biologics facility investment, subsidized AMT equipment financing, and accelerated depreciation for pharmaceutical infrastructure. Sandoz's fully integrated KSM-to-FDF plant in Kundl, Austria, proves coordinated action can resolve dependence on Chinese sources. A modest 50 million euro grant from the EU enabled enzymatic synthesis upgrades at this facility, making it cost-competitive with Chinese 6-APA and API sources.[90]

Expand production to lower-cost, more reliable allies and leverage API and KSM incentive programs in Japan and Europe. The U.S. International Development Finance Corporation (DFC) and the Export-Import Bank should extend low-interest financing to projects that build API and KSM capacity in lower-cost allied nations. Geographic diversification of the U.S. supply chain should explore friendshoring partnerships with Argentina, Brazil, and Mexico. Within five years, the ASPR, DFC, and FDA should collaborate on the goal of completing qualification of at least one allied-nation KSM/API supplier for each U.S. priority essential medicine. Within a decade, the U.S. goal should be ensuring that there is domestic or allied production capable of meeting at least 50 percent of the normal U.S. demand for priority products' KSMs or APIs.

Archetype Two: Erosion of U.S. Biopharmaceutical Manufacturing and Clinical Trial Capacity to China

The defining characteristic of Archetype Two is systemic competitive displacement of the United States across the full value chain for key innovative biotechnology products—R&D, clinical development, contract research and data management organization services, and commercial manufacturing—enabled by state-backed industrial policy at a scale and speed that U.S. market forces cannot match. These products require a "whole of value chain" industrial strategy, including robust federal investment in foundational R&D.

Case Study: Monoclonal Antibodies

Monoclonal antibodies (mAbs) are an innovative product class deployed in cancer immunotherapy, autoimmune treatment, and antiviral therapies, with a global market exceeding $380 billion.[91] Monoclonal antibodies represent the case study of this archetype: emerging dependence on China where the vulnerability is most advanced and the trajectory most alarming. The value chain does not suffer from a specific upstream choke point but rather systemic competitive erosion across every stage—discovery, development, manufacturing, and market access—enabled by state-backed Chinese industrial policy operating at a scale and speed that U.S. market forces and fragmented government policy have not matched.

Why This Product Is a National Security Concern

Beyond their important everyday uses, mAbs are employed in response to pandemics and biological threats, including Ebola and anthrax. Supply disruption of inputs and finished mAbs products would cascade across most critical hospital treatments simultaneously. The COVID-19 pandemic previewed this fragility when capacity constraints forced direct government intervention to secure raw bioreactor materials and single-use components.[92] New manufacturing facilities for mAbs require up to eight years to build, making domestic recovery impossible on any crisis-relevant timeline. The global biotechnology market is forecasted to reach more than $9 trillion by 2035.[93] A recent CFR task force on U.S. economic security highlighted biotechnology as one of the most critical domains for U.S. economic and national security, warning that the United States is wielding last century's tools in a twenty-first-century era of economic warfare.[94]

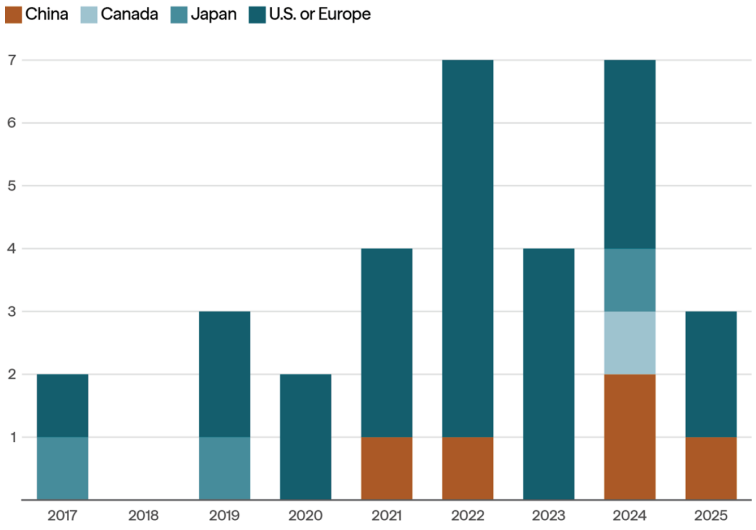
Structural Vulnerability

The risk of systemic competitive erosion across the entire value chain categorically distinguishes mAbs—and Archetype Two cases generally—from the upstream concentration risks of Archetype One. The risk of dependence, however, is the same. Over the past decade, China has deliberately built end-to-end biomanufacturing capacity, with WuXi Biologics as the primary vehicle. Its "Win the Molecule" model integrates services from discovery through commercial manufacturing, capturing U.S. client programs early and deepening dependence at every subsequent stage.[95] A Biotechnology Innovation Organization survey found 79 percent of pharmaceutical companies use WuXi or other Chinese manufacturers, reflecting accumulated manufacturing know-how and client relationships that cannot be quickly unwound.[96] WuXi alone added nearly 209 new integrated projects in 2025, roughly half from U.S. clients, and manages 74 late-stage and 25 commercial manufacturing projects.[97] The scale and efficiency of WuXi's model creates switching costs for firms that compound as development programs advance, and structural dependence that cannot be quickly reversed even when individual companies wish to do so.

The most alarming indicator rests in late-stage clinical data. At the Phase 3 level—the most direct leading indicator of immediate commercial competition—our analysis shows that Chinese firms hold roughly thirty-two of fifty-five mAb programs globally. The late-stage pipeline of this promising therapeutic class is increasingly a China story.

The U.S. and Europe Still Lead mAb Approvals, but China's Presence Is Growing

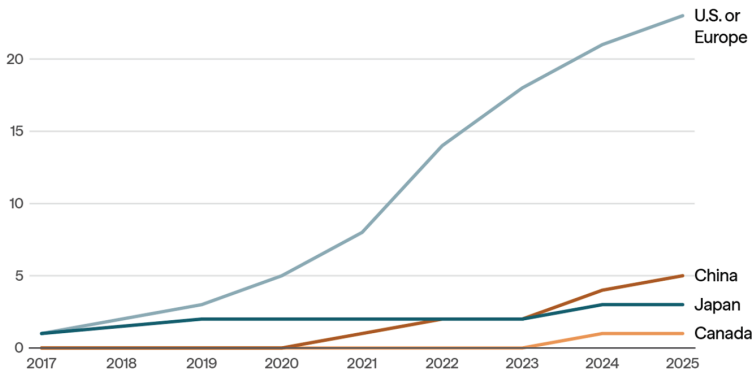
Global monoclonal antibody approvals by region of origin, by year of first global approval, 2017–25



Source: Nature Reviews Drug Discovery

The U.S. and Europe Still Dominate Global mAb Approvals, but China Is Accelerating

Cumulative global mAb approvals by region of origin, 2017–25

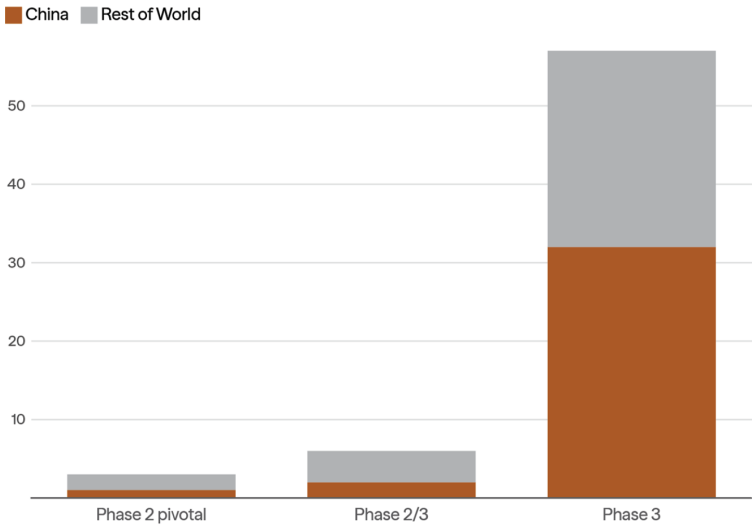


Source: Nature Reviews Drug Discovery

China biotech licensing activity surged to $137.7 billion in 2025, a tenfold increase from 2021.[98] Biosimilars—similar, FDA-approved versions of existing biologic drugs—are the near-term future of the mAb market. Chinese manufacturers hold no current U.S. market share but have already obtained FDA approvals, positioning them for biosimilar entry as patents expire. Meanwhile, China has reduced its own upstream supply chain exposure by developing domestic alternatives to U.S. or European sources of single-use bioreactor bags, filters, and cell culture media. Meanwhile, U.S. and European dependence on Chinese contract research and manufacturing has only deepened and become more entrenched.

China Has Nearly as Many Monoclonal Antibodies in Phase 3 Trials as the Rest of the World Combined

Number of mAbs per region group by most advanced development phase



Source: Nature Reviews Drug Discovery

China could feasibly weaponize the emerging dependence in this product class to create economic, strategic, and political leverage. It could directly choke off supplies of an innovative medicine or countermeasure developed and manufactured in China on which U.S. patients have come to rely. The competitive loss of U.S. capacity to China at every stage of the value chain—discovery, development, manufacturing, and market access—also undermines U.S. economic security and capability to produce in a timely way the effective countermeasures and cancer medicines on which many Americans depend.

Chinese Firms Account for Over a Quarter of the Late-Stage mAb Pipeline

Late-stage clinical mAbs by company, number of candidates



Source: Nature Reviews Drug Discovery

The U.S. policy response has been inadequate to this emerging dependence. The BIOSECURE Act, intended to address Chinese penetration of U.S. biopharmaceutical supply chains, was significantly diluted by the time it was enacted in December 2025. Even where legislative intent exists, commercial entities generate resistance sufficient to weaken policy before it takes effect.[99]

An Industrial Policy for Archetype Two Biologics: A Whole-of-Value-Chain Response

A credible Archetype Two industrial policy, which would address systemic competitive erosion across the full biologics value chain, needs to combine immediate interventions that reduce lock-in risk with future investments that rebuild U.S. and allied competitive capacity. All four pillars of the value chain should be addressed: R&D; clinical and regulatory science; manufacturing assets; and biologics workforce and data infrastructure. Any industrial policy should also ensure that secure U.S. and allied alternatives are commercially viable—not merely asking private firms to absorb concrete higher costs for abstract national-security benefits or compromising patient access.

The challenge is that China is building end-to-end biomanufacturing capability while U.S. market actors are optimizing for cost, speed, and convenience. Private life sciences firms and clinical trial sponsors have strong incentives to use established China-based or China-owned contract research, development, and manufacturing organizations (CRDMOs) for their integrated services, rapid execution, and lower costs. Market forces are more likely to deepen that dependence than correct it. The right time to address this emerging "rare earths"-type dependence in the U.S. pharmaceutical supply chain is now, before it fully arises.

Near-Term Interventions

Make the BIOSECURE Act the floor, not the ceiling, in sustaining U.S. biotech supply. Implementation of the BIOSECURE Act is a necessary first step but does not fully resolve private-sector dependence, especially in biologics programs that are not yet federally procured but could become critical to U.S. public health, defense, or pandemic preparedness. Where national security is at stake—including medical countermeasures, pandemic-response platforms, and strategically important antibody or protein therapeutics—HHS, BARDA, DOD, NIH, and other funders should require China-risk plans across the board. Those plans should mandate qualification of an alternate U.S. or allied CRDMO before a predetermined development milestone. Contractual terms should also preserve technology-transfer rights, escrow or portability of process data, and contingency plans for relocating clinical or commercial production before

pivotal trials or launch. This approach reduces lock-in with Chinese service providers without the potential chaos from forcing a sudden rupture.

Pilot a U.S. first-in-human trial acceleration model. The United States should create a first-in-human biologics acceleration pilot at the FDA and invest in clinical trial capacity at designated university medical centers and academic health systems of excellence, targeting shorter trial start-up timelines while maintaining strict scientific, ethical, and safety governance.

The FDA's pre-investigational new drug (IND) application and processes create significant uncertainty for U.S. trial sponsors, leading them to over-engineer study designs to avoid the risk of clinical holds after IND submission and delays. Each trial site could have its own institutional review board (IRB) that reviews the clinical trial application and any subsequent substantial amendments. Approximately 2,300 U.S.-based IRBs currently exist. The combination of regulatory uncertainty and cumbersome processes make U.S. trials slower to initiate and more time-consuming to conduct, leading sponsors to look abroad for these critical FIH trials that establish potential commercial viability and are a crucial funding milestone for many early biotech ventures.

Australia and Norway each offer potential models. Australia accelerates first-in-human and early-stage trials through a risk-based clinical trial notification (CTN) and clinical trial application pathway, with the latter reserved for high-risk, novel therapies. Australia also offers a national single-application and tracking infrastructure (National One Stop Shop) as well as standardized operating procedures—streamlining timelines while preserving governance through mandatory IRB approval and drug regulatory inspection and backstop powers. Norway's NorTrials program serves as a public-private national entry point linking industry sponsors with hospitals, feasibility support, central ethics committees, and funded clinical trial centers.

The U.S. Lags on Clinical Trial Start-Up Times

A U.S. pilot can adopt operational features of the Australian and Norwegian models to streamline its trial start-up timeline, without sacrificing scientific, ethical, or safety governance.

Country / system	Startup timeline / key feature
United States	30-day IND review + multi-site IRB (avg. ~145 days local model); hospital contracting adds further delays
Australia (CTN)	6-12 weeks from notification to first patient enrolled for lower-risk studies
Australia (CTA)	Advance review by the Therapeutic Goods Administration (TGA) plus HREC. Used for high-risk, novel treatments with limited safety data.
Norway (NorTrials)	Single-point public-private access; streamlined consent and contracting
China (NMPA)	30 working-day IND review (cut from 60 in April 2025); 2-3x faster enrollment due to large patient pools

Sources: FDA; Tufts CSDD; TGA; Synergy BioPharma; NorTrials.no; Business Norway; NMPA; Pharmaceutical Executive; Clinical Leader

A U.S. pilot should adopt operational features of these two models without undermining patient safety or the scientific integrity of the trial. Congress and the FDA should also consider authorizing a narrow, optional CTN-like pathway for well-characterized drug platforms or lower-incremental-risk early studies, coupled with the FDA's call-in authority, suspension authority, and strict eligibility criteria. A NorTrial-like approach to investing in U.S. university and hospital trial sites could boost capacity while ensuring the distribution of those sites supports the scientific objectives of a diverse trial subject population that can draw from rural areas as well.

Incentivize adoption of advanced biologics manufacturing technologies. The foundation of the U.S. system of biomedical innovation has been its partnerships between U.S. universities, entrepreneurs, and large drug firms, as well as its openness to tapping the best talent from abroad.[100] That system is under siege and must be preserved and bolstered. Reducing the regulatory and commercial uncertainty that firms face when switching from legacy processes to adopt new technologies can help. The FDA should reduce this friction around adopting new technology by providing

model comparability protocols for assessing new technologies and expedited review of post-approval manufacturing changes. The FDA's existing Advanced Manufacturing Technologies Designation Program recognizes but does not fully resolve this inertia. On the demand side for a limited period, Medicare could pay a modest additional amount for qualifying biologics that meet defined manufacturing-resilience criteria. This could create incentives for manufacturers to accelerate the adoption of new technologies such as continuous manufacturing.

For biologic assets with national-security relevance, the FDA, BARDA, DOD, ASPR, and NIH should require trial sponsors and manufacturers to disclose critical supplier risk beyond the first tier. Covered inputs should include cell banks, plasmids, vectors, media, resins, filters, single-use bags and tubing, vials, stoppers, cold-chain inputs, analytical reagents, and quality-control assays. Disclosure requirements should focus on single-source dependencies, suppliers in foreign countries of concern, and inputs whose loss would materially delay clinical development, scale-up, or commercial supply.

Long-Term Interventions

Build allied-country CRDMO alternatives. The Development Finance Corporation should finance a portfolio of trusted CRDMOs in allied and partner countries. Though these would not immediately replicate the scale or integration of the largest China-based providers, they could create a healthier, more competitive market for biologics development and manufacturing services. DFC loans should target infrastructure expansion in allied country CRDMO networks where China risks are the highest.

Fund and authorize a National Biologics Manufacturing Excellence Center. The United States should establish a National Biologics Manufacturing Excellence Center to build the workforce and technical capabilities needed for advanced biologics production. Working with universities, community colleges, trade colleges, the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), and industry, the center should link classroom training, hands-on pilot-scale facilities, apprenticeships, and employer-recognized credentials to close existing U.S. workforce gaps.

Build AI-ready biodata and digital CMC infrastructure. Future competitiveness in biologics will depend heavily on data and artificial intelligence (AI) readiness. Building on the U.S. Data for the Bioeconomy Initiative, the White House should create an interagency effort, coordinated by the

Office of Science and Technology Policy (OSTP) but involving HHS, FDA, NIH, National Institute of Standards and Technology (NIST), and BARDA, to develop a secure, AI-ready biodata and digital chemistry, manufacturing, and controls (CMC) initiative for comprehensively developing, producing, and testing biologics.[101] The initiative should standardize data provenance, metadata, batch records, analytical methods, process-development data, and comparability datasets so that advanced analytics and AI tools can accelerate process development, technology transfer, regulatory review, and manufacturing troubleshooting.

Archetype Three: Dependence on China for the R&D Infrastructure for Sensitive Biotechnology

The defining characteristic of Archetype Three is vulnerability not in manufacturing fragility for existing drugs but losing control over R&D infrastructure underlying future pharmaceutical innovation, compounded by biosecurity risks accelerating with AI-driven sequence generation. Policy responses need to focus on biosecurity screening standards, intellectual property (IP) protection, and investment to create parity for U.S. synthetic biology platforms.

Case Study: Synthetic DNA

Synthetic DNA occupies a categorically different position from the other five case studies in this report: the vulnerability is centered on ongoing control over the R&D infrastructure that will underlie future pharmaceutical innovation on synthetic DNA, combined with biosecurity and IP risks that will grow more acute as AI-driven sequence generation accelerates.

Unlike prior case studies focused on supply disruption of existing products, the risks here are primarily forward-looking: control over synthetic DNA inputs and process is inseparable from control over the trajectory of U.S. biotechnology broadly. The Australian Strategic Policy Institute has a Critical Technology Tracker stretching back two decades that assesses "technology monopoly risk" as measured by concentration of scientific and technological research expertise within a single country. Synthetic DNA received the highest rating for risk of monopolization by China, just ahead of novel antivirals and antibiotics.[102]

Why This Product Is a National Security Concern

Synthetic biology—which leverages synthetic DNA sequences composed of individual nucleotides, the chemical building blocks of DNA—entails scientists designing, building, and testing synthetic DNA sequences in fields as varied and important as agriculture, industrial manufacturing, and therapeutics. DNA synthesizers allow researchers to make everything from heat-resistant crops to vaccines at the cost of just tens of thousands of dollars. The global synthetic biology market is projected to grow from $18.9 billion in 2025 to nearly $70 billion by 2033.[103] As synthetic biology grows more sophisticated and scientists discover new ways to leverage the technology, control over the inputs and process becomes more important, especially as AI becomes capable of designing novel protein sequences and therapeutics.

Dependence on adversary-controlled sources of synthetic DNA creates exposure to intellectual property theft, data exploitation, and potential erosion of scientific dominance. China has already demonstrated an interest in accumulating genetic data—including through widespread COVID-19 testing, acquisition of U.S. genomic firms, and intra-PRC surveillance—suggesting its synthetic DNA industry is a potential intelligence vector.

Further, the programmable nature of synthetic DNA also makes it a potential tool of warfare: AI-enabled, mail-order synthetic DNA theoretically allows adversaries and bad actors to design, print, and build biological and chemical weapons with minimal effort.

Structural Vulnerability

Three firms—GenScript, Twist, and Integrated DNA Technologies—account for approximately 86 percent of global synthetic DNA supply, with WuXi as a major additional player. One of these firms—GenScript—is a Chinese company, while the other two have a significant presence in China.[104] In addition, the nucleotide inputs for synthetic DNA production, both in house and at scale, appear to be highly concentrated in China, although exact data on the scope of the problem is not available.

As U.S. researchers increasingly route research and manufacturing orders through Chinese CRDMO platforms, those firms accumulate expertise,

process knowledge, and build client relationships that deepen dependence over time—directly analogous to the offshoring dynamic that hollowed out small-molecule API manufacturing. Gradually, this dynamic helps raise Chinese biotech prospects at the expense of U.S. intellectual property and biotech research, as well as the nation's development and manufacturing capabilities. Next-generation enzymatic synthesis technologies from U.S. and European firms could eventually diversify supply but remain pre-commercial and offer no near-term relief.

Speed and IP protection drive synthetic DNA procurement decisions—as synthesis fidelity has improved, quality is relatively standard across commercial synthetic DNA providers, removing a competitive lever that might favor higher-standard U.S., Japanese, or European producers. The risks most consequential for national security—biosecurity exposure, IP theft, genomic data accumulation—are diffuse, abiding, and national in character, borne by the public rather than the purchasers whose sourcing decisions create the vulnerability. No buyer has a commercial incentive to pay premiums for stronger screening standards.

Menu of Industrial Policy Tools: Archetype Three

Archetype Three reflects a different type of vulnerability than the upstream concentration and value chain erosion seen in the previous archetypes. The risk is that China will rapidly acquire control over the synthetic biology R&D infrastructure itself. Nucleic acid synthesis is a critical control point in modern biotechnology, and federal policy has already recognized screening as a key mechanism for reducing the risks of bioweapons.[105]

Therefore, the objective of U.S. industrial policy should be to prevent synthetic DNA and broader synthetic biology infrastructure from following the same offshoring and concentration trajectory that eroded U.S. API manufacturing and increasingly threatens biologics. The risks in this case, however, extend beyond supply disruption and include genomic data concentration, IP theft, and potential biosecurity threats.

Effective policy responses should operate across three layers: transparency and screening of new uses and technologies to identify potential risks and prevent misuse; investment in viable domestic and allied alternatives; and demand-side coordination to ensure the commercial viability of secure and new technology-based sources.

Near-Term Interventions

Mandate DNA supply chain transparency and provenance disclosure. U.S. federal authority to oversee and set policy for DNA synthesis security is currently scattered across multiple agencies and offices, including the Office of Science and Technology Policy (which issued voluntary screening guidelines), the CDC (oversight of select agents), HHS and ASPR (which oversee preparedness), and the FBI. We agree with the National Security Commission on Emerging Biotechnology that the natural home for this activity is the U.S. Department of Commerce (DOC).[106] The DOC has already exercised partial jurisdiction over the DNA synthesis sector under the Export Control Reform Act of 2018 and the Export Administration Regulations.

The federal government lacks visibility into DNA synthesis supply chains at the commercial level. The Office of Science and Technology Policy's 2024 nucleic acid screening framework applied solely to federally funded research, leaving the broader commercial market unregulated.[107] By executive order, commercial DNA synthesis providers operating in the U.S. market should be required to disclose corporate ownership structures, nucleotide input sourcing by country of origin, and order-routing practices. This disclosure should indicate whether orders placed with U.S.-branded entities are fulfilled through facilities in foreign countries of concern such as GenScript's Singapore operations. The NIH, BARDA, and FDA should separately require that federally supported drug development programs disclose the source, ownership, and input provenance of synthetic DNA used in research, process development, and manufacturing. This parallels the Tier-N supplier risk disclosure recommended for biologics but applies to the R&D layer rather than the commercial manufacturing layer. Gradually, this data may enable FDA and Commerce to identify where synthetic biology input concentration is formed before it reaches the API-level dependence that characterizes Archetype One.

Mandatory biosecurity screening—performing sequence-of-concern checks against known pathogen and toxin databases—should be extended beyond federally funded research to all commercial DNA synthesis orders. If the Biosecurity Modernization and Innovation Act of 2025 were enacted, it would provide the legislative framework for doing so. Meanwhile, BARDA and NIH should condition procurement and grant funding on demonstrated compliance with screening standards, creating a de facto requirement for federally adjacent research. These screening standards

should apply to where a DNA sequencing order is fulfilled, not just where it is placed. This requirement would serve to prevent third-country transshipment from operating as a compliance workaround.

Evaluate export controls on advanced DNA synthesis technology. The DOC Bureau of Industry and Security should evaluate controls on advanced DNA synthesis equipment and enzymatic synthesis platform technology to prevent transfer of next-generation capabilities to Chinese firms before domestic and allied alternatives are commercially established.[108] Controls in this domain should therefore be paired with affirmative investment in U.S. and allied next-generation platforms (see Medium-Term Interventions), so that the window created by controls is used to build competitive alternatives rather than merely delay Chinese capability development.

Medium-Term Interventions

Invest in next-generation enzymatic DNA synthesis platforms. Current commercial synthetic DNA production relies mainly on phosphonamidite chemistry—a decades-old process that is cost-competitive at scale but depends on upstream nucleotide inputs heavily concentrated in China. Enzymatic DNA synthesis offers an alternative pathway operating under aqueous conditions, eliminating toxic chemical byproducts, and enabling longer, more accurate sequences. But it remains pre-commercial and hasn't yet reached the investment needed for broad adoption. ARPA-H and BARDA should fund a dedicated scale-up program for enzymatic synthesis platforms at U.S. and allied firms, structured as milestone-based contracts rather than open-ended grants, to accelerate the transition from laboratory demonstration to commercial viability.

Establish federal procurement preferences and offtake commitments for domestic and allied suppliers. Domestic and allied DNA synthesis capacity cannot be sustained on market economics alone if Chinese-linked competitors continue to undercut on price. BARDA, NIH, DOD, and ASPR should establish explicit procurement preferences and, where appropriate, advance purchase commitments or offtake agreements for synthetic DNA sourced from domestic or allied providers meeting defined biosecurity and provenance standards. NATO, which has a strategy for fostering responsible development of emerging biotechnologies and an innovation fund, could be a platform for these joint purchasing arrangements for defense and preparedness applications.[109] Such joint allied commitments would signal durable demand to potential investors in next-generation platforms and

prevent the market from consolidating entirely around the lowest-cost producers. Loan guarantees through the DFC or a domestic financing mechanism for capital-intensive platform investment by U.S. or allied firms can further help private firms raise capital for expanding DNA synthesis capacity.

Long-Term Interventions

Coordinate with allies on biosecurity standards and genomic data reference infrastructure. The United States should pursue harmonized biosecurity screening standards with key partners—including Australia, Canada, the European Union, Japan, and the United Kingdom—through existing frameworks such as the Biopharmaceutical Alliance, NATO, and emerging science-and-technology agreements. Harmonization should cover sequence-of-concern databases, screening methodology requirements, and provenance documentation standards, so that third-country routing cannot be used to circumvent requirements in any single jurisdiction. Coordination should also include reference biological material and "omics" data standards, thus ensuring genomics and other high-throughput biological data are interoperable and reproducible, reducing reliance on Chinese-linked platforms for foundational research infrastructure.

CROSS-CUTTING REQUIREMENTS FOR REDUCING U.S. SUPPLY CHAIN DEPENDENCE

Governance Continuity

The dependencies outlined in this report cemented over decades across multiple administrations because no single institution had both the mandate and authority to act. SAPIR, Section 232 trade investigations, and the Biopharmaceutical Alliance are not only reactive measures and siloed approaches, but they rest on reversible executive action or discretionary appropriations. The 2008 heparin contamination crisis resulted in FDA regulatory arrangements, including a memorandum of understanding with China's FDA, which failed to address the underlying supply chain concentration.[110] The COVID-era DPA invocations for medical supplies were not followed up with durable manufacturing investment.

Meanwhile, the experience of the CHIPS Act is instructive, converting executive intent into statutory support and dedicated funding. The large bipartisan funding commitment was paired with a White House–level mandate, a dedicated implementation office, and stable multiyear appropriations that attracted talent, created institutional momentum, and established reporting requirements that made both progress and failure visible, and forced cross-agency alignment.[111]

The vulnerability of the U.S. pharmaceutical supply chain spans FDA, DOD, HHS and ASPR, the Department of Commerce, and the Office of the U.S. Trade Representative, without a single cabinet agency fully owning it. Reform of the U.S. pharmaceutical supply chain has diffuse stakeholders—patients, hospitals, GPOs, generic drug importers, pharmaceutical benefit managers—with sometimes competing agendas. Effective supply chain coordination is essential for items with national security implications as coordination failures between firms and fragmented government agency oversight lets dependencies and vulnerabilities go unaddressed. A

dedicated coordinating body should sit at the White House level comparable to the National Security Council, Domestic Policy Council (DPC), or the National Economic Council to mandate action across agencies. It must be empowered to solve problems, not merely coordinate: directing agency timelines, fast-tracking regulatory approvals for new KSM and API suppliers, triggering emergency import pathways, overseeing the criteria for SAPIR procurement, and coordinating allied frameworks.

A U.S. Infrastructure for Measurement and Early Warning

These documented dependencies were visible in trade data and investigational new drug (IND) or abbreviated new drug application (ANDA) submissions for years before they reached crisis level. The United States simply lacked an institution with the mandate to look, the data infrastructure to see, and the authority to act on what it found.[113] Without a strong monitoring function, even adoption of archetype policy tools recommended in this report will fall short—reacting to today's vulnerabilities while allowing new ones to form undetected.

The barrier is organizational, not informational. The FDA should systematize IND, ANDA, and Drug Master File submission data that already exists on API and KSM manufacturing sites into a searchable database, accessible across coordinated agencies. Its mandate should include publication of an annual pharmaceutical competitiveness index tracking U.S., allied, and Chinese capabilities tier by tier. That would serve as an early-warning function that, had it existed, would have been capable of flagging forming dependencies in real time.

A monitoring function—similar to the publication of a drug shortage list but operating one to two tiers upstream—should flag markets at risk of developing vulnerabilities before they occur. Where concentration exceeds defined thresholds, FDA and the U.S. Department of Commerce should be required to notify the national security apparatus and initiate a remediation timeline.

Finally, the bilateral trade data comparison methodology utilized in this report (surfacing transshipment by comparing nominal and actual country of origin) should be institutionalized as a regulatory tool by FDA and DOC, rather than leaving it to academic or policy publications.

Allied Coordination as Force Multiplier

The Biopharmaceutical Alliance and the EU Critical Medicines Act represent meaningful commitments on paper, but without shared inventories, crisis allocation rules, mutual inspection recognition, and joint purchase commitments, allied coordination functions as a consultative forum, not a supply guarantee. Operationalizing these frameworks will make every archetype intervention more effective and cheaper: shared reserves reduce the required scale of domestic strategic stockpile holdings; mutual inspection recognition lowers regulatory costs and compresses timelines that currently make supplier diversification impractical during shortage conditions; and joint purchase commitments create demand signals that justify KSM-level investment in partner countries where commercial incentives are insufficient.[113] DFC financing for allied CRDMO capacity applies with equal force to fermentation-based antibiotic inputs and porcine mucosa collection.

The main caveat is that all such mapping needs to include the KSM tier. If all the nations participating in the BIO-5—the biopharma partnership between United States, the European Union, India, Japan, and the Republic of Korea launched by the Biden White House—sourced identical intermediates from identical Indian manufacturers dependent on Chinese inputs, that coordination would only produce the semblance of diversification. Regulatory synchronization—expedited U.S. market-entry pathways for allied suppliers with equivalent GMP standards—stands as an immediate deliverable that could quickly make allied supply a credible buffer without any required legislation.

Security for the R&D Pipeline

This report's concern over pharmaceutical manufacturing has now shifted a stage earlier to the innovation pipeline, establishing additional risk before structural concentration has even begun. The COINS Act establishes Treasury Department oversight of outbound U.S. investment in sensitive technology sectors but does not clearly touch on pharmaceutical and biotechnology licensing, the channel where dependence of the R&D pipeline is currently deepening.[114] Every licensing agreement transfers not only commercial rights but process knowledge, clinical data, and development expertise, the same intangible attributes that, in manufacturing, accumulated in Chinese CRDMOs. Once embedded in Chinese agencies, they are not recoverable through downstream manufacturing policy.

Extending the COINS Act to cover national security–relevant licensing categories would apply the same logic used throughout this report but at a stage earlier. U.S. companies licensing Chinese assets in covered categories should retain technology-transfer rights, maintain a qualified domestic or allied development pathway, and disclose the arrangement to relevant federal agencies—a requirement that the archetype policy menus recommend for manufacturing.[115]

Restricting Chinese licensing without addressing U.S. research funding cuts, however, simply trades one vulnerability for another. Proposed NIH budget reductions, FDA staffing cuts, and scaled back investment in U.S. countermeasures are narrowing the U.S. R&D base while China expands its footprint.[116] Rebuilding this domestic R&D infrastructure is the demand-side complement to any licensing restriction on China and a necessary condition under which allied and domestic alternatives become viable.

Pairing Innovation Funding With an Adoption Strategy

The United States has world-class research funding and a strong public-private innovation ecosystem—NIH, BARDA, DARPA, and ARPA-H, combined with private venture capital—that represent a genuine strategic advantage. The central policy challenge is converting those strengths into approved, scaled, and economically viable domestic and allied manufacturing capacity.

Newer platforms—continuous manufacturing, AI-enabled process optimization, advanced bioprocess analytics, cell-free and enzymatic synthesis, and modular biomanufacturing—can shift the cost and speed assumptions that have so far favored production in China and India, but U.S. manufacturers have weak incentives to adopt them once a biologic is approved because process changes require compatibility studies, new regulatory submissions, and risk of supply disruption.[117]

Technology funding policy should therefore be paired with adoption policy. The FDA and HHS need to reduce the friction of switching to advanced manufacturing through clearer comparability pathways, pre-negotiated post-approval change protocols, regulatory sandboxes for new modalities and precursors, and procurement preferences for domestically produced goods using advanced domestic technologies. AI compounds both the opportunity and the urgency: as it lowers the time and cost of biologics

design, the bottleneck shifts toward who controls data, DNA synthesis, validation tools, and scale-up infrastructure. The fundamental issue is that R&D supply chain security is as central to biosecurity and competitiveness as commercial manufacturing itself.

Anticipating and Mitigating Unintended Consequences

The main risk with any industrial policy tool is creating new problems while trying to solve the original supply chain problem. A policy instrument that looks attractive as industrial strategy can raise procurement costs, create retaliatory procurement barriers abroad, lock-in obsolete capacity, or slow speed of innovation. Those unintended consequences should be anticipated and mitigated in policy development and implementation stages.

Buy-local provisions raise costs, which matter most in high-volume, price-sensitive generic markets such as statins, analgesics, and antibiotics. Local-content rules can also risk triggering reciprocal policies abroad. China's volume-based procurement (VBP) illustrates how procurement mechanics can functionally exclude foreign firms even without explicit buy-local rules: in one VBP round, Pfizer, AstraZeneca, Roche, Gilead, Novartis, and other non-Chinese firms received zero volume.[118]

Volume guarantees also create overcapacity and lock-in risks if health-care demand shifts. COVID-19 vaccine advance purchase agreements scaled production rapidly, but post-pandemic demand reversals led to canceled or reprogrammed contracts in both the United States and the EU. The same risk applies to antibiotics, APIs, or biologics. The same lock-in risks extend to supplier networks, fill-finish relationships, and regulatory filings built around a specific platform.

Priority review vouchers (PRVs) and extended exclusivity avoid the need for direct appropriations but decouple rewards from policy goals. The transferability of PRVs allows them to be converted into tradable financial assets, which can be a significant incentive. Ipsen sold a PRV for $158 million in 2024, and Rocket Pharmaceuticals sold one for $180 million in 2026.[119] Yet, PRVs are triggered by regulatory approval, not by sustained U.S. manufacturing, supply continuity, or follow-on R&D, which limits their effectiveness. Extended exclusivity carries similar downsides: a JAMA Health Forum analysis of four top-selling drugs found delayed generic entry led to approximately $3.5 billion in excess spending over two years.[120]

Stricter quality enforcement is most likely to prove the cleanest long-term tool. The FDA announced in 2025 it would expand unannounced inspections at foreign facilities producing essential medicines, building on pilots in India and China.[121] The primary immediate risk is supply disruption if many foreign facilities simultaneously fail inspections.

Rejecting foreign clinical trial data can guard against approvals based on evidence of questionable quality, but a broad rule raises R&D costs and slows medical technology development. The sintilimab (an mAb used for various cancers) case is illustrative: an FDA advisory committee voted fourteen to one that additional trials were needed to demonstrate applicability to U.S. patients before approving the China-developed PD-1 inhibitor. The FDA subsequently issued a complete response letter to Lilly and Innovent, notifying them that their marketing application could not be approved in its current form.[122] The better approach, however, could be clearer expectations for multiregional trials, bridging data, and U.S.-relevant comparators rather than blanket rejection.

Export controls on pharma R&D tools could protect choke points but can accelerate China's domestic substitution. The Bureau of Industry and Security's 2025 biotechnology rule restricting certain flow cytometers and proteomics mass spectrometers prompted China to develop domestic alternatives.[123] The Illumina case is illustrative: after China barred Illumina from exporting sequencing instruments, the domestic Chinese sequencer market share rose substantially while Illumina's fell.[124] Export controls may buy time, but they can also accelerate the creation of competitive Chinese alternatives.

CONCLUSION

China's dominance across critical U.S. pharmaceutical supply chains now extends well beyond legacy APIs and KSMs. Its position in monoclonal antibodies, biologics manufacturing, and synthetic DNA infrastructure has expanded rapidly, with full value-chain erosion accelerating in certain areas. Those vulnerabilities are not the result of normal market dynamics or an excessive U.S. focus on cost efficiency but rather decades of sustained and coordinated Chinese state investment, industrial policy, and strategic subsidization. Critically, Beijing has continuously demonstrated that it will weaponize supply chain concentration for foreign policy purposes, doing so through informal means that maintain plausible deniability and avoid the legal consequences of a declared embargo. The U.S. pharmaceutical chain is not exempt. It is increasingly the next frontier.

This report's central finding is that the true scope of U.S. vulnerability is systematically underestimated and often poorly understood. Efforts to reshore or diversify U.S. supplies at the API or FDF stage only mask the near-total concentration upstream of key starting materials. Third-country transshipment obscures the degree of U.S. reliance on China for essential medicines, falsely suggesting that U.S. supply chains are resilient. Shortages of amoxicillin, heparin, and norepinephrine are already triggered by ordinary demand surges or disease outbreaks, without any adversarial action. These everyday shortages have already forced U.S. hospitals to ration care, delay surgeries, and substitute less effective treatments, leading to unnecessary patient deaths. These are not edge cases, but stress tests—and the United States has failed them. An effort by China to weaponize U.S. pharmaceutical dependence could do far worse.

The U.S. dependence on China for essential medicines has also moved beyond manufacturing into the innovation pipeline itself. Every licensing agreement signed with a Chinese biotech firm transfers commercial rights, process knowledge, clinical data, and development expertise that cannot be recovered through downstream U.S. manufacturing policy alone. The same dynamic that hollowed out small-molecule API manufacturing is now playing out in biologics and synthetic biology, but it is taking place at an earlier stage where intervention would be more effective and is more urgent.

For its economic and national security, the United States must respond with a package of coordinated measures built around the three archetypes of supply chain dependence.

Each of these industrial policy tools carries real risks: higher procurement costs, reciprocal retaliation, lock-in of obsolete capacity, or acceleration of Chinese domestic substitution. Disciplined, targeted implementation—calibrated to the specific archetype and its root cause—will be needed to mitigate these unintended consequences.

The tools for success exist, but it is past time to recognize that U.S. pharmaceutical supply chain security and resilience is a national and economic security problem that demands the same urgency and level of resources that the United States is devoting to reducing dependence on China for critical minerals and rare earths. The question now is whether the United States will manage to do so before a crisis makes the cost of decades of inaction all too visible to the American public and exceedingly painful for everyone touched by the health care system to bear.

APPENDIX: SUMMARY TABLE OF RECOMMENDATIONS

Policy Tool	Recommendation	Lead Agency / Actors
Archetype One: Upstream Supply Chain Concentration and Fragility		
Near-Term—Acute Risk Management (0–2 years)		
1. Create a functional ecosystem for a strategic reserve for KSMs and APIs	1.1 Direct ASPR to purchase at least an 18-month supply of essential KSMs and APIs for the SAPIR facility under a dynamic life-cycle rotation program.	ASPR, FDA, HHS Supply Chain Resilience & Shortage Coordinator
	1.2 Coordinate and fund a distributed network of aseptic filling sites—equipped with robotics, isolator technology, and single-use systems—capable of converting stockpiled APIs into finished drug product during shortages or emergencies.	ASPR, FDA
	1.3 Require liability protection frameworks before manufacturers use stockpiled APIs and KSMs outside their control.	HHS, Congress
2. Create allied coordination mechanisms for KSM production	2.1 Pursue a plurilateral critical medicines trade bloc offering preferential terms to allied partners, paired with mutual recognition arrangements enabling allied sharing and purchasing of critical KSM and API stockpiles.	USTR, DOS
	2.2 FDA should launch a program to more readily authorize temporary API importation from well-regulated allied markets and proactively identify and assess foreign sources for essential medicines where China holds concentrated market dominance.	FDA
3. Create risk communication plans for essential drug shortages	3.1 ASPR, CDC, and state and local public health agencies should develop pre-positioned communication plans for exceptional essential drug shortages caused by geoeconomic coercion, export restrictions, conflict, or other deliberate supply choke points. These plans should guide communications with the public, hospitals, and clinicians to prevent panic buying, misinformation, and disorderly allocation during national security–relevant supply disruptions.	ASPR, CDC, State and Local Public Health

Policy Tool	Recommendation	Lead Agency / Actors
Longer-Term—Demand-Side Interventions (3–5 years)		
4. Require targeted API and KSM sourcing disclosure and labeling	4.1 Implement a phased, tiered mandatory disclosure requirement beginning with confidential, product-specific reporting to regulators for essential medicines.	FDA, CBP, Congress
	4.2 Build toward aggregate public reporting and labeling consistent with BIOSECURE Act compliance requirements.	FDA, Congress
	4.3 Extend pending legislation's country-of-origin requirements to all U.S.-sold pharmaceuticals—finished dosage and APIs—across the full supply and distribution chain.	Congress, FDA, CBP
5. Bolster KSM- and API-level domestic investment, with well-defined Buy America terms that account for transshipment	5.1 Use VA, DOD, and Medicaid Buy America provisions to create stable baseline demand for domestic and trusted allied APIs and KSMs.	DOD, VA, CMS
	5.2 Medicare Part B should offset higher U.S. manufacturing costs through higher hospital reimbursement rates, modeled on the N95 respirator approach.	CMS
	5.3 Define eligibility standards for U.S.-manufactured finished dosage forms based on whether the FDF is manufactured in the United States and the extent to which the underlying APIs are produced in the United States or allied countries, supported by reliable CMS, hospital, and GPO tracking mechanisms for additional payment determinations.	CMS, Congress
	5.4 Extend preferences to designated trusted allied sources in well-regulated markets; an exclusively Buy America provision risks near-term shortages.	Congress
	5.5 CMS should preference Medicare Part B reimbursement for domestically sourced porcine or bovine API; USDA-FDA coordination needed for slaughterhouse practices, traceability, and pharmaceutical-quality requirements.	CMS, USDA, FDA, DARPA, BARDA, ARPA-H, NIH, NSF
Longer-Term—Supply-Side Interventions (3–5 years)		
6. Target pharmaceutical tariffs on Chinese-sourced APIs and KSMs	6.1 Building on the recent Section 232 investigation, U.S. trade officials should assess whether tariffs on APIs, or on products containing Chinese-sourced KSMs and APIs, would reduce U.S. dependency risks by incentivizing supply chain shifts toward domestic or lower-cost allied production, while targeting the actual points of foreign dominance and national security vulnerability.	USTR, Congress
	6.2 Avoid blanket tariffs on generic pharmaceutical imports, which would worsen U.S. pharmaceutical insecurity by disrupting supplies of essential low-margin medicines.	Congress

Policy Tool	Recommendation	Lead Agency / Actors
7. Incentivize investment in AMTs and U.S. production	7.1 Deploy a package of coordinated public R&D investment, tax credits, and push-pull regulatory incentives to prioritize projects with measurable improvements in yield, quality, and energy efficiency.	NIH, BARDA, ARPA-H, Congress
	7.2 FDA should clarify how regulatory frameworks apply to AMTs, update AMT designation guidance to expand incentives, and reduce regulatory uncertainty as a push to adoption.	FDA
	7.3 Offer extended market exclusivity and advance purchase commitments as pull incentives for higher-cost domestic manufacturing.	Congress, FDA
	7.4 Pursue additional risk-sharing mechanisms: multiyear tax credits for API and biologics facility investment, subsidized AMT equipment financing, and accelerated depreciation for pharmaceutical infrastructure.	Congress, DOC, Treasury
8. Expand DFC and EXIM investment in allied KSM and API capacity	8.1 DFC and the Export-Import Bank should extend low-interest financing and equity to projects building API and KSM capacity in lower-cost allied nations.	DFC, EXIM Bank
	8.2 Explore friendshoring partnerships with Argentina and Mexico to geographically diversify supply chains.	DOS, DFC,
Archetype Two: Biologics Manufacturing and Clinical Trial Competitiveness		
Near-Term Interventions		
1. Make the BIOSECURE Act the floor, not the ceiling	1.1 For biologic assets with national-security implications, HHS, BARDA, DOD, and NIH should require China-dependence risk management plans in their programs, mandating qualification of alternate U.S. or allied CRDMOs before predetermined development funding milestones.	HHS, BARDA, DOD, NIH
	1.2 Include contractual terms preserving technology-transfer rights, escrow or portability of process data, and contingency plans for relocating clinical or commercial production before pivotal trials or launch.	HHS, BARDA, DOD, NIH
2. Pilot a U.S. first-in-human (FIH) trial acceleration model	2.1 Create an FIH clinical acceleration pilot and invest in streamlined clinical trial and central IRB capacity at designated centers of excellence at university medical and academic health systems, targeting shorter trial start-up timelines and ensuring adequate diversity of patient populations and rural coverage.	FDA, Congress
	2.2 Building on the model pioneered in Australia, Congress and FDA should authorize an optional CTN-like pathway for well-characterized drug platforms or lower-incremental-risk early studies, coupled with FDA call-in and suspension authority and strict eligibility criteria.	FDA, Congress
	2.3 Adopt a Norway NorTrials-like approach to investing in U.S. university and hospital trial sites to boost capacity and ensure geographic diversity supporting a diverse trial subject population.	FDA, Congress, University Medical Centers

Policy Tool	Recommendation	Lead Agency / Actors
3. Incentivize adoption of advanced biologics manufacturing technologies	3.1 FDA should reduce friction in adoption of advanced manufacturing technology by publishing model comparability protocols for assessing new technologies and expediting review of post-approval manufacturing changes.	FDA
	3.2 For a defined limited period, Medicare could pay a modest additional amount for qualifying biologics meeting defined manufacturing-resilience criteria to accelerate adoption of new manufacturing technologies such as continuous manufacturing.	CMS/Medicare
	3.3 Require trial sponsors and manufacturers of biologic assets with national-security relevance to disclose critical supplier risk beyond the first tier of supply chains, including cell banks, plasmids, vectors, media, resins, filters, single-use bags and tubing, vials, stoppers, cold-chain inputs, analytical reagents, and quality-control assays. Disclosure requirements should focus on single-source dependencies and suppliers in foreign countries of concern.	FDA, BARDA, DOD, ASPR, NIH
Long-Term Interventions		
4. Build allied-country CRDMO alternatives	4.1 DFC should finance a portfolio of trusted CRDMO alternatives in allied and partner countries to create a healthier, more competitive market for biologics development and manufacturing services.	DFC
	4.2 DFC loans and equity should target infrastructure expansion in allied-country CRDMO networks where China risks are highest.	DFC
5. Fund and authorize a National Biologics Manufacturing Excellence Center	5.1 Establish a center working with universities, community colleges, trade colleges, NIIMBL, and industry to link classroom training, hands-on pilot-scale facilities, apprenticeships, and employer-recognized credentials.	Congress, NIIMBL, Universities, Community and Trade Colleges
	5.2 Center should close existing U.S. workforce gaps in advanced biologics manufacturing through coordinated credentialing pathways.	Congress, NIIMBL
6. Build AI-ready biodata and digital CMC infrastructure	6.1 Create an interagency effort coordinated by OSTP to develop a secure, AI-ready biodata and digital CMC initiative.	OSTP, HHS, FDA, NIH, NIST, BARDA
	6.2 Standardize data provenance, metadata, batch records, analytical methods, process-development data, and comparability datasets so that advanced analytics and AI tools can accelerate process development, technology transfer, and regulatory review.	OSTP, HHS, FDA, NIH, NIST, BARDA

Policy Tool	Recommendation	Lead Agency / Actors
Archetype Three: DNA Synthesis Supply Chain and Biosecurity		
Near-Term Interventions		
1. Mandatory DNA supply chain transparency and provenance disclosure	1.1 Consolidate federal authority for DNA synthesis security in the Department of Commerce, which already exercises jurisdiction under the Export Control Reform Act of 2018.	DOC, Congress
	1.2 By executive order, the president should require commercial DNA synthesis providers operating in the United States to disclose corporate ownership structures, nucleotide input sourcing by country of origin, and order-routing practices—including whether orders placed with U.S.-branded entities are fulfilled through facilities in foreign countries of concern.	DOC, White House
	1.3 NIH, BARDA, and FDA should require federally supported drug-development programs to disclose the source, ownership, and input provenance of synthetic DNA used in research, process development, and manufacturing.	NIH, BARDA, FDA
	1.4 Extend mandatory biosecurity screening—sequence-of-concern checks against pathogen and toxin databases—to all commercial DNA synthesis orders; standards must apply to where an order is fulfilled, not just where it is placed.	DOC, CDC, ASPR, FBI
2. Evaluate export controls on advanced DNA synthesis technology	2.1 DOC's Bureau of Industry and Security should evaluate controls on advanced DNA synthesis equipment and enzymatic synthesis platform technology to prevent transfer of next-generation capabilities to Chinese firms.	DOC, BIS
	2.2 Pair export controls with affirmative investment in U.S. and allied next-generation platforms, so the window created by controls is used to build competitive alternatives rather than merely delay Chinese capability development.	DOC and BIS, ARPA-H, BARDA
Medium-Term Interventions		
3. Invest in next-generation enzymatic DNA synthesis	3.1 ARPA-H and BARDA should fund a dedicated scale-up program for enzymatic synthesis platforms at U.S. and allied firms, structured as milestone-based contracts to accelerate transition from laboratory demonstration to commercial viability.	ARPA-H, BARDA
4. Establish federal procurement preferences and offtake commitments for domestic and allied suppliers	4.1 BARDA, NIH, DOD, and ASPR should establish explicit procurement preferences and, where appropriate, advance purchase commitments for synthetic DNA sourced from domestic or allied providers meeting defined biosecurity and provenance standards	BARDA, NIH, DOD, ASPR
	4.2 NATO may serve as a platform for joint purchasing arrangements for defense and preparedness applications; such commitments signal durable demand to potential investors in next-generation platforms.	DOD, DOS, NATO

Policy Tool	Recommendation	Lead Agency / Actors
	4.3 Loan guarantees through DFC or a domestic financing mechanism for capital-intensive platform investment by U.S. or allied firms can help private firms raise capital for expanding DNA synthesis capacity.	DFC, Congress
Long-Term Interventions		
5. Coordinate with allies on biosecurity standards and genomic data reference infrastructure	5.1 Cooperate on the adoption and application of consistent biosecurity screening standards with key partners—Australia, Canada, EU, Japan, and the UK—through the Biopharmaceutical Alliance, NATO, and S&T agreements.	DOS, DOC
	5.2 This cooperation should include sequence-of-concern databases, screening methodology requirements, and provenance documentation standards so third-country routing cannot circumvent requirements in any single jurisdiction.	DOS, DOC, Allied Partners
	5.3 Coordinate reference biological material and "omics" data standards to reduce reliance on Chinese-linked platforms for foundational research infrastructure.	DOS, DOC, NIST, Allied Partners
Cross-Cutting Requirements for Reducing U.S. Supply Chain Dependence		
Governance Continuity		
1. Establish White House–level coordinating body	1.1 A dedicated coordinating body sitting at the White House level—National Security Council, DPC, or the National Economic Council—should be empowered to direct agency timelines, fast-track regulatory approvals for new KSM and API suppliers, trigger emergency importation pathways, oversee SAPIR procurement criteria, and coordinate allied frameworks.	White House NSC, NEC, or DPC
	1.2 U.S. oversight over resilient biopharmaceutical supply chains must outlast election cycles and temporary crises; create dedicated multiyear appropriations, a permanent interagency implementation office, and clear agency mandates for procurement, reimbursement, stockpiling, and industrial-base expansions—modeled on the CHIPS Act implementation structure.	Congress, White House
A U.S. Infrastructure for Measurement and Early Warning		
2. Build a pharmaceutical supply chain monitoring function	2.1 The FDA should systematize IND, ANDA, and Drug Master File submission data on API and KSM manufacturing sites into a searchable database accessible across coordinated agencies, and publish an annual pharmaceutical competitiveness index tracking U.S., allied, and Chinese capabilities tier by tier.	FDA, DOC, Congress
	2.2 A monitoring function—operating one to two supply chain tiers upstream of the existing drug shortage list—should flag markets at risk before vulnerabilities form; where concentration exceeds defined thresholds, FDA and DOC should notify the national security apparatus and initiate a remediation timeline.	FDA, DOC

Policy Tool	Recommendation	Lead Agency / Actors
	2.3 Institutionalize the bilateral trade data comparison methodology used in this report (surfacing transshipment by comparing nominal and actual country of origin) as a regulatory tool at FDA and DOC.	FDA, DOC
	2.4 Create a common standard (led by the Made in America Office in collaboration with relevant implementing agencies) for determining whether a product qualifies as U.S.-manufactured or U.S. resilience-enhancing. The standard should account for U.S. FDF manufacturing and the share of API produced in the United States or allied countries, and should be designed for adoption across agency regulations governing procurement, reimbursement, and related payment determinations.	White House, Made in America Office, CMS, DOD
Allied Coordination as Force Multiplier		
3. Operationalize the Biopharmaceutical Alliance and EU Critical Medicines Act	3.1 Establish allied supply-chain coordination mechanisms that move beyond consultative forums, including shared inventories, crisis allocation rules, mutual inspection recognition, and joint purchase commitments.	DOS, USTR, FDA
	3.2 Ensure allied coordination mapping includes the KSM tier of biopharmaceutical supply chains; if all participating nations source identical intermediates from identical suppliers dependent on Chinese inputs, coordination produces only the semblance of diversification.	DOS, USTR, FDA
	3.3 Pursue regulatory cooperation—expedited U.S. market-entry pathways for allied suppliers with equivalent cGMP standards—as an immediate deliverable that could quickly make allied supply a credible buffer without requiring legislation.	FDA
Security for the R&D Pipeline		
4. Extend COINS Act to cover national security–relevant pharmaceutical and biotech licensing	4.1 Extending the COINS Act to cover national security–relevant licensing categories would apply the same logic used throughout this report but a stage earlier, before R&D pipeline dependence has fully formed.	Treasury, Congress
	4.2 U.S. companies licensing Chinese assets in covered categories should retain technology-transfer rights, maintain a qualified domestic or allied development pathway, and disclose the arrangement to relevant federal agencies.	Treasury, Congress
	4.3 Couple restrictions on Chinese licensing with a renewed U.S. R&D investment strategy, including sustained NIH funding, adequate FDA staffing, and robust countermeasure development, so the United States reduces foreign dependency without weakening its domestic innovation base.	Congress, NIH, FDA, BARDA

Policy Tool	Recommendation	Lead Agency / Actors
Pairing Innovation Funding With an Adoption Strategy		
5. Pair technology funding with adoption policy	5.1 FDA and HHS should reduce the friction of switching to advanced manufacturing through clearer comparability pathways, pre-negotiated post-approval change protocols, regulatory sandboxes for new modalities and precursors, and procurement preferences for domestically produced goods using advanced technologies.	FDA, HHS
	5.2 Secure AI-enabled biologics R&D by directing federal science funding only toward trusted domestic and allied capabilities for biological data, DNA synthesis, validation, and pilot-scale manufacturing, preventing foreign-controlled choke points before commercialization.	White House OSTP, FDA, HHS, NIH, NSF

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Questions for the Record

U.S. SENATE SPECIAL COMMITTEE ON AGING

"BEHIND THE LABEL: FOREIGN OWNERSHIP AND CONTROL IN AMERICA'S DRUG SUPPLY CHAIN"

JULY 15, 2026

QUESTIONS FOR THE RECORD

Stephen Ezell

Senator Raphael Warnock

Question:

The Food and Drug Administration (FDA) plays a critical role in inspecting foreign and domestic drug manufacturers to ensure patient safety and supply chain security. However, a recent GAO report found a growing backlog of foreign drug inspections at the FDA.[1] The report also highlighted how the FDA's foreign drug inspections, compared to domestic inspections that mostly occur unannounced, are often preannounced up to 12 weeks in advance, providing foreign manufacturers with opportunities to mask problems before the inspection.

How many FDA foreign drug inspections were pre-announced in 2025?

Response:

It's estimated that the FDA conducts approximately 12,000 domestic inspections and 3,000 foreign inspections annually in over 90 countries.[2] On May 6, 2025, the FDA announced its intent to expand unannounced inspections at foreign manufacturing facilities that produce foods, essential medicines, and other medical products.[3] This initiative builds upon a pilot program to conduct unannounced inspections in India starting in March 2022 and in China starting in July 2023. From this initiative the National Science Foundation reported that, as of May 2024, the FDA has conducted 94/114 pilot inspections unannounced in India and 16/28 in China.[4] Beyond this, ITIF was unable to determine an exact number of pre-announced inspections in 2025.

Question:

How does FDA's inconsistent oversight over foreign and domestic drug manufacturers disincentivize domestic manufacturing of generic drugs?

Response:

The FDA's inconsistent oversight over foreign and domestic drug manufacturers holds only domestic drug manufacturers to a consistently high standard and this can encourage offshoring of elements of the pharmaceutical ecosystem that Americans rely on. Foreign manufacturers benefiting from pre-announced inspections lowers the operational hurdles they confront and increases the chances of missing critical safety concerns that could threaten American consumers. The FDA workforce is limited in how many inspections it can conduct, therefore inspections that are conducted must be completed at the highest possible standards for all drug manufacturers, and this usually takes the form of conducting unannounced inspections. If a company is found to not be in compliance with FDA regulators and receives an official action indicated (OAI) classification the FDA may also withhold approval of any pending drug applications listing that facility, withhold export certificates for drugs intended for distribution outside of the United States, and withhold Current Good Manufacturing Practice (CGMP) declarations for drugs intended for distribution outside of the United States.[5] Additionally, an FDA OAI classification may also negatively impact government purchasing contracts.[6] The FDA typically only changes OAI inspection classification after comprehensive actions are taken, and an in-person follow up inspection occurs.[7] If a company is found to be noncompliant and receive an OAI classification, financial and reputational damages can be significant. FDA noncompliance was estimated to cost $14.8 million per violation in 2026.[8] If fewer facilities abroad are adequately evaluated for noncompliance, domestic facilities face reduced competitiveness and greater compliance and safety costs while foreign entities cutting corners are not penalized. An inequitable inspection environment is only one of many components of the pharmaceutical ecosystem that encourages offshoring of drug manufacturing but it unnecessarily risks the health and safety of consumers and needlessly penalizes quality American drug manufacturers.

Question:

What can Congress do to address the gap in FDA's regulatory oversight of foreign and domestic drug manufacturers?

Response:

Congress can aid the FDA in addressing regulatory oversight gaps of foreign and domestic drug manufacturers by increased FDA's funding to expand their workforce, enable them to conduct more inspections, and to expand their unannounced foreign inspection program. Congress can ensure that the FDA has the adequate funding/resources it needs to meet its mission. Congress can pass the Pharmaceutical Supply Chain Defense and Enhancement Act, which would boost supply chain transparency by requiring drug makers to annually report to the FDA information about the source of active pharmaceutical ingredients (APIs) and key starting materials used to make drugs consumed in the United States; require drug makers to report to any federal agency that it supplies drugs with information on the foreign manufacturers that produce those drugs and components; and require the FDA to issue both public and classified reports to Congress on the strength of the U.S. supply chains.[9]

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JULY 15, 2026

QUESTIONS FOR THE RECORD

Dr. Rush Doshi

Senator Raphael Warnock

Question:

According to the Association for Accessible Medicines, generic drugs account for approximately 90 percent of prescriptions filled in the United States. Although generic drugs have been found to improve older adults' access to affordable, quality medications and reduce overall U.S. health care spending, domestic generic drug manufacturers have gradually transitioned their operations in recent years to countries with lower production and labor costs, leading to overreliance on foreign manufacturing of generic drugs.

What specifically is driving the transition of generic drug manufacturing from the United States to lower-cost countries?

Response:

The structure of the US procurement system incentivized wholesalers, distributors, and supply chain intermediaries to purchase their volumes from the lowest-cost manufacturer, sometimes at the expense of quality and resilience. That was a structure that inadvertently benefited China. We made domestic manufacturing more difficult and more expensive, while permitting Chinese producers to export into our market tariff-free and permitting drug finishers and API makers to avoid disclosing their upstream China dependency. Beijing, for its part, ran the same play it ran in rare earths: it subsidized capacity, discounted energy and inputs, tolerated pollution that Western regulators would not accept, and priced below cost to deter entry-thereby locking in a durable monopoly position. As in rare earths, it is now working to defend that position, flooding markets with below-cost exports to harm alternative suppliers in India and elsewhere.

We were also slow to see this transition coming, because the pharmaceutical supply chain is not transparent. A drug label may indicate where the product was finished, but it says nothing about a dependency two tiers upstream. Transshipment and repackaging compound the problem: a 2023 Department of Defense review found that fifty-four percent of the medicines it purchased under domestic-sourcing rules in fact originated in China, India, or sources unknown.

Question:

How can Congress incentivize foreign direct investment in domestic drug manufacturing facilities?

Response:

We need to reinvest in our own innovation and manufacturing ecosystem to make it more attractive for foreign investment. Congress should not only restore federal funding for basic research; the federal government should also extend low-cost capital to manufacturers and use tools like the Defense Production Act Title III to offer financing for domestic manufacturing. There is precedent for what a modest, targeted subsidy can accomplish: a single fifty-million-euro grant made an Austrian plant cost-competitive with Chinese penicillin chemistry.

Second, we should encourage partners to align around a shared, trusted standard to incentivize increased allied cooperation and investment. By framing allied coordination as a supply guarantee rather than a consultative forum, built on shared inventories, mutual inspection recognition, and joint purchase commitments, we can embed investment guarantees into these relationships. Congress can advance these partnerships by pursuing a plurilateral critical medicines trade bloc offering preferential terms to allied partners, and by pushing regulatory synchronization and expedited U.S. market-entry pathways for allied suppliers with equivalent GMP standards.

Question:

How would investment in private-public partnerships, such as Operation Warp Speed during the COVID-19 pandemic, bolster the domestic manufacturing of generic drugs?

Response:

Public-private partnerships can bolster generic manufacturing where the market fails on its own. Generics no longer generate sufficient economic returns to justify domestic vertical integration, so the incentives and investment in our manufacturing base described above will be critical for filling the gap private capital has failed to close. The federal government can also work with industry to reduce demand uncertainty, for example through ensuring higher Medicare Part B reimbursement rates for domestically-made products and by guaranteeing advance purchase commitments for fermentation-based facilities.

The caution is that new or expanded capacity resulting from public investments may not continue long term as market demand for the product changes. A company that took Title III funds to boost swab production for COVID-19 testing closed manufacturing sites in 2023 after a drop in demand. Without a coordinated mix of longer-term demand and supply interventions, not just isolated fixes, capacity built during a surge doesn't survive the return to normal.

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