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MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES

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C O N T E N T S

MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES

Wednesday, November 19, 2025

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

The Committee met, pursuant to notice, at 3:41 p.m., in Room 216, Hart Senate Office Building, Hon. Rick Scott, Chairman of the Committee, presiding.

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

OPENING STATEMENT OF SENATOR RICK SCOTT, CHAIRMAN

The CHAIRMAN. The U.S. Senate Special Committee on Aging will now come to order. This hearing is about something we've all used, and every American relies on - access to safe, affordable, and high-quality medicines. Generic drugs are a lifeline for millions of Americans and are a market miracle that allows for accessible treatments. That is why it is so important that we have transparency into their supply chains and full confidence in their production.

As we know from the FDA's own people, they have allowed importation of drugs from facilities that are noncompliant simply because the potential for shortage—which we should be making these drugs here in this country in the first place. In our previous two hearings on this topic, witnesses have highlighted the ways that we can bring back domestic production in an affordable, market driven way.

Today, nearly 80 percent of the active ingredients in our prescription drugs come from foreign sources. That is foolish. That means we depend on our adversaries for the very medicines our families and seniors need to survive. It is not England. It is not Germany. It is not Japan. It is our adversaries.

Consumers, pharmacies, and big buyers like hospitals don't even know the full extent of where those drugs are made or what is happening inside the plants that make them because we don't have country of origin labeling requirements. We have seen the results of that dependence in contaminated drugs, dangerous recalls, and shortages that force doctors and patients to ration care.

It is unacceptable that the most advanced country in the world can't ensure a steady, safe supply in basic medicines for its own citizens. The solution for this is very simple, we must make drugs in America again. The health and safety of Americans is too impor-

tant to leave in the hands of other nations, especially our adversaries that like Communist China. When we manufacture here at home, we can control quality, strengthen oversight, and protect patients.

We also get the benefit of creating good paying jobs and growing our economy. Today's witnesses are proof that American manufacturing works. These companies show that it is possible and profitable to make safe, affordable medicines in the U.S. However, they also face challenges that Washington has helped create.

Red tape at the FDA delays approvals and drives up costs, something I and many of our colleagues are interested in fixing. By the way, I want to thank the Ranking Member, Gillibrand, because she has been a complete partner in the report we put out, in these hearings to make sure we get change. Current procurement rules for Government agencies, large purchasers of generic drugs reward the cheapest overseas bidder rather than the safest or the most reliable product to the detriment of American manufacturing.

The difference in cost is often negligible, and foreign governments manipulate their pricing to undercut American manufacturers. The result, a broken system that leaves our patients vulnerable and our businesses at a disadvantage.

The Federal Government should lead by example. The VA, Medicare, and our military health programs should prioritize American made medicines. Unfortunately, they don't. Taxpayer dollars should support our American workers, not fund companies in China with ties to forced labor and that don't meet our safety standards.

This isn't just an economic issue. It is a matter of national security. Americans should never have to wonder whether their blood pressure medication, their insulin, or antibiotic was made safely. We can do better, and we must do better. Together we can build a stronger, safer, more self-reliant medicine system here in America.

I now would like to recognize Ranking Member Gillibrand for her opening statement, and again, I want to thank her for being a complete partner in getting this report out and these hearings.

OPENING STATEMENT OF SENATOR KIRSTEN E. GILLIBRAND, RANKING MEMBER

Senator GILLIBRAND. Thank you, Mr. Chairman. Thanks for calling the hearing, and thank you to our witnesses for testifying today. We are very grateful for your contribution. I look forward to continuing our conversation about how we can improve the quality and reliability of our generic drug supply.

This is an essential issue for our Committee to examine as many aging Americans, including over 53 million Medicare Part D enrollees, rely on at least one generic drug to treat a wide range of medical conditions. Unfortunately, the supply chain for these crucial drugs remains vulnerable to disruption, and we consistently witness issues with the quality of foreign drug products causing key medicines to go into shortage. It is unacceptable.

Every American should have access to safe and affordable generic drugs. Particularly, as older adults navigate the complex, difficult health conditions that they face, they shouldn't have to cope

with worsening symptoms, skipping doses, or trying to stretch medicines further because they can't afford them. This is an existential issue for a lot of older Americans and for New Yorkers.

I have heard from many New Yorkers about this issue. One of my constituents from Brooklyn told me: ″for the past month and a half, I have been unable to receive my generic medication because of shortages. Much of my day is spent going back and forth between pharmacies and my doctor's office playing phone tag when I should be doing my actual job. I have even had to spend money on third party services to help me find my medication when I am unable to. The entire process is exhausting, demoralizing, and dehumanizing.″

A key factor driving up these supply chain disruptions is that due to the extreme cost pressures and concentrated sourcing, key starting materials, active pharmaceutical ingredients, and finished dosage form generic drug products are increasingly made outside the United States. We have seen the number of U.S. facilities that formulate generic drugs fall by 27 percent since 2013.

In the same timeframe, we have seen a 38 percent decrease in the number of domestic facilities producing active pharmaceutical ingredients. In fact, 83 percent of the top 100 generic drugs taken by American consumers now have no U.S. based source of API, and another 11 percent only have one domestic source of API.

This means we increasingly depend on countries like India and China, where the industry has grown for these upstream materials that represent the most vulnerable chokepoint in the supply chain. This is particularly a problem because recent instability in geopolitics and global trade practices is compounding our already limited operational oversight and control over foreign sourcing and manufacturing of these key materials.

The U.S. decline in manufacturing has not only led to domestic job losses, but it also represents vulnerability in the supply chain and increasingly poses a risk to our Nation's public health preparedness and national security.

To ensure Americans have a reliable supply of safe and affordable drugs, Congress will need to work to make targeted investments in biotechnology research and infrastructure to manufacture these key ingredients in the United States.

In addition, we have to examine the underlying economic dynamics in the current marketplace and adjust incentives to fix the race to the bottom problem in generic drug pricing, which can drive manufacturing outside the U.S. and cause companies to stop production of certain drugs and chemicals altogether.

I look forward to hearing from our witnesses today to discuss these challenges and the barriers facing this industry. I am eager to work with Chairman Scott and the Committees of jurisdiction as we address these issues, strengthen our generic drug supply, and bolster our public health preparedness and national security.

The CHAIRMAN. Thank you, Ranking Member. I would like to welcome our witnesses, all of whom are leaders in the efforts to bring drug manufacturing back to the United States, ensure that every medicine we take is safe, affordable, and made to the highest standards, so now let me turn it over to the Ranking Member to introduce our first witness.

Senator GILLIBRAND. Thank you, Chairman Scott. I want to move to introduce Allan Coukell. Mr. Coukell is the Chief Government Affairs and Public Policy Officer at CivicaRx, a not-for-profit organization. CivicaRx was created by the U.S. health systems in 2018 to address drug shortages by manufacturing quality, essential medicines at sustainable prices.

Mr. Coukell served on the board of the Reagan Udall Foundation for the FDA and was a Founding Board Member and Vice Chair of the Medical Device Innovation Consortium. Mr. Coukell, you may begin your testimony.

STATEMENT OF ALLAN COUKELL, CHIEF GOVERNMENT AFFAIRS & PUBLIC POLICY OFFICER, CIVICARX, LEHI, UTAH

Mr. COUKELL. Thank you. Chairman Scott, Ranking Member Gillibrand, and members of the Committee, I appreciate the opportunity to speak with you today. My name is Allan Coukell. I am a pharmacist, and I lead public policy for CivicaRx.

Civica is a nonprofit generic drug company created to prevent drug shortages and to ensure that American patients have a reliable supply of essential medicines. We currently supply 60 health systems around the country with more than 50 injectable drugs. Over seven years, we have shipped more than 240 million vials.

To do this, we work with a range of manufacturing partners, giving preference to U.S. sourcing. Civica has a rigorous quality oversight process for its suppliers involving in-person facility audits and ongoing quality reviews. This is a unique feature of our supply model.

Also unique is that we maintain a 6-month buffer inventory of every drug, and we offer the same price to every purchaser. Civica's own newly built manufacturing facility is in Petersburg, Virginia, funded partly with U.S. Government support, this is a state-of-the-art facility for manufacturing sterile injectable drugs with the ability to make about 90 million vials a year.

We have dozens of generic drugs in development for this facility. Civica has a no China policy in our supply chain, both for finished drugs and for active ingredient, unless there is no other supply available.

Civica drugs are chosen by pharmacists and physicians from participating hospitals, and they are chosen because they are at high risk of shortage. These are products that are the bedrock of inpatient care, and surgery, and emergency medicine, antibiotics, anesthetics, blood thinners, sedatives, pain medications.

While these are essential medications, they also tend to be very low cost. It is precisely because generic drugs are so inexpensive that manufacturing has been steadily moving to India and China. Make no mistake, low prices are the principal barrier to onshoring generic drug manufacturing.

It costs millions of dollars to bring a generic injectable drug to market, and it takes several years. It requires a costly manufacturing facility and teams of people, R&D manufacturing, laboratory quality, and so on. With many injectable drugs selling for less than a dollar a vial, U.S production awfully—isn't simply financially viable.

If we want sustainable domestic production, we have to be comfortable that it is worth paying slightly more to have a safe and secure domestic industry. We should provide extra payments to hospitals that take quality into account, along with domestic sourcing and buffer inventory.

A bipartisan Senate Finance Committee discussion draft takes this approach, and since generic drugs account for one or two percent of hospital spending, such a program would have a negligible impact on overall health costs.

In combination with these long-term market fixes, Congress should invest now in an insurance policy so that we can deliver these drugs as soon as they are needed. Because it takes years to bring a product to market, we shouldn't wait until after a foreign supplier fails or cuts us off to start developing the drugs we need.

We also can't expect companies to invest in products if they won't recover their costs. Report language in the Senate Fiscal Year 2026 Labor H Bill instructs ASPR to partner with the private sector for this purpose, and Congress should fund this activity.

For a modest one-time expense, we can ensure that domestic manufacturers are ready to go as soon as they are needed. You may note here that I have been talking more about finished drug products, vials or tablets, than about active pharmaceutical ingredients.

Sometimes, we focus on API because that is where our dependence on China is greatest, but it won't do us any good to bring API back to the U.S. if we don't have a viable market for domestic finished drugs.

We have to get that part right. I want to point out that developing a drug for an existing manufacturing facility is faster and cheaper than building an entirely new facility, but when new facilities are needed, and they will be for certain antibiotics and cancer drugs, it will require investments of hundreds of millions of dollars and probably Government support with capital, as well as some assurance of sustained demand.

With modest changes to the current system, generic drugs can be produced cheaply and at scale in the United States, but we have to commit to making a market that works. Thank you for your attention and welcome your questions.

The CHAIRMAN. Thank you for your testimony. Now, I would like to turn it over to Senator Tuberville to introduce the next witness.

Senator TUBERVILLE. Thank you, Mr. Chairman. I am proud to introduce our—my witness here, one of my constituents, Mr. Tom Neely, the Chairman of Oxford Pharmaceuticals based in Birmingham, Alabama. Mr. Neely is also partner at Prost Companies, a family investment firm located in Huntsville, Alabama, where he is directly responsible for the strategic direction and daily management of Oxford.

He is also involved in the firm's real estate investment, including Broadwest, and the firm's manufacturing business, including Dorsey Trailer Manufacturing Company, located in Elba, Alabama, Mico Boat Trailer Company, located in Braidon, Florida, and Brown Precision Company in Huntsville.

Tom has extensive experience in executive management, strategic planning, mergers and acquisitions activity, and financial

oversight, and by the way, did I mention he is a graduate of Auburn University? War Eagle—go ahead.

STATEMENT OF TOM NEELY, CHAIRMAN OF THE BOARD, OXFORD PHARMACEUTICALS, BIRMINGHAM, ALABAMA

Mr. NEELY. Thank you, Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee. I appreciate this hearing very much.

My name is Tom Neely, and I am Chairman of Oxford Pharmaceuticals, a Birmingham, Alabama based manufacturer of low cost, high quality, solid dose generic medicines taken daily by millions of our seniors. This is a personal matter for me. My wife has mid-stage Parkinson's disease. Oxford manufactures one of her generic medicines, but we cannot purchase it in Birmingham. Hers is manufactured by Chinese company.

Oxford broke ground on a world-class facility in 2015 and began selling generics into the U.S. market in 2019. This period was marked by U.S. generic drug makers going out of business, but we invested $130 million.

At Oxford, we feel that high-quality generic drugs can and should be manufactured domestically. We currently make 13 generic management drugs for conditions including blood pressure, mental health, and mild pain relief. When I say we manufacture these medicines, that is indeed true. We transform our raw ingredients into finished oral tablets. We weigh, blend, compress, coat, package the tablet while adhering to an end-to-end, very comprehensive CGMP compliant quality process.

Unfortunately, in today's domestic market, offshore manufacturing of these generic medications has dangerously weakened our supply chain, with China and India controlling the market. These foreign competitors are heavily subsidized by their governments, and studies repeatedly have shown quality of their finished products is inferior to domestic produced generics.

In addition, the three big distributors, PBMs, and insurance companies care nothing about quality but focus on price. Ten of our drugs have no other U.S. owned and operated manufacturer, and three are classified as essential medicines. These proven generic drugs have been on the market for decades.

On a weighted average of Oxford products, we sell 100 tablets for $1.50. Medicare reimbursement for the same quantity and product set averages $13.25, most of which the middleman captures. India and China are aggressive with subsidies. Tax rebates, lower land and labor costs, expedited approvals, and billions in grants give India and China companies a distinct price advantage.

U.S. plants operate under continued FDA inspection, and we welcome inspections because American patients live and die on the quality of our products. We believe that it is our moral obligation to produce the highest quality generic medicines possible. Many foreign plants go years without inspection.

When FDA inspectors do visit foreign facilities, they found appalling practices which would have shut down a U.S. manufacturer. At one India generic maker, staff destroyed documents with acid and shredders to hide falsified safety data. It is within these

constraints that Oxford is only operating at 55 percent of our capacity.

We could easily quadruple our monthly output and double our workforce if we also—and we also have land and technical capability to build an onsite integrated API facility, but we need policy certainty, and most importantly, committed demand. Federal policy can help create the environment that we need to undertake this expansion. I urge the Committee to support four concrete and practical actions.

First, affirm generic pharmaceuticals as a national security industry under Section 232 investigation. Second, give the procurement priority to legitimate domestic manufacturers through the VA, DOD, and Medicare programs. Reward end-to-end domestic manufacturing through long-term Government contracts.

Third, support investment in domestic pharmaceutical manufacturing and API production through targeted grants and tax incentives, and fourth, require complete country of origin information on labeling. Patients deserve to know where their medicines are manufactured.

Managing mid-stage Parkinson's is hard enough without worrying about the safety of my wife's medications. The four solutions mentioned will be vital in changing the landscape of generic pharmaceutical manufacturing in this country. Thank you.

The CHAIRMAN. Thank you, Mr. Neely. Now, I would like to introduce Patrick Cashman. Mr. Cashman is the President of USAntibiotics, the last domestic manufacturer of amoxicillin.

Mr. Cashman has decades of experience in the pharmaceutical industry, leveraging international partnerships and holding senior leadership positions at globally recognized pharmaceutical brands.

Based in Tennessee, he oversees the R&D, quality, manufacturing, regulatory affairs, and other teams that work to provide the American people with a life—with lifesaving antibiotics. Please begin your testimony.

STATEMENT OF PATRICK CASHMAN, PRESIDENT, USANTIBIOTICS, LLC, BRISTOL, TENNESSEE

Mr. CASHMAN. Chairman Scott, Ranking Member Gillibrand, distinguished members of the Committee, thank you for the opportunity to testify. My name is Patrick Cashman, and I serve as President of USAntibiotics, headquartered in Bristol, Tennessee. We are the last remaining domestic manufacturer of amoxicillin, the most prescribed antibiotic in the United States.

My colleagues and I are in the business of the three Fs, formulating, finishing, and filling the highest quality amoxicillin in the United States. We never import finished form drugs, and we have never and will never purchase our active pharmaceutical ingredients from China or India. Our facility has supplied this critical medicine to American patients for more than 40 years.

Until 2008, every dose of amoxicillin came—in this country was produced at our Bristol plant. Then came the years of escalating subsidized competition from Indian and Chinese drug makers. By 2020, our production lines had gone dark, our assets were in bankruptcy, and the United States had become entirely dependent on foreign sources for the most prescribed antibiotic in America.

In 2021, private American investors rescued the facility because they recognized the national security imperative of domestic antibiotic production. Over the past four years, we have revived the plant, rehired and expanded our workforce, and restored America's ability to manufacture this lifesaving medicine.

Seniors account for a disproportionate share of antibiotic prescriptions. Adults over 65 receive antibiotics at rates 50 percent higher than younger Americans. Hip replacements, cardiac procedures, cancer surgeries, all life extending interventions that depend on reliable antibiotic access. Pneumonia alone causes over 50,000 Americans annually, with seniors representing the overwhelming majority of deaths.

Without antibiotics, routine surgeries become lethal gambles, and common infections become death sentences. Yet the U.S. remains dangerously exposed. China produces approximately 45 percent of the active pharmaceutical ingredients used in amoxicillin today and supplies the majority of API used by Indian manufacturers. The result is most amoxicillin on pharmacy shelves represents Chinese chemistry with Indian finishing.

We source exclusively from trade agreement compliant European partners, but we control only about five percent of the U.S. market, despite having capacity to meet 100 percent of the national demand as we once did. If our facility were to close permanently, it would take at least five years and hundreds of millions of dollars to rebuild domestic capacity.

That timeline assumes favorable regulatory and economic conditions that are far from guaranteed. More realistically, rebuilding could take a decade. Here is the paradox that brought me before you today. In 2021, our amoxicillin facility was rescued from bankruptcy by Jackson Healthcare, one of the largest healthcare staffing firms in the country.

They have invested tens of millions in private capital to restore domestic manufacturing capacity. Because of that ownership structure, USAntibiotics is now excluded from competing as a prime contractor for federal amoxicillin contracts structured as small business set asides.

Since January 2023, we have sold roughly $1 million to the Federal Government through the federal supply schedule. During that same period, the Department of Health and Human Services spent approximately $40 million on foreign origin amoxicillin. That contract was structured as a small business set aside, thereby excluding America's only domestic manufacturer from competing. The irony is devastating.

The company that saved domestic capacity cannot sell to the Government that claims to prioritize supply chain security. Meanwhile, small business re-packagers import Chinese and Indian drugs and slap American labels on the bottles. To revitalize domestic manufacturing of generic antibiotics and to protect our healthcare supply chain, I respectfully offer the following recommendations.

First, create procurement pathways that allow domestic manufacturers of critical medicines to compete regardless of parent company size. Second, define domestic manufacturing to exclude simple repackaging of foreign products. Third, establish a strategic na-

tional stockpile procurement preference for genuine domestic manufacturers.

Fourth, provide long-term purchasing agreements that enable capital investment and workforce retention. We are not asking for subsidies or handouts. We are asking that when the Government buys antibiotics, it prioritizes genuine American manufacturing.

USAntibiotics stands ready to secure America's antibiotic supply chain. We have the infrastructure, we have the expertise, and the commitment, but we need Congress to align procurement policy with national security reality. Thank you for attention. I welcome your questions.

The CHAIRMAN. Thank you, Mr. Cashman. Next, I would like to introduce our final witness, Dr. Eric Edwards. Dr. Edwards is the CEO of Phlow, a domestic drug ingredient manufacturer working to secure the supply chain for medications. With extensive experience in the pharmaceutical industry, Dr. Edwards understands the Nation's acute reliance on foreign generic medications.

As CEO of Phlow, Dr. Edwards has spearheaded Phlow's partnerships with federal agencies like the Department of Health and Human Services and Department of War to shore up our supply chains and address the critical need for drug ingredient manufacturing in the United States. You may give begin your testimony. Thanks for being here.

STATEMENT OF ERIC EDWARDS, MD, PH.D,
CEO, PHLOW CORP., RICHMOND, VIRGINIA

Dr. EDWARDS. Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee, thank you for the opportunity to testify on a matter that directly impacts the health and well-being of millions of Americans, namely our Nation's growing dependence on fragile foreign pharmaceutical supply chains and resulting drug shortages that continue to threaten patient safety, public health, and national security. My name is Eric Edwards.

I am a physician, scientist, and co-founder of Phlow Corp, a leading American pharmaceutical company created to advance the domestic development and manufacturing of critical medicines and help reshore our medicine supply chain. I also continue to serve as a volunteer paramedic in Virginia, providing care in my local community where, during an emergency, the consequences of drug shortages are most acutely felt.

In my own clinical experience, there have been moments when critical drugs, such as epinephrine for allergic emergencies, were simply unavailable. Substituting or improvising can mean the difference between life and death. Our pharmaceutical dependence is not just a public health concern, but rather a national security threat.

If conflict disrupt Asian trade routes or trigger export bans, the U.S. could lose access to medicine ingredients needed for critical care, for oncology, for infectious disease treatments. Furthermore, military readiness could be severely compromised by disruptions in the supply chain as purposeful adulteration or export bans on key drug ingredients could also leave our warfighters without vital medicines.

Over the past few years, Congress has taken significant steps to secure the rare earth mineral industrial base, including by expanding the national defense stockpile. That level of urgency is required for APIs. Just as rare earths underpin critical technologies, APIs underpin the entire pharma supply chain, and without them, we cannot make a single critical medicine.

Phlow was created to help solve this problem. In partnership with the U.S. Government, we have built a state-of-the-art advanced manufacturing campus in Virginia designed to domestically produce APIs at both small and large scale. Through our groundbreaking partnership with the Administration for Strategic Preparedness and Response, Phlow is developing and supplying a broad catalog of essential APIs.

For each program, Phlow reconstructs the chemistry, sources starting materials domestically or from allied nations, and leverages state-of-the-art in development and manufacturing approaches such as continuous manufacturing to drive efficient, higher yielding production, cost competitiveness, and a reduction of our environmental impact, all on U.S. soil.

To date, we have completed five API development programs, filed four drug master files with the FDA, and have a dozen additional API programs in various stages of development. We are also proud to support the DoD/DOW in strengthening the warfighter supply chain. Importantly, we worked with the U.S. Government to conceive of and build the Nation's first strategic active pharmaceutical ingredient reserve, or SAPIR Program, designed to function as a national security buffer for medicine supply chains.

Through SAPIR, we are working to maintain an inventory of ingredients for the most essential medicines and precursor chemicals identified by the Federal Government, helping to protect Americans during future public health emergencies until we can make these medicines on U.S. soil once again.

Despite considerable progress, the onshoring movement remains fragile. For this transformation to succeed, certainty, focus, and sustainability are essential. No company, no matter how mission driven, can sustain long-term domestic production without predictable demand and multi-year commitments.

America must invest in additional advanced manufacturing capacity. Several key policy enablers are also required. First, to prevent future shortages and secure our supply chain, the Government must create a comprehensive long-term plan, as well as support a centralized authority to align policy and funding, while bringing stability for patients and predictability for manufacturers.

Second, the market will not shift back to the U.S. if buyers of essential medicines remain structurally rewarded for choosing the lowest immediate cost, even when those savings come at the expense of long-term security and patient safety.

Third, to build enduring resilience, the Administration and Congress must resource these programs with multi-year contracts, similar to how we support defense and energy infrastructure. This allows U.S. manufacturers to plan, to invest, and to scale with confidence.

Fourth, we must level the playing field and ensure that domestic manufacturers can compete fairly against foreign producers who

benefit from heavy tax subsidies, lacks of environmental and labor standards, and currency manipulation, advantages that artificially suppress prices and distort global markets.

Finally, as previously recommended by this Committee, it is critical that Congress prioritizes work to close the Acetris loophole. This loophole breaks the connection between made in America and the actual location of pharmaceutical ingredient manufacturing, enabling continued dependence on foreign API supply chains—even in federal purchasing programs intended to prioritize domestic production.

If we fail to act decisively, the next crisis will not be hypothetical. The shortages our great nation has been coping with have shown us the harm they can cause. However, if we succeed in creating a durable, competitive, and secure domestic pharmaceutical manufacturing industrial base, we will have restored one of the most critical pillars of national resilience.

I thank this Committee for your leadership and shining light on this issue. Pharmaceutical supply chain vulnerabilities are not inevitable. They are a product of choice. Together, we can choose to build a safer, more resilient, and more self-reliant future for all Americans. Thank you, and I welcome additional questions.

The CHAIRMAN. Thank you. I am comfortable that we are going to see big change. I mean, we are going to—you know, we are going to see a plan, a supply chain plan, and we are also going to get legislation passed that is going to require a country of origin for ingredients and for manufacturing, so let me turn it over to questions. We will start with Senator Johnson.

Senator JOHNSON. Thank you, Mr. Chairman. Again, I just want to applaud you for holding these hearings. I think they are probably, you know, if not the most important, some of the most important hearings we are holding in this Congress. I want to thank the witnesses for the solid testimony and solid recommendations.

Now, it is interesting I met with Dr. Patrick Soon-Shiong yesterday, a man of incredible accomplishment, but one of the things he did, he is the founder of American Pharmaceutical Partners. I mentioned this hearing, and he said, well that is you know, similar to what happened in 2008 with heparin.

This is not a new issue. We had contaminated heparin back in 2008 coming from China. It was on purpose. It was contaminated with a cheaper ingredient that could not be detected by normal measurements, and I see one of our witnesses shaking their head, but I will ask you about it, but I would like to enter into the record.

I have got a white paper I think written by API—APP. One by the American Health and Drug Benefits, and then one from the Science Director, European Journal of Pharmaceutical Sciences, which we have talked about this.

Senator JOHNSON. Mr. Coukell, you were shaking your head. What—describe this. Again, this is nothing new. This happened in 2008 and here we are in 2025. We are describing the same problem which we have not addressed.

Mr. COUKELL. You are exactly correct, Senator. In 2007, 2008, somebody in China figured out how they could spoof the standard test for the active ingredient in heparin. They did so for economic reasons.

We call it economically motivated adulteration, and they sold defective drug into the United States. That led to a kind of realization about how dependent we are on those foreign supply chains. FDA was given new authorities, the inspectional framework was rejiggered, but structurally——

Senator JOHNSON. We solved the problem, right? We fixed it?

Mr. COUKELL. Structurally we are still headed in the wrong direction. Civica actually has heparin with U.S. API. Most of the heparin comes originally from the intestinal mucosa of pigs. China has a big swine herd and most of the world's heparin comes from China.

Civica has heparin API from the U.S., but it is more expensive than the Chinese heparin, so you know, if we are going to fix the problem, we have to be willing to source from the U.S.

Senator JOHNSON. Let's talk because I want to go back to the precursor chemicals. A new term I have—the key starting materials. Is that the same thing?

Dr. EDWARDS. Yes. Precursor chemicals, even going back all the way to petrochemicals, are the chemical starting materials that feed into the intermediates and ultimately the active pharmaceutical ingredients.

Senator JOHNSON. How many of those key starting materials, precursor chemicals are there? I mean, are we talking about hundreds? Are we talking about a few dozen?

Dr. EDWARDS. No, thousands and they are—the majority are made in China.

Senator JOHNSON. That is a refining process?

Dr. EDWARDS. Correct——

Senator JOHNSON. There are literally thousands. I mean, are there a smaller batch of general categories and then specific types within those categories?

Dr. EDWARDS. I think it is important to note for this Committee—and thank you, Senator, for raising this—that there are thousands of drugs in our supply chain themselves, and it is really critical for us as a nation to prioritize. We must focus. We cannot boil the ocean. We must secure our industrial base, focusing on those critical essential medicines that are prioritized by criticality, vulnerability, and reach.

I would say there is a smaller subset that we can identify linked to a smaller group of active ingredients that are necessary to sustain the health of our population, because there are some medicines that have no therapeutic alternative, and others where we are not as concerned about the supply chain failing because alternatives are readily available.

Senator JOHNSON. You know, so one of the key precursor chemicals is oil itself, correct? Then we have plant based. Would that be considered, you know, things that are extracted from plants, or from bacteria, or from algae, or from—I mean, can you just describe that chain starting from the most basic all the way up to API and then to the final drugs?

Dr. EDWARDS. Sure. Certain key starting materials are derived from the petrochemical industry. Some, ironically, are derived from the rare earth mineral industry. There is a connection there.

Some of these starting materials are synthesized to create solvents or reagents like toluene or benzene that we require in order to manufacture these active ingredients. Still others can be built leveraging synthetic biology, to your point, Senator.

For example, one of our active pharmaceutical ingredients where we could not source the key starting material in any domestic location, we partnered with a company to leverage a synthetic biology approach or fermentation to help actually manufacture that starting material, which is one way to do it more cost competitively, so across the spectrum, there is a variety of chemical sources.

Some are synthetically derived. Some are biotechnologically derived. Regardless, it starts with mapping and knowing where they are coming from and focusing and prioritizing in order to ensure that we get a start somewhere.

Senator JOHNSON. If I could just real quick, Mr. Chairman, because I want to go quick to Tom Neely. What are your raw materials? Because you said you wanted to create the capability to produce API, so your raw materials are still API from where?

Mr. NEELY. Well, the one I am speaking of comes from China. Of the 13 product families that we produce, two come from China, and everyone else comes from outside the United States, but it is Europe mainly.

Senator JOHNSON. Again, because you are compounding these things or you are turning them into drugs, probably have a greater sense of quality control, unless they are doing something like they did with the heparin, where they disguised the adulteration.

Mr. NEELY. To me, it is all about vertical integration and the synergies you get from vertical integration. If you are able to build an API plant right next to a manufacturing plant, you are going to have some cost savings. That is what it is going to take because China is so cheap.

Senator JOHNSON. Again, my guess, I know, Mr. Chairman, you are all over this, is we require labeling to know exactly where not just the API comes from but precursor chemicals.

I think that will radically change because people will demand complete U.S. supply chain for their drugs. They will demand it, and they will pay a higher price. By the way, drugs are not—particularly generic drugs are not that high a spend in terms of our overall medical bill, price tag, so.

Mr. NEELY. Senator Johnson, you are hitting the nail on the head because if I am buying an API from Europe, for example, but they are getting their precursor from China, it defeats the purpose.

Senator JOHNSON. Right. Thank you, witnesses. Thank you, Mr. Chairman.

The CHAIRMAN. Ranking Member Gillibrand.

Senator GILLIBRAND. Thank you, Mr. Chairman. In this series of hearings, we have heard about a variety of incentives to help support domestic manufacturing, such as targeted grants, low interest loans, tax incentives.

From your company's perspective, what is the most impactful economic incentive that would determine how you choose to invest and operate in the U.S.? What is the most significant factor currently limiting your ability to operate in the U.S.? How do current procurement rules shape the market as a race to the bottom?

How would purchasing and procurement signals from the Federal Government impact domestic manufacturing capability? We can start with Tom and go across.

Mr. NEELY. Thank you, Ranking Member Gillibrand. For me, it is all about volume. Keep in mind that one dose at the factory that we work in costs a penny and a half. We have to add volume, not price. Price is secondary, but it is really to maximize the capacity of our plant.

We have to operate 24/7. Today, we have the capability of producing 1.8 billion doses annually, and what right now we are doing is one billion, and because the distributors are focused just on price, so there needs to be a little bit of a break there, and in my mind, and I am not an economist, but in my mind, if we had a system very similar to sugar, for example, because we cannot produce today all the domestic demand.

If we had a carve out, a marketplace where you had priority, and if we are producing in the United States and we fulfill our total demand, that would help us tremendously.

Senator GILLIBRAND. Interesting. Allan.

Mr. COUKELL. Thank you, Senator. I mentioned that we have a couple of dozen generic drugs in development for our facility. Some of those are products that are selling right now at prices that frankly in the U.S. you couldn't buy an empty glass vial and fill it with sterile water for that price.

We are developing these products, but we don't expect to sell them unless and until there is a drug shortage. As Mr. Neely says, if you have a pharmaceutical manufacturing facility, you would like to run it full. That makes it efficient and amortizes the cost of all of your personnel and quality over more units.

There are a lot of drugs that at today's prices we can make competitively in the U.S., but for those very low cost drugs, which are also some of the most essential products, we have got to create a consistent demand for U.S. products.

Senator GILLIBRAND. Mr. Cashman.

Mr. CASHMAN. Thank you, Senator Gillibrand. The Federal Government, in the case of amoxicillin, has structured all recent contracts as small business set asides, and this policy exists for good reasons, helping small businesses compete against larger corporations.

When applied to critical medicines with severe supply chain vulnerabilities, it produces negative consequences for industry, taxpayers, and patients. USAntibiotics would have closed permanently without Jackson Healthcare's rescue from bankruptcy in 2021. No one else stepped up.

No private equity firm saw a profitable opportunity. No pharmaceutical company wanted to enter a low margin generic antibiotics market. Jackson Healthcare viewed this acquisition as a national security imperative, not a money making proposition. Because now with this patriotic investment, we are effectively barred from selling to the Federal Government as a prime contractor.

The Government's rules prevent only American manufacturers from competing while allowing foreign competitors, often subsidized by their own government, to dominate federal procurements.

Senator GILLIBRAND. Dr. Edwards.

Dr. EDWARDS. Thank you, Ranking Member Gillibrand, for this question. First and foremost, you all may have seen today the U.S., China, and Economic Security Review Commission finally released their annual report calling for exactly what Senator Johnson spoke to relating to urging the disclosure of country of origin for all APIs and key starting materials.

I think that is really, really important from a policy perspective, but the central obstacle in restoring the reliability of our pharmaceutical supply chain is not a lack of data here. It is actually a lack of aligned incentives.

The market will not shift back to the United States if the buyers of essential medicines, including hospitals, clinics, wholesaler intermediates, GPOs, remain structurally rewarded for choosing the lowest immediate cost, even when those savings come at the expense of long-term security and patient safety.

Candidly, information about quality sourcing and supply chain fragility is important, it is critical, but it is little more than a warning label if purchasers are neither financially supported nor contractually required to act on those labels.

To change outcomes, federal entities should adopt procurement policies that value supply chain reliability and quality. Strategic investment in domestic sourcing helps save lives by strengthening national health security, reducing drug shortages, and mitigating the potential future for the wide disruptions they can cause.

Senator GILLIBRAND. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Tuberville.

Senator TUBERVILLE. Thank you, Mr. Chairman. Gentlemen, thanks for being here. Mr. Neely, you mentioned in your testimony the need for federal procurement reform. Do you currently sell to the VA or the DOD?

Mr. NEELY. We do, but it is a slow process right now. We need to see a lot of growth in that area. It is a very important channel for our products. It starts, I believe, with the 232, and then it migrates into changes in a few policies of the VA, and DOD, and Medicare, quite frankly, so that we can source the VA and the DOD effectively. At the same time, we maximize the capacity of our operation.

Senator TUBERVILLE. Is this a bid process?

Mr. NEELY. There is two parts to it. There is FSS, which is the Federal Supply Schedule, and we have seen growth there. Now, we have bid unsuccessfully on several opportunities.

We have been shut out to date. The last bid we got shut out by a firm that is Chinese American, and that is partnered with India American. Now, they followed the policy, so I am not saying that they didn't. There is gray area in the policy, but if it could be clearer and give us the opportunity, and level the playing field, we would have won that bid.

Senator TUBERVILLE. You said that in your opening statement that you could quadruple your production. You know, what would you need to do that?

Mr. NEELY. We have a facility set up so that all we would need is about $18 million of capital expenditure and equipment. The plant is available for additional packaging lines and granulation processing.

All we need is $18 million. Now, we have $130 million invested in the plant right now, but it comes down to a business decision and a return on investment.

If we could get to that point, we would increase our capacity from 180 million doses a month to over 600 million doses a month, but right now all we are doing is selling 100 million doses a month because the distributors all care about just cost. That is it.

Senator TUBERVILLE. Thank you. Mr. Coukell. Is that how you pronounce that?

Mr. COUKELL. Senator, Coukell.

Senator TUBERVILLE. Coukell, okay. Your commitment to domestic manufacturing is a no China policy, is that correct?

Mr. COUKELL. Unless the product is not available anywhere else.

Senator TUBERVILLE. Yes. What changes to the market price do you think are the most important to make U.S. generic drug production financially viable?

Mr. COUKELL. Thank you, Senator. As I mentioned, there are some injectable drugs that with today's prices are financially viable now. There are drugs that are selling at, you know, at $0.30, $0.40, and those aren't financially viable in the U.S.

We need some system where purchasers select for quality, select for domestic manufacturers, and if that costs a little bit more, we probably need to make them whole for that cost.

Senator TUBERVILLE. Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Tuberville. Mr. Neely let's talk about inspections, so do they—does the FDA tell you when they are going to inspect you?

Mr. NEELY. No.

The CHAIRMAN. Okay. What if they walked in and found a violation, what would happen?

Mr. NEELY. Depending on the severity of that violation, if we received a 483, we would be closed, and a 483 is against the law. John Schultz, our President, and I would probably be indicted.

The CHAIRMAN. The FDA often announces foreign inspection weeks in advance. It gives manufacturers plenty of time to prepare. Just recently, the FDA found an Indian facility in violation citing flying birds, skittering lizards, and roaming cats in the right of the manufacturing plant. If that happened to you, what would happen?

Mr. NEELY. We would be closed. The difference is right now in India, since we receive so much generic product from India, that all they do is either they move their operation to another plant and swap the different medications produced, or they threaten the United States by saying if you close this plant, you are going to incur a shortage of product. That is the national security issue that we face today.

The CHAIRMAN. Have you ever heard of the FDA waiving a violation? Would they waive a violation for you if it was going to cause a shortage?

Mr. NEELY. No, sir.

The CHAIRMAN. Have you heard them ever waive a violation for a foreign manufacturer?

Mr. NEELY. Anecdotally, I have heard it in the press.

The CHAIRMAN. Mr. Coukell, how does Civica's model serve to limit shortages?

Mr. COUKELL. Thank you, Senator. We do a number of things that are different from the traditional generic supply chain. It starts with long-term commitments. The hospitals that partner with Civica commit to multi-year fixed-volume contracts. We in turn provide that commitment to our suppliers. That creates a level of stability that doesn't usually exist in the generic drug business.

The CHAIRMAN. You have to commit to price to that.

Mr. COUKELL. We commit to price as well.

The CHAIRMAN. Yes——

Mr. COUKELL. That is right. That lets companies know that they are going to have market share, lets them invest in quality. That gives them a commitment to that product. Another thing that we do that is unique is we target a six-month buffer inventory of every drug.

The reason we do that is if somebody drops out of the market, then we can draw down on that inventory while somebody is making new batches, because it takes a while for companies to ramp up production, even if they have FDA approval to make that drug. We also do a really rigorous quality oversight process of our suppliers.

We are going out actually visiting their facilities, walking the floors, doing an audit, looking at their records, and then we do that on an ongoing basis to ensure that we are choosing suppliers that are less likely to have a failure to supply in the future.

The CHAIRMAN. Thank you. Mr. Cashman, what would happen to our Nation's supply of antibiotics if your plant were closed?

Mr. CASHMAN. Chairman Scott, we would be completely dependent on Indian and China. All of the API comes from either China or India, with the exception of one producer in—well, several producers in Europe. With our plant closing, there would be no finished dosage forms whatsoever produced in the United States.

The CHAIRMAN. How many months or years of supply of amoxicillin do we have in the country? Do you have any idea?

Mr. CASHMAN. No, sir. I don't know that. What I can comment on is we keep a year's worth of API supply at our facility, and we have about a year's worth of finished goods products in our facility as well.

The CHAIRMAN. Does the FDA inspect your facility?

Mr. CASHMAN. Yes, it does.

The CHAIRMAN. Okay. If you had flying birds and lizards, what would happen?

Mr. CASHMAN. We would be shut down.

The CHAIRMAN. Would they care if there was a shortage?

Mr. CASHMAN. Excuse me?

The CHAIRMAN. Would do you think they would care if there was a shortage—?

Mr. CASHMAN. Chairman Scott, no, I don't think they would care.

The CHAIRMAN. Dr. Edwards, why is it so important that we make active drug ingredients or APIs right here in the United States?

Dr. EDWARDS. The active pharmaceutical ingredients are the components of the drug that give that medicine the therapeutic effect. Some might say it is the most critical component, given that

definition. For us, we have lost this industrial base over four to five decades now.

It has gotten to the point where, in many cases abroad, we rely on a single source outside the United States to produce the medicines that our seniors and Americans rely on every single day to treat a variety of acute and chronic issues.

For us, this truly is a matter of national public health security, but it is also a matter of national security as our war fighters on the battlefield have to deal with the fact that they may be having to utilize a drug that is made with ingredients coming from a potential foreign adversary. It is simply unacceptable.

The CHAIRMAN. Mr. Neely, is it too much to ask that plants don't have flying birds and skittering lizards?

Mr. NEELY. No, sir, it is not, and I think it is important to state that quality is not cheap. For every $1.00 of expense that we spend, $0.38 is spent on quality. What I am seeing is——

The CHAIRMAN. Say that again.

Mr. NEELY. Every $1.00 of expense that is spent in our plant, $0.38 is based on quality—is spent on quality. What I am seeing is our foreign competition is cutting their cost so that they can come up with the lowest price possible to sell to the distributors to get the contracts or get the formulary.

Senator GILLIBRAND. Related. Drug manufacturers around the globe are frequently the target of cyber-attacks. These attacks are perpetrated for a wide range of reasons by competitors, adversarial nations, even non-state actors, and can cause disruptions in the supply chain and impact the availability of key drugs and their components.

Which link of the supply chain is most vulnerable to cyber-attacks, and in what ways does cyber resilience protect domestic drug production? What types of measures does your company take to promote cybersecurity?

How much does this cost out of your operating budget? For Mr. Coukell directly, how can new and existing domestic drug manufacturers engage with CISA, the FBI, DHS, and other federal authorities for robust cybersecurity protections? You can start Mr. Coukell.

Mr. COUKELL. Thank you, Senator. I think it is an important risk to flag. We often think about what if a country were to cutoff our supply, but you can shut down a pharmaceutical plant the way you can shut down any business with a cyber-attack or a cyber ransom attack, and if you Google, India cyber ransom attack pharma, you will find a long list of companies there that have been targeted.

Which is not to say that we are not also at risk in the U.S. Of course, those sorts of attacks know no borders, but it is reasonable to think that a company that is cutting corners on its manufacturing quality is probably not also investing in cybersecurity the way it should.

There are a number of federal programs to support U.S. manufacturers, but there is no doubt, to ensure our supply, we need to be ensuring that our domestic manufacturers and our manufacturing partners have top notch cybersecurity.

Dr. EDWARDS. Yes. Thank you, Ranking Member Gillibrand. This is a critical, critical aspect of the pharmaceutical supply chain and

resiliency across them, and I think every single node of the supply chain is at risk, not one more than another.

In combination and in partnership with the Administration for Strategic Preparedness and Response, Phlow's government program incorporated cybersecurity into the infrastructure build from day one. We have partnered with the FBI, Homeland Security, and CISA in order to test our systems and to come on top of this infrastructure build because we know that fragility and that vulnerability is real.

In 2017, for example, Merck experienced a ransomware attack that ended up having an impact of over $1 billion in potential damages. This is not something that is theoretical. It has happened in the past, and in the age of where we are today and the vulnerabilities that we are experiencing from a geopolitical conflict potential, this is only going to become even more of a threat.

For us, it is about not building an infrastructure and then trying to decide on, let's layer cybersecurity on top of it. It is about integrating that cybersecurity posture from day one and ensuring that anyone who works alongside the Government supply chain to secure our critical industrial base is making sure that we are prepared for the future as a matter of national public health security.

Mr. NEELY. I do think that the new regulation around DSCSA and serialization has improved so that we track every batch, every case, every bottle down to the consumer level. If there is ever a recall, we can identify where it is.

Senator GILLIBRAND. Also related, Mr. Neely, you talked about that there needed to be some support. You weren't specific about what the support was, but I want to challenge some of the witnesses about what supports would actually matter.

Dr. Edwards, you mentioned your groundbreaking partnership with the Administration for Strategic Preparedness and Response, known as ASPR, in your testimony. Mr. Coukell, you mentioned in your testimony that your facility in Petersburg, Virginia is funded with U.S. Government support with ASPR through the Biomedical Advanced Research and Development Authority, known as BARDA. Can you both, Dr. Edwards and Mr. Coukell, speak about your experiences, what is working, what is not working.

Mr. Neely and Mr. Cashman, if you want to add, what types of support you would want. Because it is relevant for us because we are definitely going to do the transparency stuff. That is like very much common ground—something the chairman and I want to work on immediately, but more is needed, and we need more color on the issue. Go ahead, Dr. Edwards.

Dr. EDWARDS. Thank you for that question, Ranking Member Gillibrand. You know, ASPR has undertaken a critical mission since we first got started with them over five years ago through now multiple Administrations, and a pandemic, and on the other side of that pandemic, to try to address pharmaceutical supply chain sovereignty.

However, they need help. The GAO has repeatedly recommended that HHS implements a formal department wide mechanism to coordinate drug shortage activities. This would ensure that FDA, CMS, DOD, DOW, and ASPR, and other agencies work together rather than in silos, which is really what is happening today. There

need to be clearly defined roles, goals, and outcomes among the agencies.

Finally, ASPR and any other agency that is tasked with this extremely important mission should ensure that they receive long-term sustainable funding as well, to support companies like ourselves, but also others who are working to bring back this industrial base, as this is not something that Phlow can do alone.

You need multiple Phlow's. You need multiple companies working together. Really helping them raise up their posture and have the support they need going back to that centralized authority would be a critical step in the right direction, specifically.

Mr. COUKELL. Thank you, Senator. The funding that we received from ASPR to invest in our plant was very important. Taking into account the capital costs and the startup costs, nearly a third of that funding came from ASPR. That was during the pandemic when there were resources to make those kinds of investments.

In recent years, the Office of Industrial Base Management and Supply Chain within ASPR, which is the office that has the expertise and the mandate to make these sort of targeted investments, has had very low, very flat budget, and hasn't had the ability to make additional investments, so they can do more, but we have to support them to do more.

Mr. NEELY. Ranking member, mine is pretty simple. I would think that this Committee would want a plant that is just fairly new to be at full capacity. To be at full capacity, an $18 million grant to build out three packaging lines and another granulating piece of equipment could quadruple the throughput through our operation.

Mr. CASHMAN. I would second that, Ranking Member. I would also add that we need a very comprehensive approach. Strategic antibiotic manufacturing fund with targeted grants and low interest loans would be very, very helpful, similar to the CHIPS Act.

Second, tax incentives for domestic API production, including immediate expensing of new equipment and enhanced R&D deductions. Third, supply chain visibility, which you mentioned, which I think is so important for patients and doctors and hospitals to know where their medications come from.

Fourth, recognition that essential medicines are a national security assets, making manufacturers eligible for industrial based support available to other critical sectors. You know, there is a lot of different tools we could employ here, but we need a sustained commitment. I think that is a message we hear from every one of us up here, and it has to be a long-term sustained commitment. Thank you.

The CHAIRMAN. I think Mr. Coukell, didn't you say about—you were talking about the hospitals ought to be compensated for quality, didn't you say in your testimony? Right now I think under Medicare Advantage they are. I think—so but it has nothing to do with medicines, right?

Mr. COUKELL. Thank you, Senator. Let me clarify. What I really meant is right now the thing that drives generic drug purchasing is price.

The CHAIRMAN. Only price?

Mr. COUKELL. To the exclusion of everything else. What we need I think is a system as we have at Civica where when we are looking at a supplier, we are looking at what supplier is less likely to fail us in the future? What are their quality systems? What is their quality maturity? We need to drive purchasing to factor that in.

Which is not to say we become indifferent to price, but we ought to weigh some other things that are pretty important along with price when we choose what drug suppliers we are going to use.

The CHAIRMAN. You know, we have to look at this, but I bet CMS already ranks people enough on quality that they have the ability to put information out whether hospitals and probably Medicare Advantage for sure, or all the health plans, are doing this. They probably—and I bet they already have that ability without even any new legislation, if it was important to them.

I will find out. What would happen—what would happen for each of you if you got 100 percent of the volume from the Department of War and the VA of the things you do today? What would happen to your business?

Mr. NEELY. Quite frankly, Chairman, I would make money for the first time in 10 years.

Mr. COUKELL. I think every company would welcome that, and for the company that got that business, it would be tremendously significant. I do want to make the point that DoD and VA are both one or two percent of the total market.

Changing how they procure drugs, very meaningful to whatever company gets that business, but it is not enough to shift the whole market and bring back. For that we are going to have to get into Medicare and the commercial market.

Mr. CASHMAN. In our case at USAntibiotics it would be transformational. It would be so important for us to have that volume. It would give us a solid base of manufacturing volume to grow on and grow our commercial business on as well.

Dr. EDWARDS. In our case, it would help us baseload our facilities, support the 1.5 million active duty soldiers, secure a supply chain of 25 to 50 drugs that these soldiers depend on a daily basis, and enable us to send a market signal that is real. That will help spur additional private investment and help us grow and sustain our business when that type of demand signal starts to reveal itself because, where do we start?

We start on the federal supply schedule and what the Government actually has authority to do. Ultimately, it can then move into CMS and some of the other challenging environments. Starting somewhere is better than nowhere and we need to get started.

The CHAIRMAN. What would happen to—let's take it from the patient standpoint. If that happened, what would be the benefit to a soldier or sailor, or to a—somebody in a VA facility? What would happen to their quality of care?

Dr. EDWARDS. Chairman Scott, we know that not only patients but also physicians, they don't have a clue where their medicines are made or what they are using, so the first thing that we would emphasize in this is that we would restore trust.

We would begin making sure that we are able to restore trust in the quality of these medicines. We would know where they are coming from. It is really important that we not only emphasize lo-

cation, but we also emphasize quality manufacturing as well. They both go hand in hand.

I think what would happen is we would experience the health and well-being, and more important, the national resiliency, we would experience a change in that, that is significant. It is significant for the well-being and the quality of care that is being provided.

Based off of some of the testing and the reports coming out of the Pentagon and Kaiser and others, we would hopefully experience less adverse events or subpotent medications that have entered our supply chain when we know where they are coming from.

Mr. NEELY. If I could just expand on that, I did an informal poll of my family. We take 23 generic drugs. Now, they are all Medicare, okay. Of the 23, 20 are produced in India, two were in China, one in Canada. Not one is made in the United States.

The CHAIRMAN. You probably—and you don't even know where the ingredients are from.

Mr. NEELY. The only way I was able to find out is because I am in the industry. I research the NDCs, but for example, take a cholesterol medication. It is repackaged. It is owned by a distributor.

You would think, okay, it is a United States product. You do the NDC, it comes from a plant in India. It is labeled in India. India ships it to the United States. They send the bill to Ireland, and but the owner of that business is here in the United States, but they never touched that medicine.

The CHAIRMAN. Did you want to add something?

Mr. COUKELL. Well, I will just make one additional point, Senator, which is I think there is an important difference between a product defect on a given day, which is important and that is a risk to a patient, but it is different from a company that has inadequate quality systems.

At some point in the future, the FDA is going to come along and find they are pouring acid on their records or cutting corners in some other way, and they will have a failure to supply.

Part of what we want to do is shift the market to companies that are less likely to cause a drug shortage and have a failure to supply, which doesn't necessarily mean that on a given day their product is defective.

The CHAIRMAN. We had testimony from Dr. Ball from the University of Indiana that you have an over 50 percent increased chance of hospitalization and death if you take a generic drug from India or China.

Would any of you like to talk about the—how the Department of Commerce should use their Section 232 investigations to support domestic manufacturers? Anybody want to comment on that?

Mr. NEELY. Well, I will because I think it jump starts the whole reformation of what we need to do. It provides some ability to go in and fix the procurement problem, number one.

You know, we have a long time, it seems to me, to reform the entire industry. We have got to get started and we have got to get started as fast as possible. That 232 is the first part of making sure that we can respond to other problems that we have in this industry faster.

The CHAIRMAN. Mr. Cashman, why don't you have contracts with the Department of War, or with the VA—you don't have contracts with the Department of War or VA, right?

Mr. CASHMAN. No, Chairman Scott, we do not. The reason for that is we are not considered a small business.

Many of the amoxicillin contracts—all of the amoxicillin contracts in recent years, have been small business set asides. Because Jackson Healthcare, a fine Georgia corporation, made an investment in our facility, and they spent millions of dollars saving our facility, our facility is not considered a small business, and therefore we can't compete for those small businesses set asides.

The CHAIRMAN. Are any of you familiar with any independent quality testing for imported medicines from China and India? Is that happening?

Mr. COUKELL. Senator, I am not aware of any.

The CHAIRMAN. Anybody else?

Mr. CASHMAN. The Department of Defense has a quality investigation or testing program, which is something we think all imported medications should have tested before they are sold in the United States.

Dr. EDWARDS. I am familiar with a couple of pilot programs that are looking to test.

The CHAIRMAN. It doesn't surprise you that every drug that comes in is not tested?

Dr. EDWARDS. Yes, I think——

The CHAIRMAN. Think about—USDA, you can't buy meat unless you have a USDA inspector at that plant, right?

Dr. EDWARDS. We operate off of an honor system, Chairman, Scott.

The CHAIRMAN. For something you put in your body.

Dr. EDWARDS. Correct.

The CHAIRMAN. We don't do it for cattle.

Dr. EDWARDS. Or groceries, or clothing, or anything else.

Mr. NEELY. Yet at our plant—excuse me, but at our plant, we have an end-to-end testing process and program.

We test every raw material that comes into our plant. We do efficacy testing. We do dis-solvency testing. We do breakage testing throughout the entire process, from the beginning of the raw material to when it is packaged.

The CHAIRMAN. All right. Do you have any other questions? All right. Does anybody else want to add anything that we didn't ask? Anything we should have asked that we didn't ask?

Okay. I think I want to thank everyone for being here today and participating. I look forward to continuing to work with members on this Committee.

I want to thank—especially thank the ranking member for her efforts in this and the fact that we have been able to do this on a bipartisan manner.

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. Thanks, everybody.

[Whereupon, at 04:57 p.m., the hearing was adjourned.]

APPENDIX

Prepared Witness Statements

U.S. SENATE SPECIAL COMMITTEE ON AGING

"MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES"

NOVEMBER 19, 2025

PREPARED WITNESS STATEMENTS

Allan Coukell

Summary of Testimony:

•Civica is a non-profit generic drug company created by US health systems and philanthropies to prevent and mitigate drug shortages.

•Civica currently delivers more than 50 injectable medications,[1] each chosen by US hospitals because they are at risk of shortage, with more than 240 million vials of medicine delivered to date.

•Civica prioritizes domestic manufacturing, both in sourcing from contract suppliers and in our own U.S. sterile injectable fill-finish manufacturing facility located in Petersburg, Virginia. We also conduct direct quality oversight of our suppliers.

•Civica has a "no China" policy in our supply chain, both for finished drugs and for active pharmaceutical ingredient, unless there is no other supply available.

•Despite this commitment to domestic production, the financial model for producing generic drugs is challenging with many generic drugs selling below the marginal cost of domestic production.

•There isn't a single "silver bullet" policy that will restore domestic manufacturing, but a key component of any successful effort will be ensuring market prices that allow for domestic production. Targeted investments can also create new manufacturing capacity at an affordable cost.

•Onshoring active ingredient production cannot succeed unless a manufacturer has FDA approval to turn that API into a finished drug product and a viable domestic market.

Full Testimony:

Chairman Scott, Ranking Member Gillibrand, and Distinguished Members of the Committee, thank you for the opportunity to speak with you today on the issue of "Made in America" pharmaceuticals.

My name is Allan Coukell. I am a pharmacist by training, and I lead public policy for Civica, Inc., also known as Civica Rx, which is a non-profit generic drug company created specifically to mitigate and prevent drug shortages by ensuring a reliable supply of quality essential medicines for U.S. patients.

Civica currently provides more than 50 drugs to 60 health systems, accounting for 1400 hospitals around the country. Over the past seven years, we have delivered more than 240 million vials, serving about 90 million American patients. To provide these medications, we work with a range of manufacturing partners, giving preference to U.S. sourcing whenever possible. Civica has a rigorous quality oversight process for its suppliers involving in-person facility audits and ongoing quality reviews.

We also have our own newly built pharmaceutical manufacturing facility located in Petersburg, Virginia, funded partly with U.S. government support from ASPR/BARDA. It is a state-of-the-art sterile injectable finished dosage form manufacturing facility with the ability to make 90 million vials and 50 million pre.lled syringes per year, as well as to fill and assemble autoinjector pens used for insulin and other products. We have dozens of generic drug products in development for this facility.

Civica has a "no China" policy in our supply chain, both for finished drugs and for active pharmaceutical ingredients (API), unless there is no other supply available.

The drugs that Civica supplies are chosen by pharmacists and physicians from US health systems because they are at risk of being in shortage. These are the products that are the bedrock of emergency and in-patient health care- products like antibiotics, anesthetics, blood thinners, sedatives, and pain medications. These tend to be long-established, low-cost drugs. Most of them are on one or more essential drugs lists.

[1] In nearly 80 distinct presentations.

As this Committee knows, generic medications account for 90 percent of prescriptions in this country, but less than 15 percent of drug spending.[2] While branded drugs are mostly produced domestically, generic drugs are more likely to be produced offshore - increasingly in low-cost manufacturing environments such as China and India. Our dependence on foreign-made active ingredients is even greater than our dependence on foreign finished drug products - a point I will return to.

It is precisely because generic drugs are so inexpensive - and because U.S. systems for drug procurement are so efficient at pushing prices down - that manufacturing has been steadily exiting the US for decades. Make no mistake: low prices are the principal barrier to onshoring generic drug manufacturing.

Let me provide a real-world example. There is a widely prescribed antinausea medication that typically sells for under $0.40 per vial. That is an astonishingly low price for a medicine that can only be produced in an expensive manufacturing facility after a complex process of scientific development, quality oversight, time-consuming testing and analytics, facility inspection and regulatory approval. Even the packaging is subject to strict regulatory requirements. While each of these steps is necessary to ensure patient safety, it would be difficult or impossible at that price for a US manufacturer to compete. Numerous injectable drugs sell for less than $1.

Creating a sustainable market

Generic drugs are the foundation of inpatient medical care. They also cost less in the United States than they do in other OECD countries.[3] In discussing how we create a sustainable market for domestic production, we must be comfortable that it is worth paying slightly more for a reliable and safe supply of quality domestic medication.

The good news is that - at least for the sterile injectable drugs that I am focused on today - it should be possible to substantially increase domestic supply at a manageable cost and in a reasonable timeframe. Indeed, while I focused a moment ago on products selling for less than a dollar, there are others at higher prices that don't need support. Therefore, a policy that puts a floor price on domestic drugs would achieve the desired goal.

One possible approach, developed as a bipartisan discussion draft by the Senate Finance Committee, would be to provide extra payments to hospitals that take into account quality and supply resiliency, along with domestic sourcing, when purchasing generic drugs. Since generic drug spending accounts for only one to two percent of total hospital expenditures, such a program would have a negligible impact on overall health spending but could help to incentivize hospitals to purchase from domestic and/or more resilient suppliers.

The Senate Finance discussion draft was framed in response to drug shortages, but the general approach can also be applied to onshoring. Stakeholders generally recognize that that framework, in its 2024 form, needs to be streamlined. Nevertheless, this approach is directionally correct in that it offsets the incremental costs associated with choosing domestic, higher quality suppliers and holding a buffer inventory to mitigate supply disruptions.

Targeted investments as an insurance policy

In combination with long-term market .xes, Congress should invest in an insurance policy so that domestic manufacturers can develop low-cost products now so the drugs can be ready when they are needed. It takes two to three years to develop a generic drug for an existing manufacturing facility, but companies cannot invest in products if they won't recover their costs. We should support companies to develop these products now and obtain FDA approval, rather than waiting for the day when the foreign supply fails. The FY26 Senate Labor HHS Appropriations bill has report language instructing the Administration for Strategic Preparedness and Response (ASPR) Industrial Base and Supply Chain Management office (IBMSC) to fund generic drug development. Congress should direct funding to ASPR to implement the policy.

Creating new manufacturing facilities

The above policies would support manufacturing of domestic drugs in existing facilities. The cost to onshore a drug into an existing facility is two orders of magnitude less than the cost to create a new manufacturing facility where none cur-

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[2] Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report (Sept. 2024), available at https://accessiblemeds.org/resources/blog/2024-savings-report./

[3] For every dollar the other countries on average pay for generic drugs, in the U.S., consumers pay 67 cents. Andrew W. Mulcahy, et al. ″International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies,″ July 1, 2022, https://aspe.hhs.gov/reports/international-prescription-drug-price-comparisons

rently exists. However, in some cases entirely new manufacturing facilities will be required. New facilities are capital intensive - typically in the hundreds of millions of dollars - and the facility startup costs can be as high, or higher, than the capital costs. Because of the complex development and approval process mentioned previously, more than four years may elapse from the start of construction to the first commercial sales.

No single facility can produce every drug. For example, in the injectable drug space, liquid-fill vials require different equipment than powder-fill vials. Some drugs, such as penicillin-type antibiotics, require their own dedicated facilities. Many cancer drugs also must be separated from facilities where other products are produced.

At current market prices, if new facilities need to be built to enable domestic production, it will require government support for capital investment - combined with some assurance of sustained demand in the face of low-cost foreign production.

Active pharmaceuticals ingredient (API) facilities are different from the facilities that produce finished dosage forms, such as vials and tablets. They require different equipment and expertise. While policymakers interested in onshoring drug production often focus on API (because that is where our dependence on China is greatest), it does no good to produce domestic API unless there is a U.S. facility with an FDA-approved finished dosage form.

Removing harmful market distortions

Generic drugs are beyond doubt the single most effective cost-saving strategy ever deployed in American healthcare.[4] They reduce prices as much as 95 percent below the pre-competition prices of branded drug products.[5] And yet government policies distort the market by introducing mandatory rebates that disincentivize production and prevent prices from rising the way they sometimes need to in a properly functioning market. Congress should remove the market distortions from mandatory rebates on generic drugs, allowing prices to rise to sustainable levels.

Regulatory reforms

Finally, I would like to address the potential for regulatory reform to support domestic manufacturing. Building and qualifying a new pharmaceutical manufacturing facility is a multi-year process. Even developing a new drug for an existing facility is typically a two- to three-year undertaking, The first federal oversight is typically an FDA inspection that occurs in the months after a drug application is filed with the agency. There are opportunities to de-risk this by allowing FDA inspection to occur earlier, and the agency has recently announced a program to enable such earlier engagement.[6]

However, most or all generic drug facilities are multi-product facilities, meaning they are not breaking even until they have multiple different FDA-approved products. The financial viability for a new generic drug facility typically depends not only on the first product approved, but on having a portfolio of approved drugs, each with a typical FDA review time of one year. By shortening the review time for drugs manufactured on already-approved lines and allowing manufacturers to submit drug stability data on a rolling basis, this cycle could be reduced by as much as nine months. This change would have a major impact for new domestic facilities.

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[4] The Association of Accessible Medicines, the generic industry trade association, calculates savings of $445 billion from generics and biosimilars in 2023 and $3 trillion over the prior decade alone.

[5] Ryan Conrad & Randall Lutter, Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices (2019), available at https://www.fda.gov/media/133509/download?attachment.

[6] Food and Drug Administration. FDA Announces New FDA PreCheck Program to Boost U.S. Drug Manufacturing. 07 August 2025. https://www.fda.gov/news-events/press-announcements/fda-announces-new-fda-precheck-program-boost-us-drug-manufacturing

Conclusion

Thank you again for your attention to this important topic and for the opportunity to be with you today. I welcome your questions.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES"

NOVEMBER 19, 2025

PREPARED WITNESS STATEMENTS

Tom Neely

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

Thank you for the opportunity to testify on an issue central to our nation's health security: strengthening domestic manufacturing to produce safe, affordable, and dependable medicines.

My name is Tom Neely, and I am the chairman of Oxford Pharmaceuticals, a U.S. manufacturer of generic oral solid-dose medicines based in Birmingham, Alabama. Our 150,000-square-foot facility-built from the ground up with a total investment exceeding $130 million during an almost 10-year development period-was approved by the FDA in 2019 and is among the most modern generic pharmaceutical production plants in the country.

Oxford produces 13 product families of generic medicines, 10 of which have no other U.S.-"owned" and operated manufacturer, and three of which are classified as critical medicines. Our portfolio is focused on chronic disease management, spanning cardiovascular and blood pressure treatments, mental health, and pain management therapeutics. From amlodipine, the fifth-most prescribed drug in America, to trazodone, the 11th-most prescribed therapy, we manufacture high-quality generics on which millions of Americans rely daily.

We founded Oxford on the belief that these medicines can be made in America to the highest standards of quality and accountability. Our team takes pride in the enormous value we deliver to consumers. Unlike many generic manufacturers-in-name-only, including those with significant federal procurement awards, we don't import finished tablets from India and China only to repackage or relabel them. We procure raw materials, weigh, blend, compress, coat, package, and perform quality tests on everything within the four walls of our facility. We perform the full transformation of active pharmaceutical ingredient into finished dosage form that defines end-to-end American manufacturing.

At Oxford, our purpose is simple: ensuring that Americans can trust and afford the medicines they take and proving that we can still make them here at home.

I. A Fragile System Subject to Overseas Dependence

Two decades of offshoring and price compression from imports have gutted American generic pharmaceutical manufacturing. Our domestic peers are a dying breed, leaving Oxford as one of the last remaining U.S. manufacturers of generic pharmaceuticals.

Understanding the pharmaceutical supply chain reveals how deeply foreign governments have penetrated every stage of American medicine production. The process begins with key starting materials, the basic chemical building blocks. These materials are synthesized into active pharmaceutical ingredients, the compounds that provide therapeutic effects. Manufacturers then transform APIs into finished dosage forms through weighing, blending, compressing, and coating. Wholesalers distribute these finished products to pharmacies, hospitals, and clinics. China dominates the first two stages while India controls much of the third stage but is itself heavily reliant on China for its precursor chemicals. American manufacturers like Oxford operate in stage three but depend heavily on foreign-origin APIs. This nested dependence means a single disruption or chokepoint in China or India cascades through the entire system, potentially leaving American patients without essential medicines.

More than 80 percent of the active pharmaceutical ingredients (API) used in U.S. prescription drugs have no domestic source.[1] With China being the sole source for approximately 45 percent of all key starting materials on the global market, Beijing casts a long and dangerous shadow over the pharmaceutical supply chain.[2] Meanwhile, India produces about half of the generic finished drugs used in the United States but remains heavily dependent on China for its own active ingredients and starting materials.[3]

America's foreign dependence is both deliberate and engineered. As a manufacturer that has fought to sustain robust domestic operations, we face competitors backed by entire foreign countries and their industrial policies. Building a pharma-

ceutical plant in India costs a fraction of what it costs in the U.S. For a low-margin, high-volume business like generics, these advantages are already almost insurmountable. In addition, India has dedicated roughly $4.5 billion in production-linked subsidies for pharmaceutical exports through its national incentive program. It also provides discounted utilities and financing to its companies as well as minimal regulatory overview and barriers.

China offers its own tax rebates, cheap industrial power, and soft loans. In China's ″12th Five-Year Plan,″ the central government allocated CNY 10,000 million (about $1.65 billion) for the Key Drug Innovation Program. Local governments added another CNY 30,000 million (about $4.96 billion).[4] These state-backed advantages make it nearly impossible for U.S. producers to compete on price alone.

Every tablet that leaves our factory is undercut by foreign government-subsidized competitors who treat medicine as a strategic export. The current U.S. trade model has distorted and manipulated the market, directly harming U.S. manufacturers like us and ultimately the well-being of American citizens.

U.S. policy opened our market to unlimited, unfettered drug imports from anywhere, letting the chips fall where they may. Other countries then ruthlessly dominated and captured our industry.

The consequences are visible across our country. The number of U.S. plants producing generic drugs has fallen by more than 40 percent since 2013.[5] Facilities in states such as Louisiana, New Jersey, and California have closed or gone idle. In Shreveport, Dr. Reddy's Laboratories abandoned its 1980s-build facility, which now stands empty after years of losses.[6] That facility once supplied household medicines used by tens of millions of Americans weekly but today is little more than a monument to our policy failures. Its closure shows what happens when we treat medicine as an ordinary consumable. We cannot watch our industry get offshored under the false belief that America has simply been outcompeted.

For Oxford and other U.S. manufacturers, the message is clear: we are on borrowed time. The current policy threatens our livelihood and existence.

II. Foreign Safety Failures and Double Standards

Unrestricted generic pharmaceutical trade has failed American consumers and patients because of foreign states' determination to own the global means of production and their willingness to subvert safety standards in a race to the bottom. Foreign governments have succeeded in creating an enormous U.S. national security weakness that can be weaponized or leveraged at will.

Our own government has created a widening divide between what it demands of American manufacturers and what it tolerates from foreign suppliers. No country should accept a two-tiered system of drug safety with one standard for domestic producers and another more lax regime for importers, but that's the reality U.S. manufacturers and patients face today.

U.S. plants operate under continuous FDA inspection, strict documentation, and full compliance with Good Manufacturing Practices. These are sound safety measures that we're proud to follow. They guarantee the integrity of our medicines. Every Oxford employee understands that quality isn't optional-it defines who we are. When our team upholds those standards, they're not just satisfying a regulation; they're protecting someone's health.

Our facility was built to exceed FDA requirements, with HEPA-filtered environments, validated cleaning systems, serialized packaging, and duplicated digital and paper-base batch recording safeguards. We welcome inspectors at any time because transparency and safety define our operation.

This commitment becomes unsustainable when not everyone plays by the same rules. Many foreign manufacturing facilities go five years or more without FDA inspection.[7] When inspected, advance notice is given in at least 90 percent of cases.[8] Recently, the FDA began conducting more surprise inspections of overseas facilities. Still, the FDA's foreign inspection program fails to provide the same level of quality assurance as U.S. products because of funding and staffing realities and the massive volume of foreign-origin KSM, API, and generic drugs.

When oversight is this inconsistent, patient outcomes suffer. Indian-made generic drugs have a 54% higher rate of severe adverse events compared to those made in the United States.[9]

Recent FDA reports reveal what these safety gaps look like in practice. The lack of consistent oversight lets foreign plants conceal unsafe practices until U.S. inspectors finally arrive. At India-based Intas Pharmaceuticals, for instance, investigators discovered shredded and acid-doused documents in an apparent attempt to hide falsified safety tests and records.[10]

When FDA inspectors entered an undisclosed Indian facility run by Hetero Labs, they found birds flying through storage areas, lizards crawling over raw ingredients,

and cats weaving between pallets.[11] Damaged drums with torn labels sat open to the air, and an uninspected truck full of material drove away after staff refused to allow the FDA team access.[12] Inspectors had already been denied entry to the facility for two hours while the assistant manager and warehouse staff ″had ran out of plain sight upon announcing our intent to inspect the facility.″[13] Such conditions are unthinkable in any U.S. facility-they would trigger an immediate shutdown. Yet this site still ships medicine into our supply chain.

Hundreds of foreign producers have received FDA Form 483 letters for data falsification, contamination, or document destruction. Foreign-site inspections uncover severe violations more than twice as often as U.S. sites, but penalties remain rare.[14] This double standard puts patients at risk by creating uneven regulatory burdens that punish companies like ours that invest heavily in safety, people, and process controls.

At Oxford, quality is a moral obligation. Every batch we make is tested, recorded, and traceable. Our employees know the medicines they manufacture serve their own families and neighbors. Only domestic production ensures this accountability.

Quality isn't cheap, but unsafe imports cost much more in recalls, shortages, and adverse patient outcomes.

III. The Economics of Survival for U.S. Manufacturers

Major U.S. institutional buyers of generic drugs prioritize price over quality or safety. Generic drug production is a low-margin, high-volume business where price trumps all. This business reality facilitates capture by state actors who can heavily subsidize their own industries. They know that if subsidies can be maintained for even a relatively short period, domestic U.S. production can be displaced.

But this does not mean that Americans have seen price savings.

For a typical Oxford product, we receive about $1.50 per hundred tablets. Medicare reimbursement for the same quantity averages $13.25. A handful of large intermediaries absorb the difference. Wholesalers, pharmacy benefit managers (PBMs), and group purchasing organizations (GPOs) dominate this space.

Three Group Purchasing Organizations-Vizient, Premier, and HealthTrust-control about 90 percent of hospital generic contracting,[15] while three PBM-aligned distributors handle roughly 90 percent of retail generic purchases,[16] giving a handful of intermediaries near-total market power.

These middlemen now capture at least $64 of every $100 spent on generic drugs.[17] Rather than passing savings from importing cheap drugs on to patients, these intermediaries use their market power to extract profits from both ends-forcing U.S. manufacturers to sell at ever-lower prices while inflating downstream markups to preserve their own margins. They pit domestic producers directly against imports, leveraging subsidized foreign bids to drive U.S. firms into unsustainable pricing. The result is a race to the bottom, in which production shifts to the lowest-cost, least-regulated source regardless of safety or reliability.

India and China's drug pricing playbook is elegantly simple, if devious. It begins with highly subsidized foreign manufacturers flooding the U.S. market with cheap drugs, allowing middlemen to leverage those low prices to force price concessions from U.S. producers. Of course, once U.S. producers are edged out of the market, foreign suppliers raise prices.

For small and midsize U.S. producers, this system is economically impossible to survive. When subsidized foreign competitors undercut prices through government subsidization and shortcuts on quality, U.S. facilities close-and once that happens, domestic capacity and technical expertise disappear.

Oxford currently operates at 55-60% production capacity because import-dominated market conditions dominate the landscape, but with the right policy support and a relatively modest $17 million investment, we could quadruple output to 750 million doses per month and double employment. That production capability already exists within our facility. The missing piece is a stable home-market environment that values security and quality over the imagined benefits of global free trade and the short-term arbitrage of middlemen.

IV. Rebuilding U.S. Capacity: What the Industry Needs to Expand Production and Secure the Supply Chain

The collapse of America's generic pharmaceutical manufacturing base didn't happen overnight, and rebuilding will take some years, but we can and must start-and we must start now. Every month of delay means another factory closure, another skilled team lost, and deeper dependence on inferior imports.

For decades, federal policy on drug imports has been simple: keep the borders open and hope cheap imports don't destroy domestic capacity. That hasn't worked. For certain agricultural commodities like sugar and peanuts, U.S. policy has always

favored a ″managed trade″ approach in which import volumes-actual outcomes-are capped through quotas. The U.S. generic pharmaceutical supply chain should be at least as secure as the U.S. peanut butter supply chain.

Oxford sees four immediate steps that Congress can take to rebuild capacity and restore a reliable supply of American-made medicine.

1. Affirm Generic Pharmaceuticals as a National Security Industry Under Section 232

We strongly support the Department of Commerce's Section 232 investigation into imports of generic pharmaceuticals and pharmaceutical ingredients. From our perspective on the ground, it is clear that imports of generic drugs are impairing U.S. national security.

The stakes are staggering. More than 133 million Americans, roughly 40 percent of the U.S. population, live with at least one chronic disease requiring daily medication. Cardiovascular disease alone affects 127 million adults who depend on blood pressure and cholesterol medications. Another 38 million Americans manage diabetes with daily therapies. Mental health conditions requiring pharmaceutical treatment affect 57 million adults. If China or India restricted access to key starting materials, APIs, or finished dose generics, these Americans would face immediate treatment interruptions. Patients managing hypertension would risk stroke. Diabetics would face dangerous blood sugar swings. Heart disease patients could suffer cardiac events. Americans battling depression or anxiety would lose access to stabilizing therapies. The human cost would be catastrophic, measured not in dollars but in preventable deaths and suffering.

Once the Department of Commerce has made this finding, the President is delegated broad authority to adjust imports.

Simply deploying a sweeping ad valorem tariff of 25, 50, or even 100 percent will not work. That's because most of the markup on generic drugs is in domestic distribution, intermediary margins, and retail. If the declared import value of a particular product is half a penny, a 100 percent tariff that adds another half a penny to the cost of a dose will not be sufficient for sourcing decisions. Foreign suppliers can easily absorb these kinds of changes.

Instead, we believe a quota system can simultaneously rebuild our domestic supply chain, one drug and API at a time, without disrupting domestic availability or inflating consumer prices.

Rather than across-the-board ad valorem tariffs, we propose ″specific tariffs″ applied against the actual measured export volume that shows up on a ship, not whatever price the importer claims they paid overseas.

Policymakers should pair these specific tariffs with a finite import quota limited to licensed importers and regularly adjust that based on forecasted domestic consumption and production at home and in import-concession countries. We guarantee market space for domestic producers and allow limited imports only for what's beyond current capacity.

Our business collaborated with the Coalition for a Prosperous America to sketch out how such a system could work, with real-world drug examples: See ″To Restore Generic Drugs, Use Sugar's Sweet Model″, October 22, 2025, available at https://prosperousamerica.org/to-reshore-generic-drugs-use-sugars-sweet-model.

Our proposed quota system will not increase costs for U.S. patients or Medicare reimbursement expenses. Historically, changes in production costs have been absorbed by market intermediaries-wholesalers, pharmacy benefit managers (PBMs), and group purchasing organizations (GPOs)-who capture roughly 64 percent of the final drug cost.[18] When these middlemen began sourcing cheaper imported drugs, production costs fell, yet patient prices and Medicare reimbursement amounts did not. The same logic applies in reverse: restricting imports will not raise prices-it will simply redirect profits away from intermediaries and toward sustainable domestic production. Under this proposal the Medicare reimbursement would remain flat.

Any price correction from a quota system would amount to pennies per dose, but it would finally allow U.S. manufacturers to compete in their own market on a sustainable footing and would encourage a wave of onshoring to meet national security objectives. It is essential that both finished generic drugs and active pharmaceutical ingredients (APIs) be included in the scope of the quota system, with product-specific quotas adjusted as domestic capacity ramps up for that product. A petitioning system modeled on the U.S. International Trade Commission's Miscellaneous Tariff Bill System, or more recently the U.S. Department of Commerce's Inclusion Rounds in the steel and aluminum Section 232 actions, would perfectly suit the proposed product-by-product reshoring. These systems give U.S. producers official, regular input in determining which products are covered and what tariff rates apply.

2. Reform Federal Procurement to Reward Quality and U.S. Production

U.S. manufacturers need a CHIPS-style approach to medicine production-one that treats generic pharmaceuticals as a strategic industry rather than a disposable commodity. Federal purchasing power through the Department of Veterans Affairs, the Department of Defense, and Medicare can serve as a cornerstone of market stability and a strong signal for investment in domestic capacity.

The Department of Health and Human Services (including Medicare and Medicaid programs, plus BARDA and ASPR), the Department of Veterans Affairs, and the Pentagon collectively account for roughly 45 percent of all U.S. prescription-drug expenditures, giving the federal government unparalleled leverage over pricing and supply stability.[19] [20] [21] That leverage should be used not just to help seniors and low-income Americans, but to reward and rebuild reliability, resilience, and safety through domestic manufacturing.

Long-term federal contracts for essential generics and active pharmaceutical ingredients can anchor demand for U.S. plants-ensuring steady production, higher quality, and preventing shortages driven by today's concentrated import reliance. Tools like the Strategic National Stockpile and the Defense Production Act can further help sustain a baseline of domestic essential medicine manufacturing. The cost of these reforms would be minimal-pennies per dose-but the benefits would be enormous: secure supply chains, consistent quality, and thousands of well-paying American jobs.

Domestic medicine production strengthens supply-chain reliability and upholds rigorous quality standards. That stability benefits both patients and manufacturers alike. The federal government can provide the demand signals we need to compete and scale.

3. Reshore and Vertically Integrate API Production

Every manufacturer knows that a supply chain is only as strong as its weakest link. For pharmaceuticals, that link is the active pharmaceutical ingredient. We cannot rebuild our pharmaceutical base without rebuilding ingredient production.

At Oxford, we currently import most of our APIs because virtually no U.S. suppliers remain, but we have both the land and the engineering capability to build a dedicated API plant on our Birmingham site. With predictable demand and the right policy support, companies like ours can bring API manufacturing back to U.S. soil.

Policies such as production and investment tax credits under the proposed PILLS Act would directly reduce the cost gap that has driven API and finished drug production overseas and jumpstart new U.S. capacity. A 35 percent production tax credit on U.S.-made ingredients, paired with a 25 percent investment tax credit for new or modernized facilities, would make domestic manufacturing economically viable again. Combined with long-term federal procurement contracts that provide a stable demand signal and a Section 232 framework that limits unfairly subsidized imports, these measures would give American firms the certainty needed to invest.

Building that capacity would mean traceability, quality, and reliability from molecule to medicine. It would make our supply chain safe and resilient against disruptions, whether from politics, pandemics, or natural disasters.

4. Restoring Geographic Transparency and Safety in the Medicine Supply Chain

Patients deserve to know where their medicines come from. Country-of-origin labeling should be required for both active pharmaceutical ingredients (APIs) and finished dosage forms. This simple step would introduce transparency, empower hospitals, federal procurers, and other buyers to choose safer sources, and reward companies that uphold the highest standards.

Even the FDA and the Department of Defense struggle to determine where the ingredients in essential medicines are originate.[22] Roughly 22 percent of active pharmaceutical ingredients for the military's essential drugs lack a verifiable source country.[23] This lack of visibility leaves federal buyers, hospitals, and pharmacies alike blind to risk, making it impossible to track vulnerabilities before they cause shortages or safety failures.

Congress should require full supply-chain disclosure:

- •Country of origin listed on all drug labels for both API and real manufacturing drug labels.
- •Public FDA database linking each finished product to its manufacturing and API sites.
- •Mandatory reporting of production changes, site closures, and inspection outcomes.

Moreover, to secure a safe medicine supply, additional FDA reforms are essential-including unannounced foreign inspections and tougher enforcement when violations occur, such as import bans. By closing the loopholes that let unsafe suppliers hide

behind opaque distribution chains, we can protect American patients from risks that are too often discovered only after the medicine has been taken.

Ultimately, this reform is about restoring trust. Patients and hospitals should know whether their medicines were produced under U.S., European, or other trusted regulatory systems-or in a high-risk plant overseas that has not been inspected for years. Transparency empowers accountability. It ensures that safety, reliability, and quality once again guide the U.S. medicine supply chain.

V. The Human Cost of Inaction

This issue affects American citizens every day. With the shuttering of the Shreveport facility, we lost more than a building. We lost skilled workers: chemists, operators, technicians who spent decades producing lifesaving medicines, only to see their plant close because they could no longer compete with subsidized imports.

Across the country, former pharmaceutical production-linked communities in New Jersey, Pennsylvania, Louisiana, and beyond are now home to idle or demolished facilities. These plants once supported thousands of good-paying, middle-class jobs and sustained local economies. The economic damage is long-lasting, and rebuilding those capabilities takes years. If we lose the remaining domestic producers, we lose not only capacity but an entire generation of expertise. At some time in the future our national security may require this workforce.

VI. Why This Matters for Seniors and Patients

The Committee on Aging is right to make this a priority. America's seniors are the largest users of generic medicine and the most at risk when shortages occur.[24] Generic medicines serve as the foundation of treatment for roughly 90 percent of Americans taking prescription drugs. More than 270 million people in this country filled at least one prescription last year, and the vast majority of those prescriptions were generics.

When a foreign plant halts shipments or fails inspection, it's seniors who face delays, rationing, or sub-optimal treatment.[25] Hospitals scramble to stretch limited supply, pharmacists search for less-than-ideal substitutes, and patients face higher costs and worse care.[26] [27] For vulnerable and elderly patients, drug shortages can be life-threatening. Delays or interruptions in treatment can worsen health outcomes and significantly increase the risk of serious illness or death.[28]

These crises result from a global race to the bottom, where foreign manufacturers cut corners and American producers are close amid unsustainable pricing. The real cost of cheap imports is an unstable drug supply that puts patients at risk.

The cost of rebuilding U.S. capacity is small compared to the cost of dependence. For Oxford's products, the difference between a sustainable domestic price and a foreign import price is often less than one cent per tablet. In return, Americans would gain a reliable supply, verified safety, and high-quality domestic manufacturing jobs.

VII. Oxford's Commitment and Readiness

•Oxford stands ready to do its part. We have the workforce, the technology, and the physical capacity to expand immediately. With capital support and stable demand, we could:

•Quadruple monthly output from 180 million to 750 million doses.

•Employ 200+ people in skilled pharmaceutical manufacturing roles.

•Build an on-site API facility to vertically integrate our supply chain domestically and reduce foreign reliance.

Our experience proves that making medicines in America is possible. What's needed now is a framework that rewards companies for doing the right thing and allows the domestic industry to expand nationwide-producing safe, consistent, high-quality products under U.S. oversight.

VIII. Securing America's Medicines: The Path Forward

Rebuilding trust in our medicines starts with rebuilding the ability to make them.Congress has recognized that industries like semiconductors, aluminum, rare earth minerals, and batteries represent national strategic assets. Generic pharmaceuticals deserve the same recognition. If we lose control of medicine production, we lose control of public health itself.

This is an issue we must confront-and we must begin now. The industry stands at a crossroads between continued collapse and lasting renewal. Rebuilding capacity becomes more challenging and costlier every year we delay.

Oxford urges Congress to:

1. Affirm generic domestic pharmaceutical manufacturing as a national security priority under Section 232.

2. Create procurement incentives and long-term contracts for U.S.-made medicines.

3. Support investment in domestic API production and vertical integration.

4. Require U.S.-level safety standards for all imported drugs and full transparency so patients and hospitals know where their medicines come from.

Protecting America's seniors means protecting America's medicine supply. At Oxford, we have the skill, the knowledge, and the determination to help rebuild our nation's generic pharmaceutical supply chain. What we need now is the will of the federal government to act.

Submitted by: Tom Neely Chairman Oxford Pharmaceuticals Birmingham, Alabama

References

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[1]Olin Business School, Washington University in St. Louis. (2021, August). U.S. Health Security at Risk Because of Medicine Manufacturing Limits. https://olin.washu.edu/about/news-and-media/news/2021/08/study-us-health-security-at-risk-because-of-medicine-manufacturing-limits.php

[2]Council on Strategic Risks. (2024). The National Security Rationale for Stockpiling Key Pharmaceutical Ingredients https://councilonstrategicrisks.org/2024/03/05/the-national-security-rationale-for-stockpiling-key-pharmaceutical-ingredients

[3]Exiger. (2020). A Bitter Pill: America's Dependence on China-Made Pharmaceuticals. https://www.exiger.com/perspectives/a-bitter-pill-america-dependence-on-china-made-pharmaceuticals/

[4]Huang, M., et al. (2014). Key Drug Innovation Program in China: A Review of Policy and Outcomes. Health Research Policy and Systems, 12(27). https://health-policy-systems.biomedcentral.com/articles/10.1186/1478-4505-12-27

[5]Stolberg, S. G. (2025, November 4). Trump's New Plan for Generic Drug Manufacturing Draws Mixed Reactions. The New York Times. https://www.nytimes.com/2025/11/04/health/generic-drug-manufacturing-trump.html

[6]Ibid.

[7]U.S. Government Accountability Office. (2024). FDA: Foreign Drug Manufacturing Inspections - Challenges Persist (GAO-24-107359). https://www.gao.gov/products/gao-24-107359

[8]White & Case LLP. (2025). FDA Foreign Inspections: Key Developments and Strategic Shifts. https://www.whitecase.com/insight-alert/fda-foreign-inspections-key-developments-and-strategic-shifts

[9]Kelley School of Business, Indiana University. (2025, February 19). All Generic Drugs Are Not Equal: Study Finds Generics Made in India Have More Severe Adverse Events. https://blog.kelley.iu.edu/2025/02/19/all-generic-drugs-are-not-equal-study-finds-generics-made-in-india-have-more-severe-adverse-events/

[10]U.S. Food and Drug Administration. (2023). Inspection Report: Intas Pharmaceuticals Limited. https://www.fda.gov/media/164602/download

[11]FiercePharma. (2024, October 3). Finding Birds, Lizards, and Cats - FDA Says ″Oh My!″ in Scathing Hetero Form 483. https://www.fiercepharma.com/manufacturing/finding-birds-lizards-and-cats-fda-says-oh-my-hetero-scathing-form-483

[12]Ibid.

[13]Ibid.

[14]White & Case LLP. (2025). FDA Foreign Inspections: Key Developments and Strategic Shifts. Ibid. https://www.whitecase.com/insight-alert/fda-foreign-inspections-key-developments-and-strategic-shifts

[15]Association for Accessible Medicines. (2023, June 22). White Paper on Drug Shortages. https://accessiblemeds.org/wp-content/uploads/2024/11/AAM—White—Paper—on—Drug—Shortages-06-22-2023.pdf

[16]Ibid.

[17]USC Schaeffer Center for Health Policy & Economics. (2017). The Flow of Money Through the Pharmaceutical Distribution System. https://schaeffer.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/

[18]Ibid.

[19]U.S. Department of Health and Human Services, Office of Inspector General. (2024). Drug Spending in Federal Programs. https://oig.hhs.gov/reports/featured/drug-spending/

[20]U.S. Government Accountability Office. (2025). Prescription Drugs: Federal Spending and Oversight Gaps (GAO-25-107187). https://www.gao.gov/assets/gao-25-107187.pdf

[21]U.S. Government Accountability Office. (2021). Prescription Drugs: Federal Purchasing and Contracting Trends (GAO-21-111). https://www.gao.gov/assets/gao-21-111.pdf

[22]U.S. Government Accountability Office. (2020). Drug Supply Chain Security and FDA Oversight Gaps (GAO-20-718363). https://www.gao.gov/assets/720/718363.pdf

[23]U.S. Senate. (2023). FY23 National Defense Authorization Act Section 860: Risk Management for DoD Pharmaceuticals. https://www.warren.senate.gov/imo/media/doc/FY23/20NDAA/20sec/20860/20Risk/20management/20for/20DoD/20Pharmceuticals1.pdf

[24]Association for Accessible Medicines. (2024, January). 2024 U.S. Generic and Biosimilar Medicines Savings Report. https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf

[25]Rowland, C. (2023, June 27). Cancer Drug Shortage Highlights Fragile Generics Supply Chain. The Washington Post. https://www.washingtonpost.com/business/2023/06/27/cancer-drug-shortage-generics/

[26]Owens, C. (2023, March 21). Drug Shortages Upend Cancer Treatments Across U.S. Axios. https://www.axios.com/2023/03/21/drug-shortages-upend-cancer-treatments

[27]Johns Hopkins Bloomberg School of Public Health. (2023). Drug Shortages Are Affecting Cancer Treatments. https://publichealth.jhu.edu/2023/drug-shortages-are-affecting-cancer-treatments

[28]National Center for Biotechnology Information. (2023). Drug Shortages and Their Impact on Patient Care. https://www.ncbi.nlm.nih.gov/books/NBK608930/

U.S. SENATE SPECIAL COMMITTEE ON AGING

"MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES"

NOVEMBER 19, 2025

PREPARED WITNESS STATEMENTS

Patrick Cashman

Chairman Scott, Ranking Member Gillibrand, and distinguished members of the committee:

On behalf of the millions of Americans who require antibiotics every year to protect against life-threatening bacterial infections, thank you for your attention to the security and resilience of the United States' pharmaceutical supply chain.

My name is Patrick Cashman, and I serve as President of USAntibiotics, headquartered in Bristol, Tennessee. USAntibiotics is the last remaining end-to-end domestic U.S. manufacturer of amoxicillin, the most prescribed antibiotic in the country.

The facility I lead has a proud history of supplying this critical generic medicine to American patients for more than 40 years. Until around 2008, every dose of amoxicillin needed to treat life-threatening bacterial infections in this country was produced at our Bristol plant. The years that followed were punctuated by escalating subsidized competition from Indian and Chinese generic drugmakers. In the space of 12 years, we had crashed from 100 percent of the U.S. market to zero, our production lines were dark, and our assets had been placed into bankruptcy.

But our story didn't end there. The company was rescued in 2021 by its first-ever American owners, who felt passionately that the United States could not be dependent on hostile foreign powers for such a critical resource as antibiotics.[1] Over the last four years, we've revived the facility, rehired and grown our staff, and restored consumer confidence in America's antibiotic supply chain with the assistance of great partners like Walmart.

The challenge of creating a resilient domestic antibiotic supply chain is enormous and urgent. It's not simply a question of public health but national security. A country without stable, secure access to life-saving antibiotics cannot grow its economy or defend itself against threats.

My testimony today will outline the unique challenges faced by U.S. manufacturers of critical generic medicines, such as amoxicillin. I will devote particular attention to well-intentioned but counterproductive government contracting barriers that sideline U.S. manufacturers like ours. I will also propose policy recommendations to ensure our healthcare supply chain remains secure, resilient, and American-made.

I. The Strategic Importance of Domestic Antibiotic Manufacturing

Antibiotics are the backbone of modern medicine. Without them, routine surgeries become life-threatening and common infections become lethal. Our nation's health security, military readiness, and emergency preparedness hinge on reliable access to antibiotics.

According to the Centers for Disease Control and Prevention, amoxicillin alone accounts for approximately 50 million prescriptions annually in the U.S., making it the single most prescribed antibiotic.[2] It treats a wide range of infections, particularly in children. Yet the overwhelming majority of today's U.S. amoxicillin supply is sourced from overseas, often from a small handful of producers, many of which are concentrated in India and China. Today, USAntibiotics serves approximately 5% of the U.S. market, even though we have the underutilized capacity to meet 100% of the country's demand once again.

Seniors account for a disproportionate share of antibiotic prescriptions and surgical procedures. According to CDC data, adults over 65 receive antibiotics at rates 50 percent higher than younger Americans.[3] Hip replacements, cardiac procedures, and cancer surgeries-all of these life-extending interventions depend on reliable access to antibiotics.

Now, consider the post-operative risks when antibiotics are unavailable or of low quality. A routine hip replacement becomes a life-threatening gamble. A cardiac stent placement risks deadly infection. Cancer surgery-already traumatic-becomes even more dangerous. During the 2022 and 2023 amoxicillin shortages, hospitals across the country were forced to ration antibiotics, delay elective surgeries, and

substitute less effective treatments.[4] Elderly patients and children were impacted most by these shortages.

This vulnerability extends beyond surgeries. Pneumonia kills roughly 50,000 Americans annually, with seniors representing the overwhelming majority of deaths.[5] Urinary tract infections, which disproportionately affect older women, can become life-threatening sepsis without prompt antibiotic treatment. Skin infections from minor wounds become dangerous without reliable antibiotic access.

These shortages occurred during peacetime and under normal economic conditions alike, without any overt effort by foreign manufacturers to restrict supply. Imagine what happens during a crisis when foreign governments decide to prioritize their own populations over exports. Imagine what happens if China decides to weaponize pharmaceutical exports the way Russia weaponized energy exports to Europe.

We must treat antibiotic production with the same strategic urgency as energy independence or semiconductor manufacturing. Rebuilding domestic capacity is not optional. It's essential to ensure a safe, stable supply chain.

If our facility were to shutter operations permanently, it would take at least five years and hundreds of millions of dollars to construct a new facility capable of producing amoxicillin. That timeline assumes favorable regulatory treatment, available capital, and a skilled workforce-none of which are guaranteed. More realistically, rebuilding domestic amoxicillin capacity from scratch could take a decade.

That would be half a decade or more in which this country would be entirely reliant on China and India, during which time one or both countries could restrict our access. Quality matters. Source matters. Security of supply matters.

The quality gap is equally alarming. A 2025 peer-reviewed study found that serious adverse events-including hospitalization, disability, and death-were 54 percent higher for generic drugs manufactured in India than for equivalent drugs made in the United States.[6] That difference represents real people, real harm, and real cost. When quality fails, patients suffer-and our entire healthcare system pays for it in higher costs, longer hospital stays, and lost trust.

The FDA's inspection system also requires urgent reform. Domestic facilities are typically inspected without notice, allowing regulators to see real working conditions. By contrast, foreign inspections are often announced up to twelve weeks in advance, giving manufacturers time to conceal problems. That is not a level playing field, and it does not ensure safety. Although the FDA announced in May of this year that it would expand its use of unannounced inspections at foreign manufacturing facilities, it is not clear that FDA has the funding or workforce capacity to fulfill that commitment.[7]

Mandatory, independent quality testing of all imported medicines is both reasonable and essential. The Department of Defense testing program with Valisure provides a potential model for larger-scale safety assurance testing of imported pharmaceuticals.[8]

II. Recognition and Validation of Our Strategic Importance

Earlier this year, the U.S. Food and Drug Administration launched the Commissioner's National Priority Voucher program to recognize critical pharmaceutical manufacturing that addresses urgent public health needs. This competitive program represents the FDA's acknowledgment that certain medicines and certain manufacturers warrant special regulatory recognition and support.

USAntibiotics was selected for this distinction based on our production of Augmentin™ XR. This recognition validates what we've long argued: domestic antibiotic manufacturing represents a strategic national priority. The FDA understands the vulnerability created by foreign dependence.

Federal pharmaceutical procurement policy needs to catch up with what the FDA already knows. The agency charged with ensuring drug safety and efficacy has recognized our importance. The agencies charged with purchasing life-saving medications for the federal government have not.

III. The Fragility of Global Antibiotic Supply Chains

Antibiotic manufacturing contains multiple single points of failure, and almost all of them are overseas. The supply chain spans continents and involves dozens of steps, from key starting materials to active pharmaceutical ingredients to finished drug products. Any interruption along this complex chain would have catastrophic consequences for public health.

China produces approximately 45% of the active pharmaceutical ingredients used in amoxicillin today, and it also accounts for a majority of the global key starting material market.[9] Even as India leads the world in finished form amoxicillin exports, its drugmakers are highly reliant on Chinese-made amoxicillin API. The re-

sult is that the majority of amoxicillin on pharmacy shelves today is simply Chinese chemistry with Indian finishing.

USAntibiotics has never purchased, and will never purchase, Chinese API. We source exclusively from Trade Agreement Act-compliant partners in Europe, but many of our subsidized foreign competitors don't share these supply chain concerns, buying instead from wherever the prices are lowest.

The concentration risk is staggering. Suppose China restricted API exports, whether for economic leverage or during a geopolitical crisis, millions of Americans could lose access to life-saving medicine within weeks. The Strategic National Stockpile would likely not sustain the country for more than a few months in the event of a bacterial pandemic. The United States has no domestic manufacturing alternative to USAntibiotics-which is why the risk of our closure is so significant.

This vulnerability extends beyond amoxicillin. The same dynamics affect dozens of other critical generic medicines. The U.S. has offshored our pharmaceutical industrial base to countries that may not share our interests, and we've done so without any meaningful contingency planning. The Department of Defense has conducted multiple studies documenting these vulnerabilities, yet procurement practices have not changed.

Some might argue that market forces will naturally correct these vulnerabilities, that if Chinese or Indian supply becomes unreliable, manufacturers will diversify, but that argument ignores the economics of generic drug manufacturing. Margins are so thin that manufacturers cannot afford to maintain redundant supply chains. They source from the cheapest supplier, which is often the most subsidized, meaning China.

Others might argue that stockpiling provides adequate insurance against supply disruptions, but stockpiles are expensive to maintain, have limited shelf life, and cannot possibly cover all essential medicines in sufficient quantities. Stockpiles are a temporary buffer, not a strategic solution.

The only real solution is domestic manufacturing capacity for critical medicines. That capacity must be maintained during peacetime even if it costs more than foreign alternatives, because once it's gone, it cannot be quickly rebuilt - and may never return.

IV. Unique Challenges to Domestic Generic Antibiotic Manufacturing

While all pharmaceutical manufacturers face global competitive pressures, generic antibiotics like amoxicillin represent a uniquely challenging market.

1. Unfair Global Competition and Market Distortions

Generic antibiotics are among the lowest-cost pharmaceutical products in the world. Amoxicillin, in particular, is often sold at razor-thin margins. A typical bottle of generic amoxicillin might wholesale for just a few dollars, leaving manufacturers with pennies in profit per prescription.

Indian and Chinese manufacturers benefit from significant state subsidies, lower labor costs, and less stringent environmental, regulatory, quality, and safety standards. These advantages allow them to undercut U.S. manufacturers on price, often selling at or below their production costs. One 2022 study found that a lack of regulatory oversight in China and India allows their drugmakers to cut production costs by as much as 25 percent.[10]

These pricing tactics often resemble anti-competitive dumping practices, in which foreign producers flood the market to eliminate competition. The playbook is straightforward: subsidized manufacturers offer below-market pricing to drive out unsubsidized competitors, then raise prices once competition is eliminated. We've seen this pattern in steel, solar panels, and countless other industries.

Recently, some Indian drugmakers have been selling amoxicillin at a price below our chemical costs for active pharmaceutical ingredients. That means they're offering finished products for less than we pay just for the raw materials. Either they're selling at a loss (subsidized by their government) or they're using such substandard ingredients that quality is suspect.

U.S. manufacturers must comply with rigorous FDA regulations, maintain higher quality standards, and absorb higher input and operational costs. Our workers earn middle-class wages with benefits. Our facilities meet U.S. environmental standards. We pay U.S. taxes. While these standards are vital for public safety and American prosperity, they create an uneven playing field that deters domestic investment.

The competitive disadvantage compounds over time. Foreign manufacturers gain scale advantages by supplying not just their domestic markets but global markets. They invest in newer equipment and more efficient processes. They develop expertise and institutional knowledge. Meanwhile, domestic manufacturers like USAntibiotics struggle to survive on a five percent market share, unable to invest in growth because we're fighting for survival.

2. Lack of Long-Term Purchasing Commitments

Generic manufacturers often operate without secure or long-term purchasing agreements. Most buyers, whether they are pharmacy chains, hospitals, or distributors, prioritize cost over reliability or origin. They purchase on short-term contracts, often as short as 90 days, and switch suppliers solely on price.

This purchasing behavior leaves U.S. manufacturers vulnerable to market fluctuations and unable to make long-term capital investments or retain specialized labor. A U.S. generics manufacturer cannot reasonably invest tens of millions in new equipment when its largest customer might switch to a foreign competitor next quarter based on a price difference of pennies per unit.

Contrast this with defense or semiconductor procurement, where the federal government frequently uses multi-year contracts to ensure stability and scalability. Defense contractors operate under contracts that span years or even decades. These long-term commitments allow contractors to invest in facilities, retain skilled workers, and plan for the future.

The Berry Amendment has required the Defense Department to buy American textiles, food, and hand tools since 1941. The Trade Agreements Act restricts government purchases to U.S. and designated country products. The Buy American Act requires federal agencies to procure US domestic materials and products, subject to conditions. Federal agencies routinely avoid Chinese telecommunications equipment despite lower costs. The government pays premiums for American-made vehicles, construction materials, and technology solutions.

Why? Because economic security, supply chain security, and national security sometimes require paying more for domestic production. Because supply chain resilience has value beyond immediate cost savings. Because maintaining domestic industrial capacity serves strategic objectives that transcend quarterly purchasing decisions.

Pharmaceutical procurement should align with these existing practices. Yet it doesn't. Antibiotics are treated as commodities to be purchased from the lowest bidder, regardless of source or supply chain resilience.

The government could transform this dynamic with relatively modest changes to procurement practices. Long-term contracts with domestic manufacturers provide the revenue stability needed to justify capital investments and workforce development. Even if those contracts cost pennies more per unit than foreign-origin alternatives, the national security benefits would far exceed the incremental costs.

3. Lack of Recognition for National Security Relevance

Generic antibiotics are not treated as strategic assets in the same way that weapons systems or critical minerals are. This means manufacturers cannot access the same financing tools, tax incentives, or industrial base support programs available to other critical infrastructure sectors.

Defense contractors can access Defense Production Act authorities, guaranteed loans, and preferential tax treatment. Semiconductor manufacturers received tens of billions in direct subsidies through the CHIPS Act. Energy manufacturers and operators benefit from investment tax credits and accelerated depreciation.

Generic drug manufacturers receive none of these benefits, even though pharmaceutical supply chain failures could kill more Americans than most military threats.

The threat to U.S. national security and public health posed by antibiotic shortages is just as real, and arguably more acute and more immediate, than many threats that receive significant federal support. We must reclassify generic critical medicines as national security assets and build policy around that recognition.

V. The Small Business Set-Aside Paradox: How Government Policy Threatens America's Last Antibiotic Manufacturer

In 2021, USAntibiotics was rescued from bankruptcy by Jackson Healthcare, one of the largest healthcare staffing agencies in the United States.

When the Bristol facility faced permanent closure, Jackson Healthcare and its founder, Rick Jackson, recognized the national security imperative in restoring domestic antibiotic production. He stepped in when no one else would, including our government. Over the last four years, Jackson has spent many tens of millions to reactivate our production lines and even more to underwrite our losses. They are the only reason that the United States still possesses antibiotic manufacturing capacity.

But by virtue of our ownership by a larger company, USAntibiotics has been precluded from participating as a prime contractor in small business set-aside contracts for amoxicillin. The federal government has recently structured virtually all amoxicillin contracts on a small business set-aside basis, effectively locking out

America's only domestic manufacturer from competing as a prime for federal government business.

This is the height of irony. USAntibiotics would have closed permanently without Jackson Healthcare's ownership. No one else was willing to rescue this facility. No private equity firm saw a profitable opportunity. No pharmaceutical company wanted to enter the low-margin generic antibiotics market. Jackson Healthcare stepped up when others walked away - viewing the acquisition out of bankruptcy of USAntibiotics not as a profitmaking opportunity, but as a U.S. national security imperative.

Jackson has subsidized our losses while we've worked to rebuild market share and achieve profitability. They've invested tens of millions when others invested nothing. They've created jobs when other pharmaceutical facilities were closing. They've restored domestic manufacturing capacity when the trend was toward greater foreign dependence.

And now, because of that patriotic investment, we're effectively barred from selling to the federal government through prime contracts.

The government's small business set-aside policies exist for good reasons. They're designed to help small businesses compete against larger corporations. They prevent large firms from using their scale and resources to crowd out smaller competitors. These goals are admirable, and the policies serve essential purposes in many contexts.

But when applied to critical medicines with severe supply chain vulnerabilities, these policies can produce perverse and dangerous consequences. In practice, they prevent the only American manufacturer from selling to the government while allowing foreign competitors, often subsidized by their own governments, to dominate federal procurement. They treat domestic manufacturers owned by successful American companies worse than foreign manufacturers owned by Chinese state-owned enterprises.

This paradox has created a reality in which a U.S.-based small business repackager of foreign-origin drugs can partner with a Chinese or Indian enterprise to the detriment of the only U.S. end-to-end manufacturer of that critical medicine.

Since January 2023, USAntibiotics has sold around $1 million directly to government purchasers through the United States Department of Veterans Affairs and the United States Public Health Service via the Federal Supply Schedule System. This amount represents a tiny fraction of government antibiotic purchases, and it's only possible through the Federal Supply Schedule, which operates differently from direct contracts.

In September 2022, the U.S. Department of Health and Human Services issued an approximately $40 million award for the provision of amoxicillin for the Strategic National Stockpile. This contract was structured as a small business set-aside, excluding USAntibiotics from competing. That means during roughly the same period in which the last U.S. domestic manufacturer of amoxicillin sold less than $1 million of amoxicillin to U.S. government purchasers, our government spent 40 times that amount on foreign-origin amoxicillin.

Every dollar spent on Chinese or Indian amoxicillin strengthens their industrial base while weakening ours. It sends a clear message to any entrepreneur considering domestic pharmaceutical manufacturing: the U.S. government won't support you. Even if you invest tens of millions of private capital, create high-quality manufacturing jobs, and address a critical national security and supply chain security vulnerability, the government will continue buying from foreign competitors because its procurement rules don't account for strategic considerations and prioritize lowest cost over quality.

The $40 million Strategic National Stockpile contract perfectly illustrates the problem. The stockpile exists to protect Americans during public health emergencies. Its entire purpose is to supply security during crises when normal supply chains fail. Yet HHS structured the contract in a way that excluded the only American manufacturer from competing.

The government's approach to stockpile procurement demonstrates a fundamental misunderstanding of the stockpile's purpose. The stockpile should prioritize American manufacturers for critical medicines where domestic capacity exists. This approach serves dual purposes: it ensures supply security and resilience during crises while providing the revenue stability that domestic manufacturers need to survive.

But current policy does the opposite. It treats stockpile procurement the same as any other government purchase, prioritizing short-term cost savings over long-term supply security.

The Repackager Problem

Some U.S. companies import foreign-origin amoxicillin, slap a new label on the bottle, and market it as ″Made in America.″ These repackagers add no manufacturing value. They don't operate pharmaceutical manufacturing facilities that create jobs at the scale that true end-to-end pharmaceutical manufacturing provides.

Yet current procurement rules often treat them the same as genuine domestic manufacturers like USAntibiotics.

When the government buys from a repackager instead of USAntibiotics, it's not buying American. It's buying Chinese or Indian antibiotics with an American sticker. That might satisfy the letter of some procurement rules, but it violates the spirit of domestic preference policies and does nothing to strengthen our U.S. pharmaceutical industrial base.

Some repackagers are transparent about their business model. Others use carefully worded marketing that implies domestic manufacturing without explicitly claiming it. Procurement officers who lack pharmaceutical industry expertise may not understand the difference between genuine manufacturing and simple repackaging.

A 2023 Department of Defense review found that the country of origin for API used in 22% of essential military drugs could not be identified.[11] That's not supply chain management-that's negligence.

USAntibiotics is the only end-to-end domestic manufacturer, meaning we control the entire production process from API to finished drug. We source our API from Trade Agreement Act-compliant European manufacturers, not from China. When you buy USAntibiotics amoxicillin, you're buying genuine American manufacturing with genuine supply chain security, but procurement rules don't distinguish between our approach and that of repackagers in a race to the bottom.

What U.S. Manufacturers of Generic Antibiotics Need

We are not asking for a U.S. government subsidy or handout. We're not asking for protection from competition or guaranteed profit margins. We're not asking for special treatment beyond what the government already provides to defense contractors, semiconductor manufacturers, and countless other strategic industries.

We're asking that when the government buys antibiotics, it prioritizes genuine U.S. manufacturing over cheap foreign imports, whether those imports arrive directly or are disguised by domestic repackagers.

We're asking that procurement policies align with national security imperatives rather than purely with short-term cost minimization.

We're asking that the government not allow well-intentioned small business rules to prevent the only American manufacturer from competing for contracts for medicines designated as critical to national security.

VI. How America's Allies Handle Pharmaceutical Sovereignty

The United States is not alone in recognizing vulnerabilities in the pharmaceutical supply chain. Our allies have taken aggressive action to secure domestic manufacturing capacity for critical medicines. Their approaches offer lessons for American policymakers.

The European Union launched the Critical Medicines Alliance to reshore manufacturing of essential medicines.[112] This initiative identifies critical drugs where European dependence on Asian manufacturing poses unacceptable risks, then provides funding and regulatory support to rebuild European capacity.

France announced a ?160 million fund explicitly dedicated to rebuilding domestic pharmaceutical production.[13] The French government identified 30 essential medicines for which domestic production had been lost to Asian competitors, then offered financial incentives to pharmaceutical companies willing to reshore manufacturing.

Japan has prioritized the reshoring of critical drug manufacturing through direct government investment and preferential procurement policies. The Japanese government maintains a list of strategic medicines where domestic production receives substantial support.

Germany has launched multiple initiatives to reduce its reliance on China for pharmaceuticals, including research funding for domestic API production and requirements that government purchasers consider supply chain security alongside price.

Australia established the Sovereign Manufacturing Capability Plan to identify and support critical industries, including pharmaceutical manufacturing. The plan includes direct subsidies, tax incentives, and preferential procurement for strategic goods.

These countries understand that pharmaceutical sovereignty is national security. They've moved beyond studies and reports to actual policy implementation with real

funding. They've recognized that maintaining domestic pharmaceutical manufacturing capacity requires government support, not just market forces.

Yet while our allies act decisively, America dithers. Meanwhile, our last domestic manufacturers close their doors or, in USAntibiotics' case, operate on the edge of insolvency while the government buys from foreign competitors.

We can learn from our allies' approaches without copying them wholesale. European subsidies may not be appropriate for the U.S. market. Japanese procurement policies may not fit American legal frameworks, but we must act with similar urgency and similar commitment to the principle that critical medicines require domestic industrial capacity.

The longer we delay, the more difficult rebuilding becomes. Manufacturing expertise is lost, workforces transition, facilities deteriorate, and supply chains become reliant on foreign sources. Each passing year makes domestic pharmaceutical manufacturing less viable, not more.

VII. Policy Recommendations

To revitalize domestic manufacturing of generic antibiotics and protect our healthcare supply chain, I respectfully offer the following recommendations:

1. Create Procurement Pathways for Critical Domestic Manufacturers

When the federal government solicits contracts for medicines designated as essential medicines by the Administration for Strategic Preparedness and Response (ASPR), domestic manufacturers engaged in the end-to-end production of finished-form critical medicines should be allowed to compete regardless of whether their parent company is large or small. We respectfully submit to this committee that amoxicillin is critical to national security, because it is a reliable and highly effective treatment for bacterial infections.

When the only domestic source of a strategic good is owned by a larger company, that ownership structure should not prevent government purchases if those purchases serve national security objectives.

Alternatively, Congress could direct agencies to split contract awards between set-aside and open competition, ensuring that domestic manufacturers have opportunities to serve their government. A $40 million contract could be split into a $20 million small business set-aside and a $20 million open competition. This approach preserves support for small businesses while allowing domestic manufacturers to compete.

Or Congress could create a national security exception to small business set-asides for critical medicines where domestic manufacturing capacity is at risk. This exception would apply narrowly to situations in which a domestic manufacturer faces closure due to its inability to compete for government contracts.

The specific mechanism matters less than the outcome: America's last domestic amoxicillin manufacturer should be able to compete on a level playing field for government contracts. The current situation in which we're excluded from competing while foreign manufacturers dominate government procurement is indefensible from an economic security, national security, and supply chain security perspective.

2. Define ″Domestic Manufacturing″ to Exclude Repackagers

Any Buy American or domestic preference policy for pharmaceuticals should require that the finished dosage form be manufactured domestically through a process or combination of formulating, filling, and finishing, not simply labeled or repackaged domestically. Further, it should require that the active pharmaceutical ingredients be manufactured either domestically or by a supplier from a TAA-compliant country that has submitted to regular FDA on-site inspections. Repackagers who import foreign-origin drugs should not qualify for domestic preference treatment.

A domestic manufacturer, for purposes of federal procurement preference, should be defined as a company that performs all steps necessary to convert API from a designated country under the TAA regulations into a finished dosage form, including formulation, blending, granulation, tableting or encapsulation, and final packaging.

Companies that merely repackage or relabel foreign-manufactured drugs should be explicitly excluded from domestic preference provisions. Companies that manufacture finished drugs in the United States using Chinese and Indian API should likewise not qualify for domestic preference, at least in the context of critical medicines (i.e., medicines for which it is important to maintain a domestic manufacturing capability for national security purposes).

The government should also require country-of-origin disclosure for APIs in all federal pharmaceutical procurement. Full supply chain transparency from key starting materials through finished drug products should be mandatory for any govern-

ment contract. Every government pharmaceutical contract should require detailed disclosure of the country of origin for all APIs and key starting materials.

This transparency serves multiple purposes, enabling procurement officers to make informed decisions about supply chain security, preventing repackagers from disguising foreign products as domestic, and creating accountability and enabling oversight.

3. Establish Strategic National Stockpile Domestic Purchase Requirements

The Strategic National Stockpile exists to protect Americans during public health emergencies. The stockpile should prioritize American manufacturers for critical medicines where domestic capacity exists. Congress should direct HHS to develop procurement strategies for the Strategic National Stockpile that give preference to domestic manufacturers of medicines designated as critical to national security.

Congress should appropriate multi-year funds to HHS to provide for multi-year stockpile procurement contracts that enable manufacturers to make long-term capital investments.

These longer-term contracts would serve dual purposes. They would ensure fresher stockpile inventory by enabling regular rotation rather than allowing medicines to age to expiration, and they would provide domestic manufacturers with the revenue stability needed to justify continued operations and capital investments.

4. Incentivize Long-Term Purchasing Agreements

Beyond the Strategic National Stockpile, encourage federal agencies broadly to enter into long-term contracts with domestic producers of essential medicines. This requires Congress to appropriate multi-year funds, but multi-year agreements will provide stability and predictability for manufacturers and will help us weather the storms caused by anti-competitive pricing from foreign competitors.

Defense contractors and semiconductor manufacturers operate under multi-year agreements that provide revenue stability and enable long-term capital planning. Generic drug manufacturers of critical medicines deserve the same consideration.

The government could establish Indefinite Delivery, Indefinite Quantity contracts for critical medicines, similar to those used in defense procurement. These IDIQ contracts would guarantee minimum purchase volumes while providing pricing predictability for both the government and manufacturers.

An IDIQ contract might guarantee that a manufacturer will supply between 20% and 80% of federal agency needs for a particular medicine over a five-year period, with specific delivery orders issued based on actual requirements. This structure provides manufacturers with enough certainty to justify capital investments while maintaining flexibility for government purchasers.

The Department of Veterans Affairs, the Department of Defense, the Public Health Service, and other federal healthcare providers collectively purchase enormous quantities of antibiotics. Coordinating these purchases through IDIQ contracts with domestic manufacturers would provide significant support to domestic manufacturing without requiring direct subsidies.

5. Create a Strategic Antibiotic Manufacturing Fund

Provide targeted grants, low-interest loans, and tax incentives to companies investing in domestic API and antibiotic production. The CHIPS Act offers a model that could be replicated for pharmaceuticals.

Just as semiconductor manufacturing received tens of billions in federal support to rebuild domestic capacity, critical pharmaceutical manufacturing deserves similar investment. The amounts needn't be comparable to CHIPS Act funding-pharmaceutical manufacturing requires far less capital than semiconductor fabs-but they should be meaningful enough to offset the competitive disadvantages that domestic manufacturers face.

This fund could support multiple activities. Direct grants could help manufacturers upgrade facilities and equipment. Low-interest loans could finance the construction of new API manufacturing capacity. Tax incentives could offset higher domestic labor and compliance costs.

The fund should prioritize medicines designated as critical to national security, particularly those where domestic manufacturing capacity has been lost or is at risk. Antibiotics would be a logical initial focus, but the fund could expand to cover other essential medicine categories.

6. Enforce Trade Rules to Counter Predatory Pricing

Instruct the Department of Commerce and USTR to investigate and, where appropriate, penalize unfair trade practices in the pharmaceutical sector. We cannot allow predatory pricing to destroy our last line of defense.

We support the ongoing Section 232 investigation regarding the national security effects of imports of pharmaceuticals and pharmaceutical ingredients. Section 232

investigations have been used to address perceived national security threats from steel, aluminum, and other strategic materials imports. Pharmaceuticals deserve the same scrutiny.

When foreign manufacturers engage in below-market pricing that threatens to eliminate domestic capacity, the government should use all available trade tools to counter those practices. This includes anti-dumping duties, countervailing duties to offset foreign subsidies, and tariffs justified by national security considerations.

VIII. Conclusion

Rebuilding America's generic critical medicines manufacturing capacity is not just a matter of economics or public health. It is a matter of U.S. national security.

The federal government faces a choice. It can continue policies that inadvertently favor foreign sources over the dwindling number of American generics manufacturers, or it can align its procurement policies with its stated national security goals. It can ensure that small business rules don't prevent critical domestic manufacturers from competing, demand transparency in pharmaceutical supply chains, and provide long-term contracts and policy support that domestic manufacturers need to thrive. It can recognize that pharmaceutical sovereignty requires the same commitment we've shown to semiconductor sovereignty, energy independence, and defense industrial base preservation.

USAntibiotics stands ready to play our part. We have the infrastructure, the expertise, and the commitment. We have the capacity to supply 100 percent of America's amoxicillin needs. We employ skilled workers who take pride in producing medicine that saves American lives. We source our ingredients from allied countries, not adversaries.

But we need Congress to act boldly and urgently. It's time for procurement policy to align with the national security realities of global pharmaceutical trade. Preserving pharmaceutical manufacturing in America is as important as keeping semiconductor manufacturing, defense manufacturing, or any other strategic industry. It's time to stop rewarding foreign dependence and start supporting domestic resilience.

Thank you for the opportunity to testify. I look forward to your questions and working together on solutions that protect the health and safety of every American.

Respectfully submitted, Patrick Cashman, President, USAntibiotics Bristol, Tennessee

Resources

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[1]Georgia Public Broadcasting. (2024, September 18). The only American maker of generic antibiotics wants the government to buy local. GPB News. https://www.gpb.org/news/2024/09/18/the-only-american-maker-of-generic-antibiotics-wants-the-government-buy-local

[2]Outpatient Antibiotic Prescriptions - United States. CDC. (2022) https://archive.cdc.gov/www—cdc—gov/antibiotic-use/data/report-2022.html

[3]Kabbani, S., et al. (2018). Outpatient Antibiotic Prescribing for Older Adults in the United States: 2011 to 2014. Journal of the American Geriatrics Society, 66(10), 1998-2005. https://pmc.ncbi.nlm.nih.gov/articles/PMC7909599/

[4]1 in three U.S. hospitals severely affected by drug shortages, survey finds. NBC News. (August 2023) https://www.nbcnews.com/health/health-news/drug-shortages-causing-hospitals-skip-delay-ration-care-survey-finds-rcna99007

[5]Holland, E., et al. (2025). Demographic and regional trends of pneumonia mortality in the United States, 1999 to 2022. Scientific Reports, 15(1), 10103. https://www.nature.com/articles/s41598-025-94715-6

[6]All generic drugs are not equal, study finds; Generics made in India have more 'severe adverse events'. Indiana University Bloomington. (Feb 2025) https://blog.kelley.iu.edu/2025/02/19/all-generic-drugs-are-not-equal-study-finds-generics-made-in-india-have-more-severe-adverse-events

[7]U.S. Food and Drug Administration. (2025, May 6). FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities. https://www.fda.gov/news-events/press-announcements/fda-announces-expanded-use-unannounced-inspections-foreign-manufacturing-facilities

[8]Valisure. (2023, August 8). Valisure Signs Agreement with Department of Defense to Independently Test & Quality Score Drugs. PRNewswire. https://www.prnewswire.com/news-releases/valisure-signs-agreement-with-department-of-defense-to-independently-test--quality-score-drugs-301895301.html

[9]China's position and competitiveness in the global antibiotic value chain: implications for global health. Globalization and Health. (2024) https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-024-01089-x

[10]Young, C. (2022, February). America's other health care crisis: Generic medicine supply chains. American Affairs Journal. https://americanaffairsjournal.org/2022/02/americas-other-health-care-crisis-generic-medicine-supply-chains

[11]Warren, E. (2023). FY23 NDAA section 860: Risk management for DoD pharmaceuticals. U.S. Senate. https://www.warren.senate.gov/imo/media/doc/FY23/20NDAA/20sec/20860/20Risk/20management/20for/20DoD/20Pharmceuticals1.pdf

[12]European Commission. (2024, April 24). Commission launches the Critical Medicines Alliance to help prevent and address shortages of critical medicines. https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/critical-medicines-alliance—en

[13]France to re-shore production of 50 key medicines. Le Monde. (June 2023) https://www.lemonde.fr/en/france/article/2023/06/13/france-to-re-shore-production-of-50-key-medicines—6031218—7.html

U.S. SENATE SPECIAL COMMITTEE ON AGING

"MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES"

NOVEMBER 19, 2025

PREPARED WITNESS STATEMENTS

Eric Edwards, MD

Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee, thank you for the opportunity to testify on a matter that directly impacts the health, security, and well-being of millions of Americans, namely, our nation's growing dependence on fragile, foreign pharmaceutical supply chains and the resulting drug shortages that continue to threaten patient safety, public health, and national security.

My name is Eric Edwards. I am a physician, scientist, and co-founder of Phlow Corp., a leading American advanced pharmaceutical contract development and manufacturing organization (CDMO) and certified B-Corporation created to advance the domestic development and manufacturing of critical medicines and help reshore medicine manufacturing on U.S. soil. I also continue to serve as a volunteer paramedic in Virginia, providing care in emergency settings. These are also the settings where the consequences of drug shortages are most acutely felt.

I. The Human Cost of Drug Shortages

Drug shortages are not abstract supply-chain problems. They are real crises unfolding daily in our nation's emergency rooms, ambulances, and operating suites. Across the country, clinicians are being forced to substitute unavailable medications with less effective or unfamiliar alternatives, increasing the risk of medication errors, adverse reactions, and patient harm. In my own clinical experience, there have been moments when critical drugs such as epinephrine for allergic emergencies, midazolam for seizures, or succinylcholine for intubating critical patients were simply unavailable. Every second counts for patients in these situations. Substituting or improvising can mean the difference between life and death.

II. Overreliance on Fragile, Foreign Supply Chains

The U.S. today relies on foreign manufacturers, primarily in China and India, for most of its active pharmaceutical ingredients (APIs) and associated precursor chemical ingredients, including pharmaceutical intermediates and key starting materials (KSMs). In many essential medicine categories, there is only one qualified source, and it is often overseas. Although drug shortages have not been primarily attributed to geopolitical conflicts in the past, the risk is significant due to growing global tensions and supply chain vulnerabilities, leading to an unacceptable strategic vulnerability.

III. The Geopolitical and National Security Dimension

Our pharmaceutical dependence is not just a public-health concern but rather a national-security threat. Rising global tensions make our fragile drug supply increasingly risky. If conflicts disrupt Asian trade routes or trigger export bans, the U.S. could lose access to essential APIs and precursor chemical ingredients needed for critical care, oncology, and infectious disease treatments. Future drug shortages may be significantly more severe, affecting a broader range of medications than we have seen in the past. The Defense Logistics Agency and the Department of Defense Inspector General have both warned that military readiness could be severely compromised by disruptions in the medical supply chain. A purposeful adulteration or export ban on key drug ingredients could leave warfighters without vital medicines.

Over the past few years, Congress has taken significant steps to secure rare earth minerals, once 80-90% imported, including by expanding the National Defense Stockpile through actions such as the purchase of critical minerals.

That same level of urgency is required for APIs and their chemical precursors, including KSMs, which underpin every essential medicine and medical countermeasure. Just as rare earths underpin critical technologies, APIs underpin the entire pharmaceutical supply chain, and without them, we cannot make critical medicines. Yet, the U.S. still imports over 80% of APIs, primarily from China and India, creating a hidden but serious risk exposed during the COVID-19 pandemic.

Just as Congress views the rare earth critical industrial base as vital to national security, the API industrial base for key medicines and medical countermeasures should also be safeguarded as essential health infrastructure. The same bipartisan

resolve that drove progress in rare earths can, and must now, be harnessed to restore America's pharmaceutical sovereignty, ensuring that the lifeblood of our healthcare system is made safely, reliably, and here at home.

IV. What Phlow Is Doing to Address the Crisis

Phlow was created to help solve this problem. In partnership with the U.S. Government, we have built a state-of-the-art advanced manufacturing campus in Virginia, designed to domestically produce APIs for medicines at both small and large scale. We share a campus with Civica Rx, which can produce the finished drug product for sterile injectable essential medicines. Our pharmaceutical campus integrates advanced manufacturing, process analytical technology, and digital quality control systems that are state-of-the-art, offering a high-quality, more efficient, and more sustainable way to make medicines entirely on U.S. Soil once again. Through our groundbreaking partnership with the Administration for Strategic Preparedness and Response (ASPR), Phlow is developing and supplying a broad catalogue of essential APIs. For each active ingredient program, Phlow reconstructs the chemistry, sources starting materials domestically or from allied nations if not possible to source or manufacture in the U.S., and leverages state-of-the-art development and manufacturing approaches, such as green chemistry and continuous manufacturing, to drive efficient, higher-yielding production, cost competitiveness, and a reduction of our environmental impact.

To date, we have completed five API development programs, filed four drug master files, and have a dozen additional APIs in various stages of development. Our latest program, epinephrine, is now making its way into a finished drug product, creating a product with both API and finished product manufactured in the U.S. - something that has not occurred in decades. This API was previously majority manufactured in Taiwan, highlighting the vulnerability of such a critical medicine supply chain. We are also proud to support the Department of Defense (DoD) in strengthening the warfighter supply chain through a pilot program focused on developing and manufacturing critical drug ingredients for medical countermeasures.

Phlow also co-founded the Children's Hospital Coalition, dedicated specifically to solving pediatric drug shortages. To date, we have delivered over 1.8 million doses of critical essential pediatric medicines to the Coalition to support a reliable supply of medicines that have experienced drug shortages. Furthermore, we have begun a domestic end-to-end program, from KSM to API to finished drug product, for ketamine, recently receiving the Commissioner's National Priority Review Voucher as a part of the FDA's inaugural pilot to support rapid development and approval of this critical essential medicine. Despite some misconceptions, ketamine remains vital to modern medicine as a fast-acting, versatile anesthetic that clinicians depend on for safe surgical procedures, emergency interventions, and battlefield care.

Phlow also worked with the U.S. Government to conceive of, and build, the U.S. Strategic Active Pharmaceutical Ingredient Reserve (SAPIR) program. SAPIR is designed to function as a national security buffer for medicine supply chains. Through SAPIR, we are working to maintain an inventory of end-to-end domestically produced or allied-nation-sourced KSMs, intermediates, and APIs for the most essential medicines identified by the federal government. This forward-leaning model not only allows the U.S. to secure a much larger number of critical APIs in larger quantities but also ensures that if global supply chains are disrupted, the U.S. retains the ability to rapidly convert reserve materials into finished drug products to protect Americans. Unlike traditional stockpiling, which often relies on imported finished products with limited shelf life, SAPIR focuses on the building blocks of pharmaceuticals, enabling immediate domestic surge manufacturing, longer stability windows, and far greater resilience.

V. What Is Needed for Sustainable Onshoring Success

As we discuss how to strengthen America's medicine supply chain, it is important to be clear: the goal should not be to reshore every single medicine or chemical precursor ingredient. The U.S. pharmaceutical market encompasses more than 2,000 approved medications. Attempting to onshore everything would be economically unrealistic and strategically unfocused.

Instead, we must take a disciplined, risk-based approach, one that prioritizes medicines based on clinical criticality, population reach, and supply-chain vulnerability. Some medicines, such as certain injectables used in emergency care, have no substitutes and are essential for saving lives within minutes. Others treat millions of Americans daily, meaning any disruption would have broad population-level impacts. We are at serious risk when essential drugs depend on fragile or highly concentrated foreign supply chains that can be disrupted, or even weaponized, without warning.

A national resilience strategy must therefore begin with the right-tiered list of essential medicines, regularly updated and informed by federal agencies, healthcare systems, and manufacturers. This list should continue to identify which APIs and KSMs require domestic or allied-nation production, which can be supported through diversified global sourcing, and which pose minimal risk. By doing this, we focus on the medicines that keep Americans alive in emergencies, followed by certain medications that stabilize chronic conditions and support national preparedness in times of crisis.

Despite considerable progress, the onshoring movement remains fragile. For this transformation to succeed, certainty and sustainability are essential. No company, no matter how mission-driven, can sustain long-term domestic production without predictable demand and multi-year commitments. America must invest in domestic and allied API manufacturing capacity, particularly through shared-infrastructure ecosystems that dramatically lower production costs while enabling environmentally responsible synthesis.

For Phlow, this aligns directly with our work under ASPR and the SAPIR program: if the U.S. cannot secure these earliest building blocks of medicines, it cannot secure the medicines themselves. Strategic API manufacturing is only as strong as the weakest upstream link. Therefore, this is not a one-company solution. We need a competitive marketplace of U.S. manufacturers aligned under a national strategy for medicine security.

Several key policy enablers are required:

1. Develop a Long-term and Comprehensive Strategy

Restoring our nation's pharmaceutical supply chain cannot be achieved through isolated, short-term interventions. To prevent future shortages and secure our supply chain, the government must create a comprehensive, long-term plan that encompasses demand forecasting, industrial base growth, research and development, workforce development, and procurement reform. Congress should support a centralized authority to align policy and funding, while bringing stability for patients and predictability for manufacturers. Developing and then executing such a strategy requires sustained, cross-functional partnership across the federal government; siloed decision-making is a vulnerability.

Given the finite time and resources available, this strategy must prioritize those essential medicines and medical countermeasures that treat life-threatening conditions and for which no suitable clinical alternatives exist. Prioritization is not optional, but rather necessary, to ensure that federal investments protect the most critical and high-risk segments of our healthcare system.

At the same time, this strategy should leverage advanced development and manufacturing technologies, such as continuous manufacturing, that improve yields, reduce costs, strengthen quality, and enable greener, more sustainable chemistry. Integrating such technologies into the federal industrial base plan will not only accelerate domestic production but also ensure it is economically viable and environmentally responsible for the long term.

2. Realign Payment and Procurement Policies with Reliability

The central obstacle in restoring the reliability of America's drug supply is not a lack of data, but rather a lack of aligned incentives. The market will not shift back to the U.S. if the buyers of essential medicines, especially hospitals, clinics, and wholesaler intermediaries, remain structurally rewarded for choosing the lowest immediate cost, even when those savings come at the expense of long-term security and patient safety. Information about quality, sourcing, or supply-chain fragility becomes little more than a ″warning label″ if purchasers are neither financially supported nor contractually required to act on it. To change outcomes, federal entities should adopt procurement policies valuing supply chain reliability. Strategic investment in domestic sourcing can help save lives by strengthening national health security, reducing drug shortages, and mitigating the widespread disruptions they cause.

3. Ensure Predictable, Long-Term Resourcing

To build enduring resilience, the Administration and Congress must resource these programs with multi-year contracts, similar to how we support defense and energy infrastructure. This allows U.S. manufacturers to plan, invest, and scale with confidence.

There is much to learn from the Department of Defense's long-term industrial base planning and its disciplined use of multi-year procurement, which has enabled stable domestic production of critical materials for decades. Defense contracting models demonstrate that when the government provides predictable demand signals, industry responds with sustained investment, innovation, and surge capacity.

4. Level the Playing Field

We must ensure that domestic manufacturers can compete fairly against foreign producers who benefit from heavy state subsidies, lax environmental and labor standards, weak intellectual property protections, and currency manipulation - advantages that artificially suppress prices and distort global markets. Without corrective action, U.S.-based pharmaceutical manufacturers are forced to compete not on innovation or quality, but against foreign governments underwriting the true cost of production.

5. Close the Acetris Loophole

As previously recommended by this Committee, it is critical that Congress prioritizes work to close the Acetris loophole. This loophole breaks the connection between ″Made in America″ and the actual location of pharmaceutical value creation and strategic risk, enabling continued dependence on vulnerable foreign API supply chains even in federal purchasing programs intended to prioritize domestic or allied production.

Fixing the Acetris loophole is not about limiting trade or restricting competition; it is about aligning federal procurement with national security reality. APIs account for the greatest concentration of risk in the entire pharmaceutical supply chain. When the U.S. government buys drugs formulated domestically but sourced from adversarial nations upstream, it inadvertently reinforces the very dependencies we are working so hard to reduce. For essential medicines, particularly those relied upon by vulnerable patient populations, our military, and our emergency response systems, this loophole leaves the U.S. exposed to disruptions, coercion, and shortages originating far outside our borders.

Closing this gap would also give companies like Phlow the market signals needed to invest boldly in U.S. advanced manufacturing, end-to-end pharmaceutical ingredient synthesis, and strategic API reserves.

VI. Looking Ahead

If we fail to act decisively, the next crisis will not be hypothetical. The shortages our great Nation has been coping with have shown us the harm they can cause. If the United States is not adequately prepared, the repercussions could be even more severe than those seen during past shortages of saline or chemotherapy treatments. We could see dangerous situations where anesthetics are unavailable in emergency rooms, saline or antibiotics are unavailable for a sepsis patient, or the inability of our military to access life-saving countermeasures in the midst of conflict.

However, if we succeed in creating a durable, competitive, and secure domestic pharmaceutical manufacturing base, we will have restored one of the most critical pillars of national resilience. Phlow is honored to play a role in this mission, and we stand ready to partner with the U.S. Government and our fellow innovators to make medicine security a permanent reality for the American people.

Conclusion

Chairman Scott, Ranking Member Gillibrand, and members of the Committee, thank you for your leadership in shining a light on this issue. Drug shortages are not inevitable; they are the product of choices. Together, we can choose to build a safer, more resilient, and more self-reliant future for American healthcare.

Thank you, and I welcome your questions.

Questions for the Record

U.S. SENATE SPECIAL COMMITTEE ON AGING

"MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES"

NOVEMBER 19, 2025

QUESTIONS FOR THE RECORD

Alan Coukell

Senator Raphael Warnock

Question:

Health care providers across Georgia are concerned about shortages of pharmaceutical drugs, including generic medications. Due to limited access to drugs, patients have been seeking alternative drugs and waiting longer periods for treatments.

What type of federal procurement reforms should Congress lead to address pharmaceutical drug shortages in states like Georgia?

Response:

The most common cause of a drug shortage is a quality problem in the manufacture of the finished dosage form (i.e. the vial or the tablet). Most shortages occur among injectable drugs, because these products are more complex with more exacting requirements for sterility.

Shortages are also highly correlated with price: lower cost drugs are more likely to go into shortage.[1] Every authoritative investigation into the causes of drug shortages has concluded that low prices are the root cause.[2] This is because when a drug is produced at low (or even negative) margins, a manufacturer loses the ability or the incentive to invest in quality. In addition, maintaining rigorous quality systems is expensive, so a manufacturer that cuts corners on quality can undercut prices and gain market share.

Thus, the ever-downward trend in generic drug prices is also a story of poor quality driving out good quality, which leads to shortages. This same pressure on price and quality also leads to a move of manufacturing from the United States to countries with low cost of labor and less well-developed regulatory systems, which enable manufacturers to cut corners.

Domestic manufacturing is not automatically synonymous with good quality oversight, nor is off-shoring automatically a cause of drug shortages. Nevertheless, the "race to the bottom" on generic drugs prices fuels both offshoring and quality problems. In general, purchasers of generic drugs treat all FDA-approved products as equivalent. The only factor used to discriminate between them is price. Purchasing decisions do not take into account quality history or other practices that could ameliorate the risk of shortages - practices such as diversifying sources of supply or maintaining a reserve inventory to buffer any demand or supply shock.

To mitigate and prevent future drug shortages, federal procurement should require or incentivize drug purchasing that:

1. Selects suppliers with superior quality management practices that are less likely to result in a future shortage. This could be based on a physical audit of manufacturing facilities by, or on behalf of, the purchaser and informed by regulatory history from recent FDA inspections. Related approaches include FDA's ongoing work on "Quality Management Maturity" assessments and various third-party programs in development.

2. Involve multi-year committed volume contracts, which bring stability to the generic drug market. Such agreements provide a manufacturer with a clear stable demand signal that is often lacking in the current highly labile commodity market for generic drugs.

3. Include reserve inventory that can buffer supply shocks if the supplier (or another company making a competing generic) is unable to supply. While a buffer

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[1] United States Pharmacopoeia. USP Annual Drug Shortages Report: Longstanding drug shortages persist in 2024. https://go.usp.org/2025drugshortagesreport?—gl=1*hrts0*—gcl—au*MTA1MzEwODM0MS4xNzY0NjkyOTg1*—ga*MTc3MTU5MDcxNS4xNzY0NjkyOTg1*—ga—DTGQ04CR27*czE3NjQ2OTI5ODUkbzEkZzEkdDE3NjQ2OTI5OTckajQ4JGwwJGgw

[2] For example, see FDA "Drug Shortages: Root Causes and Potential Solutions," 2019; Brookings "Federal Policies to Address Persistent Generic Drug Shortages," 2023; Duke Margolis, "Advancing Federal Coordination to Address Drug Shortages" 2023.

inventory cannot prevent a shortage indefinitely, it can frequently prevent an interruption in supply while manufacturers make additional batches of drug.

4. Ensure appropriate diversity of supply. If multiple manufacturers each hold a significant market share, they are more likely to have the ability to increase production in response to a shortfall by another supplier.

Such an approach has been proposed in a recent bipartisan discussion draft from the Senate Finance Committee.[3] With improvements to simplify and streamline, this draft could be the basis for shifting procurement towards a more resilient supply. Other authorities could be used to achieve the same goal, such as changes to the Medicare In-patient Prospective Payment Ssytem rule or a demonstration program through the Center for Medicare and Medicaid Innovatoin (CMMI).

Importantly, the SFC draft uses Medicare payment authority but would affect all purchases by providers that receive Medicare reimbursement (i.e. based on purchase invoices, not on which patients are covered by Medicare). This approach is essential to achieving a scale that would impact the supply. Direct federal procurement, such as through the Veteran's Administration and the Department of Defense, would affect only a small portion of the market and would therefore not meaningfully mitigate shortages in the wider market beyond a discrete effect in these systems.

[3] Senate Committee on Finance, Medicare Drug Shortage Prevention and Mitigation Program (May 3, 2024 discussion draft), available at https://www.finance.senate.gov/imo/media/doc/050124—sfc—drug—shortages—discussion—draft—legislative—text.pdf

U.S. SENATE SPECIAL COMMITTEE ON AGING

"MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES"

NOVEMBER 19, 2025

QUESTIONS FOR THE RECORD

Tom Neely

Senator Raphael Warnock

Question:

Health care providers across Georgia are concerned about shortages of pharmaceutical drugs, including generic medications. Due to limited access to drugs, patients have been seeking alternative drugs and waiting longer periods for treatments.

In your testimony, you mentioned that Group Purchasing Organizations (GPOs) and Pharmacy Benefit Managers (PBMs) manage nearly all hospital generic contracting and retail generic purchases in the United States. What steps should Congress take to increase transparency into GPOs and PBMs and ensure profits captured by these entities are passed on to patients?

Response:

One of the central drivers of the cheap-import surge and resulting chronic drug shortages is the highly consolidated structure of purchasing intermediaries-especially Group Purchasing Organizations (GPOs) and Pharmacy Benefit Managers (PBMs). Three GPOs control 90% of hospital generic contracting, and three PBM-aligned alliances control 90% of retail generic purchasing.

Their contracting structures drive prices below sustainable production costs by pitting subsidized imports against domestic producers. This dynamic has pushed U.S. manufacturers out of the market and deepened reliance on single foreign suppliers.

To correct this structure, Congress can take the following steps:

- Revisit the GPO safe harbor and vendor-fee model. The Anti-Kickback safe harbor that allows GPOs to collect vendor fees biases contracts toward large, subsidized foreign incumbents, reinforces offshoring, and creates barriers for domestic and emerging producers.
- Require contracts-especially where federal dollars are involved-to weigh security and quality, not only price. Medicare, Medicaid, DoD, and VA purchasing, as well as GPO/PBM contracts, should explicitly factor FDA compliance history, redundancy of supply, and safe domestic or allied sourcing rather than rewarding the lowest unit cost.
- Expand supply-chain transparency and oversight. Congress should require clear disclosure of manufacturing sites and API country-of-origin. The FTC and DOJ should strengthen scrutiny of exclusionary contracting practices that shut out new or domestic suppliers.

These steps realign purchasing incentives so that the system rewards reliable, high-quality, and domestically anchored supply rather than opaque, lowest-bid foreign sourcing.

Question:

According to the Georgia Chamber of Commerce, pharmaceutical drugs are one of the largest imports in Georgia. As tariffs continue to increase the price of pharmaceutical drugs, Georgians might face a greater barrier to accessing medications.

How can Congress lead long-term solutions for strengthening domestic drug supply chains while also securing Georgians' immediate access to affordable pharmaceutical drugs?

Response:

The core tools for rebuilding the generic and API base are a Section 232 pharmaceutical Tariff-Rate Quota (TRQ), the PILLS Act production and investment incentives, and the realignment of federal purchasing toward secure, reliable supply.

First, a TRQ under the Section 232 national-security authority would set quota volumes for critical generics and APIs, allowing needed imports from trusted FDA-standard-equivalent partners to enter at zero tariffs while imposing high, specific tariffs only on over-quota volumes and on risky, subsidized supply from countries

such as China and India. Quotas are set at U.S. demand minus domestic capacity and adjusted regularly, ensuring patients maintain access while domestic capacity is rebuilt.

Second, the PILLS Act framework provides a production tax credit for U.S.-made generics, APIs, and biosimilars, plus an investment tax credit for new and modernized facilities. Together, these credits can offset much of the foreign cost advantage rooted in subsidies and weaker standards abroad, making it economically viable to reshore and expand manufacturing.

Third, federal procurement-Medicare, Medicaid, DoD, and the VA-is the single largest buyer of medicines in the country. Prioritizing safe, reliable U.S.-made products, using long-term anchor contracts, and expanding strategic API reserves all guarantee stable demand for domestic producers and reduce dependence on single overseas suppliers.

These tools do not raise out-of-pocket costs for patients in Georgia or elsewhere. Only about 36% of a generic's retail price is manufacturing; the remaining 64% goes to wholesalers, PBMs, pharmacies, and insurers. Federal reimbursement systems in Medicare Part B, Medicaid, and Part D already absorb modest cost shifts. It is the lack of domestic production that drives the 300-500% gray-market price spikes hospitals face during shortages.

A Section 232 TRQ, PILLS-style incentives, and aligned federal procurement give Congress a clear path to strengthen domestic drug and API capacity over time while keeping medicines affordable and available for Georgians right now.

Statements for the Record

Composition of OSCS contaminated heparin occuring in 2008 Statement

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Composition of OSCS-contaminated heparin occurring in 2008 in batches on the German market

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Abstract

In 2008, some 900 cases of adverse events associated with the use of heparin were reported to the Food and Drug Administration of USA and the Federal Institute of Drugs and Medical Devices in Germany. 238 patients died from heparin in the USA. In March 2008, oversulfated chondroitin sulfate (OSCS) was identified to be responsible for these cases. NMR spectroscopic evaluation of heparin samples revealed OSCS, dermatan sulfate (DS), chondroitin sulfate A and C as well as various residual solvents to be present in heparin batches, which could not be identified by means of conventional methods described in various pharmacopoeias at that time. In order to evaluate the situation on the German market, 145 representative samples were collected in 2008 and analyzed by means of ^{1}H NMR spectroscopy, water determination, optical rotation and sheep plasma clotting assay. 66 samples were found to contain pure heparin, 51 samples heparin plus DS, 5 samples heparin plus OSCS, and 23 samples heparin, DS and OSCS, each in varying amounts. In 94 out of 145 batches especially ethanol was found in strongly varying amounts up to about 9.5%. Traces of acetone and formic acid were found with concentrations up to 0.04%, as well as sodium acetate and methanol up to 0.5%. Additionally, in many batches the content of water was found to be relatively high. Whereas the optical rotation was able to identify samples with a high contamination of OCSC, all samples tested fulfilled the requirements of the anticoagulation potency assay of the European

Pharmacopoeia 6.0. The presented analysis of a representative set of heparin samples proves the suitability of ^{1}H NMR spectroscopy for the quality control of heparin of both glycosaminoglycans and residual solvents.

Introduction

Heparins are animal extract preparations and consist of heterogeneous mixtures of highly sulfated glycosaminoglycans (GAGs), which considerably differ in their individual structure. Their complex composition varies depending on the animal source material and the isolation procedure (Bianchini et al., 2007). According to the European Pharmacopoeia (PhEur) 6.0, they may be prepared from bovine lungs or from the intestinal mucosae of oxen, pigs or sheep (European Pharmacopoeia, 2008c). However, as a precaution only porcine heparin is allowed for medical applications (Alban, 2005). Meanwhile, more than half of the world's heparin comes from China. To this day, heparin preparations are the antithrombotic drugs of choice in short- and medium-term prophylaxis and therapy of thromboembolic diseases. It has to be differentiated between unfractionated heparin (UFH) and the different low-molecular weight heparins (LMWHs), which are produced from UFH. Although LWMHs increasingly replace UFH, UFH is still preferentially used in therapy of acute coronary syndrome and intensive-care medicine as well as to prevent clotting of the extracorporeal blood during hemodialysis and cardiac surgery. Beside the potential bleeding risk the most serious adverse reaction is the heparin-induced thrombocytopenia type II (Brunton et al., 2005).

In January 2008, the Center for Disease Control and Prevention (CDC) in the USA was informed by health authorities about a cluster of anaphylactoid reactions among patients undergoing hemodialysis which first occurred in November 2007. From mid-December 2007 through January 2008, Baxter Healthcare had received 350 reports of adverse events associated with the use of its heparin, many of them were serious, and four patients died (U.S. Food and Drug Administration: Information on heparin http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm112597.htm ↗). Symptoms included rapidly falling blood pressure, severe nausea, vomiting, diaphoresis, and difficulty breathing (Kishimoto et al., 2008, Blossom et al., 2008). In January and February 2008 Baxter Healthcare voluntarily recalled suspicious single and multi-dose heparin vials from the market. On February 18, 2008, it recalled all its heparin lots and stopped heparin production. After information of the public, increasing numbers of cases were reported to the Food and Drug Administration (FDA). From January 1, 2007 through May 31, 2008, 800 cases were reported in the USA and at least 238 patient died from heparin (U.S. Food and Drug Administration: Information on adverse event reports and heparin http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm112669.htm ↗). On February 14, 2008, FDA identified the Chinese company Changzhou SPL as supplier of the suspected heparin. Later, another 11 Chinese companies have become known which have supplied contaminated heparin batches to 12 countries, i.e. Australia, Canada, China, Denmark,

France, Germany, Greece, Italy, Japan, the Netherlands, New Zealand and the USA. Whereas most cases concentrated to the USA, 81 cases were reported to the pharmacovigilance department of the Federal Institute of Drugs and Medical Devices (BfArM) in Germany, being 17 hypotension cases (observed but not treated), 14 anaphylactic shocks to be treated as well as 50 cases of clotting in dialysis devices.

In April 2008, the adverse reactions were attributed to oversulfated chondroitin sulfate (OSCS), which was found in the heparin in the USA and in Germany. Meanwhile, the structure of OSCS (see Fig. 1) was elucidated by one- and two-dimensional ^{1}H and ^{13}C NMR spectroscopic methods and recently confirmed by synthesis of OSCS and further NMR experiments (Guerrini et al., 2008, Guerrini et al., 2009).

Blossom et al. (2008) studied the information provided by 21 dialysis facilities with reported adverse reactions and 23 ones without any case in the period between November 19, 2007 and January 31, 2008 (U.S. Food and Drug Administration: Information on adverse event reports and heparin). Although the final prove is still missing, they were able to epidemiologically link OSCS-contaminated heparin to adverse effects. Of 130 reactions for which information on the heparin lot was available, 128 occurred in dialysis facilities where OSCS-contaminated heparin was present clearly indicating the connection between the adverse effects and the presence of OSCS. In 95% of the cases the heparin applied was manufactured by Baxter Healthcare. The most common manifestations found in the study were hypotension in 50%, nausea in 48.7%, shortness of breath in 37.5% and facial swelling in 23.7% of the cases. In 15% of the cases, the reactions required evaluation in an emergency department and 9% of the patients needed hospitalization. None of the patients included in the study died.

Interestingly, the NMR spectroscopic evaluation of the heparin performed in various control and academic laboratories in USA and Germany revealed not only OSCS as a UFH by-product but also partially high amounts of dermatan sulfate (see Fig. 1) and residual solvents such as ethanol, sodium acetate, acetone, methanol, and formic acid.

The fact that unfractionated and low-molecular weight heparins contaminated with OSCS appeared in Germany prompted the BfArM to collect some 200 batches from all manufacturers of the German market in the first half of 2008. Within the frame of this study, the composition of 145 representative batches was evaluated by means of ^{1}H NMR spectroscopy and anion exchange (SAX)-HPLC, both integrated in the currently revised United States Pharmacopoeia (USP) heparin sodium monograph (came into force in October, 2009), the optical rotation and anticoagulant potency assay, which had proven insufficient to detect contamination with OSCS.

Section snippets

Quantitative NMR spectroscopy (Beyer et al., 2008)

For the 400 MHz ^{1}H NMR spectra of the heparin batches analyzed, 32 scans were collected into 64K data points over a spectral width of 4789 Hz (12 ppm) with the transmitter offset at 5.00 ppm, yielding a digital resolution of 0.15 Hz per point. The acquisition time was 6.84 s, followed by a relaxation delay of 1 s, resulting in a total pulse recycle time of 7.84 s to ensure full T_1 relaxation of the N-acetyl protons of heparin and its impurities (T_1 relaxation values were determined to be about 1.44 s …

^{1}H NMR spectroscopy

With the ad hoc revision of the monographs "Heparin Sodium" and "Heparin Calcium" in the PhEur 6.0 in June 2008, ^{1}H NMR spectroscopy was implemented as mandatory identity test which simultaneously identifies the heparin and evaluates the quality of heparin. This technique provides simple differentiation between heparin and its impurities oversulfated chondroitin sulfate (OSCS), dermatan sulfate (DS) and chondroitin sulfate (CS) A/C by analyzing the chemical shifts of the N-acetyl resonances. …

Conclusion

The investigation of 145 heparin samples from the German market revealed that about 20% of them were contaminated with OSCS. The fact that all these contaminated batches had passed the quality control according to the original "Heparin sodium" monograph of PhEur 6.0 strikingly illustrates its insufficiency. Indeed, one reason for the heparin scandal 2008 was the outdated heparin monographs. By ad hoc revision of the PhEur and USP monographs in June 2008, ^{1}H NMR spectroscopy and CE were …

Acknowledgement

Thanks are due to the Federal Institute of Drugs and Medical Devices for providing a grant given to UH. …

References (20)

T. Beyer *et al.*
Quality assessment of unfractionated heparin using ^{1}H nuclear magnetic resonance spectroscopy
J. Pharm. Biomed. Anal. (2008)

T. Maruyama *et al.*
Conformational changes and anticoagulant activity of chondroitin sulfate following its O-sulfonation
Carbohydr. Res. (1998)

T. Toida *et al.*
Preparation and anticoagulant activity of fully O-sulphonated glycosaminoglycans
Int. J. Biol. Macromol. (1999)

S. Alban
Carbohydrates with anticoagulant and antithrombotic properties

S. Alban
The 'precautionary principle' as a guide for future drug development
Eur. J. Clin. Invest. (2005)

P. Bianchini *et al.*
Variability of heparins and heterogeneity of low molecular weight heparins
Semin. Thromb. Hemost. (2007)

D.B. Blossom *et al.*
Outbreak of adverse reactions associated with contaminated heparin
N. Engl. J. Med. (2008)

L.L. Brunton *et al.*
Goodman & Gilman's The Pharmacological Basis of Therapeutics
(2005)

European Pharmacopoeia Commission, European Pharmacopeia
Heparin Calcium, Optical Rotation
(2008)

European Pharmacopoeia Commission, European Pharmacopeia
Microdetermination of Water
(2008)
There are more references available in the full text version of this article.

Cited by (47)

Pharmaceutical impurities and degradation products: Uses and applications of NMR techniques
2014, Journal of Pharmaceutical and Biomedical Analysis

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Analytical challenges in drug counterfeiting and falsification-The NMR approach
2011, Journal of Pharmaceutical and Biomedical Analysis

Show abstract

NMR chemical shifts in structural biology of glycosaminoglycans
2014, Analytical Chemistry

Analysis and characterization of heparin impurities
2011, Analytical and Bioanalytical Chemistry

Description of hypersensitivity adverse events following administration of heparin that was potentially contaminated with oversulfated chondroitin sulfate in early 2008
2010, Pharmacoepidemiology and Drug Safety

Quantitative NMR spectroscopy of biologically active substances and excipients
2010, Bioanalytical Reviews

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"MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES"

NOVEMBER 19, 2025

STATEMENTS FOR THE RECORD

Heparin at the Center of the Storm Statement

FDA WATCH

Heparin at the Center of the Storm

Mark Senak, JD

This past April has seen nothing less than a tug of war between Congress and the US Food and Drug Administration (FDA). During April and May, FDA staffers have been on Capitol Hill to offer testimony to Congress no less than 10 times. During the entire duration of 2006, the FDA only offered 12 testimonies. Congressional scrutiny of the agency has obviously increased in the past 2 years.

Although this Capitol Hill activity has involved many issues, the 2 that emerge as the most relevant—safety and funding—are related and were sparked by the problem of contaminated heparin. In fact, during April, matters related to the heparin contamination dominated the attention of Capitol Hill and the FDA.

Beginning in February 2008, Baxter Healthcare Corporation initiated a recall of all of its heparin products because of reports of serious adverse events in patients using that drug. It was found that the blood thinner heparin had been contaminated by inferior products that were used by some manufacturers, and the problem was occurring globally. As many as 81 people died after large injections of the product. Heparin was manufactured by multiple suppliers in China, and it is not known where in the supply chain the contamination may have occurred.[1]

An arch theme is connected with this episode of a contaminated pharmaceutical product. It must be determined how the contamination occurred (and the FDA and Baxter have offered the theory that the contamination was intentional),[2] but the bigger issue involves questions related to the safety of the current system of drug manufacturing, and what can be done in today's real-world system to minimize the risk of drug contamination. On April 29, Dr Woodcock, Director of the Center for Drug Evaluation and Research, told the Subcommittee on Oversight and Investigations Committee on Energy and Commerce, "While the contaminant was first identified in the US, the recall of this product is international in scope. The FDA has notified key regulatory international partners, and we are working closely with our Chinese and European counterparts in the investigation."[3]

The events surrounding heparin have raised a host of issues for the FDA and paved the way for realizations about the very global nature of drug manufacturing. The heparin incident has made people realize that the components of many—if not most—drugs are produced outside of the United States, where the FDA has a very limited ability to inspect the manufacturing process.

This fact further undermines the argument that drugs cannot be imported because of safety concerns, when, in fact, drugs that are manufactured here are found to be unsafe. Perhaps most important to the heparin issue is the means by which we come to understand the weaknesses in the current system, and this is a metaphor for the fact that our ability to regulate safety is far behind the current trends of globalization—whether concerning food or drugs.

The events surrounding heparin have raised a host of issues for the FDA and paved the way for realizations about the very global nature of drug manufacturing.

The heparin incidence has been at least partly responsible for a number of hearings on Capitol Hill. The first focus was on why heparin was contaminated, and whether the FDA was doing its job correctly. The secondary focus became one of how to fix the FDA so that the risk from such occurrences is minimized. This led at one point to a heated exchange between Congressman John Dingell, Chair of the House Committee on Energy and Commerce, and FDA Commissioner Andrew C. von Eshenbach during a recent congressional hearing. The commissioner was repeatedly grilled over whether the agency was doing its job correctly, and, more to the point, what funding measures would be needed to ensure that the FDA is in a stronger position when it comes to the inspection of foreign manufacturers.

The fact is, the amount of resources that would be required for the FDA to inspect each and every foreign manufacturer of every component of a medication is quite high. At question—which was unanswered in these hearings and exchanges—is whether it is reasonable to expect the FDA to successfully minimize risk abroad through a program of foreign inspections, or

whether there is a greater role for manufacturers in ensuring quality.

In the case of heparin, even if testing had been conducted at the border, it is unlikely that the contamination would have come to light.

There is a need for a deeper inspection and analysis of the heparin contamination issue to determine whether funding for a more aggressive inspection program is in fact going to solve the problem that Congress and the FDA are facing. Heparin contamination is the symptom of a larger problem facing all drug manufacturing today, and unless it is addressed with a more comprehensive approach, history may be poised to repeat itself. ■

References

1. FDA media briefing on heparin, April 21, 2008. http://www.fda.gov/bbs/transcripts/2008/heparin_transcript_042108.pdf. Accessed May 27, 2008.

2. Woodcock J. US Food and Drug Administration. Testimonial before Subcommittee on Oversight and Investigations Committee on Energy and Commerce. Ongoing heparin investigation. April 29, 2008. http://www.fda.gov/ola/2008/heparin042908.html. Accessed May 17, 2008.

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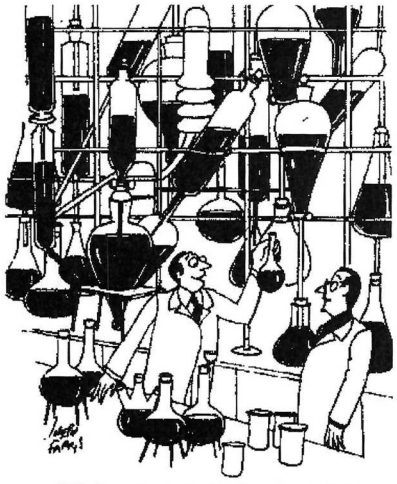
Unmanaged Moment



"We've done it! We've invented a new drug. Now we have to find a disease for it."

FDA's "Complete Response" Replaces "Approval/ Nonapproval" Letter

Responding to concerns from drug manufacturers, and after several years of deliberations, the US Food and Drug Administration (FDA) announced on July 9, 2008 (www.fda.gov/bbs/topics/NEWS/2008/NEW01859.html), that starting August 11, 2008, it would no longer be sending an "approvable" or a "nonapprovable" letter to drug sponsors in response to a new drug application. Instead, the FDA's new wording is a "complete response" letter that is intended to notify the drug maker that the review process has been completed but the drug is not yet ready to be approved, because of "specific deficiencies," as described by the FDA. When possible, the FDA will also "outline recommended actions the applicant might take to get the application ready for approval." This last comment appears to imply a change in policy in the form of a more complete explanation of the process than just mere semantics, but this remains to be seen.

The FDA noted that complete response letters are already being used for applications for biologic products, and that this change in wording is intended to remove any potential for misinterpretation by different stakeholders as a complete and final rejection of the drug. The use of "approvable" or "nonapprovable" letters was often perceived to imply a "tentative" or "conditional" approval of the drug, when in effect that was not the intent of the FDA, according to John Jenkins, director of the FDA's Office of New Drugs. Such misinterpretation carried potential clinical and financial ramifications to drug makers, patients, and investors.

U.S. SENATE SPECIAL COMMITTEE ON AGING

"MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES"

NOVEMBER 19, 2025

STATEMENTS FOR THE RECORD

National Consumers League Statement

NATIONAL CONSUMERS LEAGUE
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November 18, 2025

The Honorable Rick Scott
Chair, Senate Select Committee on Aging
G16 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Kirsten Gillibrand
Ranking Member, Senate Select Committee on Aging
628 Hart Senate Office Building
Washington, DC 20510

Dear Chairman Scott and Ranking Member Gillibrand:

As a national consumer organization that has long advocated for policies to improve the safety of medicines and protect consumers from fraud in the marketplace, the National Consumers League (NCL) was pleased to submit comments to the Select Committee on September 17 in conjunction with the hearing, *Prescription for Trouble: Drug Safety, Supply Chains, and the Risk to Aging Americans*. Our goal was to bring to the committee's attention the significant safety risks facing older adults with obesity who go online to buy untested and unapproved compounded GLP-1 drugs that are often manufactured with active pharmaceutical ingredients (API) imported from China and other foreign sources.

Our September 17 comment letter underscored why foreign API, especially when the quality and specific contents are not known, can be dangerous. Citing warnings about the safety of compounded GLP-1 drugs issued by the Food and Drug Administration in 2024 and 2025, our letter quotes FDA as stating that compounded versions "can be risky for patients" because these drugs are held to lower regulatory standards than FDA-approved medicines. The reason is because FDA regulates compounded drugs based on their primary purpose – as one-of-a-kind medicines altered to address a special patient need, such as an allergy to an ingredient – even though FDA also allows compounded drugs to be mass-produced and sold on a temporary basis during a national shortage, which occurred with GLP-1 drugs between 2022 and 2024 and is now over.

Due to this regulatory framework, compounded drugs are not reviewed for safety, effectiveness or quality by FDA;[1] compounded products are not FDA-approved; and these drugs differ in ways that can be detrimental to patient safety. The consequences for patient safety can be seen with GLP-1 weight loss drugs where FDA reports that compounded versions may contain too much or too little of the API, have a different dosage level, or have drug quality problems, such as contamination with bacteria or a harmful substance. As of September 9, 2025 , FDA received 1,424 reports of adverse events, including reports of 329 hospitalizations and 23 deaths[2] due to dosing errors and reactions to harmful ingredients. Among those most likely to be harmed by these adverse reactions are older adults, who metabolize drugs differently due to age-related physiological changes, and are more susceptible to harm from dosing errors and reactions to contaminated or impure drugs.

[1] Food and Drug Administration. Human Drug Compounding Laws. December 17, 2024. Accessible at: https://www.fda.gov/drugs/human-drug-compounding/human-drug-compounding-laws
[2] Food and Drug Administration. Dashboard, data on compounded September 9, 2025

Additionally, new health risks are a possibility with compounded GLP-1 drugs now that compounders and telehealth companies are marketing "personalized" versions with added vitamins or microdoses of GLP-1s that have never been studied. Further, state attorneys general are raising alarm bells that unregulated API in GLP-1 drugs is being sold to med-spas, which are not licensed by any state body, and to bad actors that illegally sell the API to consumers online with directions for mixing a GLP-1 drug, which is extremely dangerous.

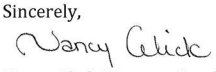
The safety challenges with compounded GLP-1 drugs are relevant as the Select Committee holds its hearing entitled *Made in America: Restoring Our Trust in Medicines* on November 19 and will hear from witnesses about the value of manufacturing API for pharmaceutical products and biologics in the US. Clearly, increasing the supply of American-made API where facilities are inspected by the FDA and the API meets FDA's standards for safety and quality is a positive step forward for the safety of the drug supply. However, these ingredients are intended for use in branded and generic drugs that go through a formal FDA approval process.

When it comes to compounded drugs like GLP-1 weight loss medicines sold without the same regulatory safeguards as required of branded and generic medicines, American-made API will not be a panacea. Although compounders may be able to obtain the API for drugs like GLP-1s from American sources, there remains the possibility of dosing errors and worse, the possibility that the American-made API will be diverted for use by unregulated med-spas that mix their own GLP-1s or sold online by bad actors to consumers with mixing instructions.

Trust is essential for Americans to take medications as prescribed by their physicians. This is why NCL supports onshoring the manufacture of more API sources to the US as a positive step to reduce pharmaceutical supply chain risks and add jobs for American workers. Yet, the potential diversion of US-made API for unapproved and unsafe uses is a reality that must be addressed, and in the case of compounded drugs, this will require robust regulatory safeguards that do not exist today.

On behalf of America's consumers, the National Consumers League thanks the Select Committee for holding this hearing and appreciates the opportunity to share our insights.

Sincerely,



Nancy Glick,Director, Food & Nutrition Policy
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U.S. SENATE SPECIAL COMMITTEE ON AGING

"MADE IN AMERICA: RESTORING TRUST IN OUR MEDICINES"

NOVEMBER 19, 2025

STATEMENTS FOR THE RECORD

White Paper: The 2008 Heparin Contamination Crisis Statement

White Paper: The 2008 Heparin Contamination Crisis—Origins, Impact, and the Critical Role of Domestic Manufacturing Capacity

Executive Summary

In early 2008, the United States faced one of the most consequential drug-safety failures in recent history. Heparin, an essential anticoagulant used in millions of surgeries, dialysis treatments, catheter flushes, and critical-care procedures every year, became contaminated with a chemically engineered adulterant sourced from China. The resulting national public-health emergency caused dozens of deaths, hundreds of severe adverse reactions, and exposed deep structural vulnerabilities in U.S. pharmaceutical supply chains.

As Baxter Healthcare recalled large volumes of heparin, the country was left with only one reliable and safe source of heparin injectables—**American Pharmaceutical Partners (APP)**, a U.S.-based sterile injectable manufacturer founded by a surgeon and scientist Dr. Patrick Soon-Shiong. APP's domestic capacity of manufacturing from the API to the finish product combined with controlled quality sourcing to ensure absence of viruses present in pigs (Porcine Endogenous Virus), ensured the continuity of heparin supply at a time when the U.S. was on the brink of a catastrophic nationwide shortage.

This white paper reviews the scientific origins of the crisis, the regulatory and supply-chain failures that enabled it, the media exposure that brought the issue to public attention, and the policy implications for future drug-shortage prevention.

I. Clinical and Pharmaceutical Importance of Heparin

Heparin is a porcine-derived anticoagulant that is indispensable across surgical, cardiovascular, critical-care, and renal-replacement settings. Its biological complexity and reliance on animal tissue extraction make it inherently vulnerable to supply-chain and quality-control failures, particularly when raw materials originate from poorly regulated global networks.

A single disruption in quality or supply can affect every hospital in the country.

Heparin is indispensable to U.S. acute-care medicine. Tens of millions of procedures and patient encounters each year cannot proceed safely without it. A failure in quality or supply—such as the 2008 OSCS contamination—poses a direct, immediate threat to national health security, with the potential for **thousands of deaths per week** if access is compromised.

Clinical and Pharmaceutical Importance of Heparin

Heparin is one of the most widely used medications in modern medicine and remains the foundational anticoagulant for acute-care medicine. Derived from porcine intestinal mucosa, unfractionated heparin (UFH) cannot be replaced in many settings by oral or synthetic agents due to its rapid reversibility, titratability, and broad clinical utility. As a result, shortages or quality failures can have **immediate and lethal consequences**.

Scale of Use in the United States

Authoritative estimates show that:

- **More than 12 million patients per year** in the United States receive unfractionated heparin in hospitals, procedural suites, emergency departments, catheterization labs, and dialysis centers.
  Source: Mismetti & Laporte, Drug Saf. 2008 (PMID: 18484782); CDC Dialysis Surveillance Reports.

- **Over 900,000 U.S. patients receive chronic hemodialysis**, and heparin is required for virtually every dialysis session—three times weekly, ~150 sessions per patient per year.
  USRDS Annual Data Report; NKF Clinical Practice Guidelines.

  This corresponds to **~135 million dialysis sessions annually**, almost all of which require UFH.

- **More than 2 million cardiac catheterizations**, vascular procedures, and cardiopulmonary bypass surgeries performed annually depend directly on heparin for intra-procedural anticoagulation.
  AHA Statistics Committee, Circulation 2023.

- Heparin is also required for **central line patency**, a procedure performed millions of times per year in oncology, ICU care, transplantation, and parenteral nutrition.

Conservatively, **heparin touches 1 in every 3 hospitalized patients** in the United States.

Heparin as an Irreplaceable Agent

Although low-molecular-weight heparins and direct oral anticoagulants exist, these agents **cannot substitute** for unfractionated heparin in critical settings because:

1. **Heparin's effect is immediately reversible** with protamine sulfate.
   No alternative anticoagulant offers this safety profile in high-risk procedures.

2. **Heparin is titratable in real time** using activated clotting time (ACT), essential for cardiac surgery, ECMO, interventional radiology, and cardiology.

3. **Heparin does not require renal clearance**, unlike LMWH or DOACs, and is therefore mandatory in kidney failure and dialysis.

4. **Heparin is essential for extracorporeal circuits** (dialysis, ECMO, CPB), where substitution is clinically unsafe.

These biological and pharmacological properties ensure that **heparin remains a single-point dependency for multiple branches of medicine**.

Consequences of a Supply Disruption

The FDA, CDC, and multiple Congressional testimonies during the 2008 crisis concluded that even a temporary interruption of heparin availability would cause:

- **Cancellation of thousands of surgeries per day**, including cardiac bypass, vascular reconstruction, and transplant operations.

- **Immediate cessation of dialysis for ~900,000 patients**, resulting in life-threatening hyperkalemia, acidosis, and uremia within 48–72 hours.

- **Critical harm to ICU patients** requiring central line access, anticoagulation for DVT/PE, ECMO circuits, and continuous renal replacement therapy (CRRT).

- **Increased mortality from myocardial infarction and pulmonary embolism** due to lack of rapid-onset anticoagulation.

Based on epidemiologic risk:

- Interruption of dialysis alone would lead to **hundreds of deaths per day**.
  NEJM: Foley RN et al., Mortality in dialysis patients (PMID: 12324418).

- Cancellation of cardiac and vascular surgeries would risk **several thousand preventable deaths per week**.

- For hospitalized patients requiring anticoagulation for atrial fibrillation, venous thromboembolism, or sympathetic shock states, **mortality risk increases several-fold** without immediate anticoagulation.
  Kearon et al., Chest 2016 (PMID: 26867885).

In total, a nationwide loss of heparin could quickly threaten **tens of thousands of lives within the first month**.

Why Heparin Supply is Structurally Vulnerable

Heparin's biological origin creates inherent fragility:

- Derived from **porcine intestinal mucosa**, requiring large, stable herds.
- Production is heavily concentrated in **China**, which supplies a majority of the world's raw heparin material.
- Complex purification steps invite economically-driven adulteration (e.g., oversulfated chondroitin sulfate in 2008), which can mimic heparin in standard assays.
- The U.S. lacks redundant domestic sources capable of immediate surge manufacturing.

This combination—**high clinical dependency + globalized biological sourcing + limited domestic redundancy**—means that heparin is among the most vulnerable drugs in the national essential-medicines inventory.

II. Origins of the 2008 Contamination Event Resulting in Over 80 Deaths in USA

A. Identification of Adverse Events

Between late 2007 and early 2008, hospitals reported clusters of rapid-onset hypersensitivity reactions in heparin-exposed patients. These included sudden hypotension, tachycardia, dyspnea, and shock—symptoms often emerging within minutes of infusion.

CDC and FDA investigations documented:

- **152 adverse reactions in 113 patients** across 13 states in a preliminary analysis (January–February 2008).
  Blossom et al., N Engl J Med, 2008 (PMID: 19052120)
  https://pubmed.ncbi.nlm.nih.gov/19052120/

Additional retrospective reviews later linked **at least 81 deaths and hundreds of serious injuries** to contaminated lots. *Kishimoto et al., N Engl J Med, 2008 (PMID: 18434646)*
https://pubmed.ncbi.nlm.nih.gov/18434646/

B. The Contaminant: Oversulfated Chondroitin Sulfate (OSCS)

OSCS, an engineered polysaccharide, was deliberately introduced into crude heparin sourced from China. Because it mimicked heparin in standard assays, it bypassed routine quality tests.

Mechanistic studies demonstrated:

- **Activation of the kallikrein–bradykinin and complement pathways**, explaining the severe anaphylactoid reactions.
  Kishimoto et al., N Engl J Med, 2008 (PMID: 18434646)
  https://pubmed.ncbi.nlm.nih.gov/18434646/

- Affected lots were traced to **multi-layered Chinese supply chains** with limited regulatory oversight.
  Hedlund et al., Perfusion, 2013 (PMID: 23042900)
  https://pubmed.ncbi.nlm.nih.gov/23042900/

III. Supply-Chain Failures and Global Vulnerability

The heparin crisis exposed several systemic weaknesses:

1. Overreliance on Chinese raw-material suppliers

At the time, more than half of U.S. heparin API originated from China, often through fragmented intermediaries without direct FDA inspection.

2. Inadequate analytical testing

Pharmacopoeia assays could not detect OSCS. Only nuclear magnetic resonance (NMR) and capillary electrophoresis later reliably identified the contaminant.

3. Limited domestic manufacturing redundancy

Baxter Healthcare—whose heparin was found to be contaminated—supplied a dominant share of the U.S. market. When Baxter's products were recalled, the United States had very few alternative sources. American Pharmaceutical Partners (APP) took the unusual steps of ensuring a quality of heparin that exceeded even the FDA standards.

ABC News' *Nightline* coverage of the heparin crisis emphasized that once Baxter's contaminated heparin was recalled, the United States faced an immediate and potentially catastrophic shortage of the drug. According to *Nightline*, **American Pharmaceutical Partners (APP) became the only company capable of supplying a large, safe, and contamination-free volume of heparin to hospitals nationwide,** ensuring dialysis centers and surgical programs could continue operating. The report noted that *"without APP's supply, countless more Americans would have been at risk,"* as the alternative was to leave compromised lots on the market. FDA officials told ABC that they permitted Baxter's remaining vials to stay in limited use only until APP confirmed it could fully meet national demand, after which FDA authorized the complete recall. The *Nightline* segment underscored that **federal regulators explicitly relied on APP's domestic sterile-injectable capacity** to stabilize the U.S. supply and prevent the crisis from escalating into a nationwide treatment failure.

IV. The National Shortage and the Role of APP in Preventing Systemic Failure

A. Acute National Shortage After Baxter Recalls

As contamination fears escalated, Baxter initiated voluntary recalls of heparin vials, multi-dose solutions, and flush products. The FDA initially allowed limited continued use of certain lots solely to avoid an immediate national shortage.

By March 2008, FDA announced a **full recall of Baxter's remaining multi-dose heparin vials** only after confirming that the U.S. supply could be maintained by another manufacturer.

That manufacturer was American Pharmaceutical Partners (APP).

B. APP as the Only Safe Domestic Supplier

A contemporaneous ABC *Nightline* investigation, "Pharmaceutical Companies Must Take Responsibility" (ABC News, 2008), and subsequent economic-development and industry publications, documented that:

- **APP became the nation's only safe and adequate supplier of heparin during the crisis**.
- Without APP's domestic production, the U.S. would have faced a full collapse of heparin availability for surgeries and dialysis.
- FDA senior officials told ABC that a complete recall was possible only because APP could meet national demand.

ABC News coverage (2008):
https://abcnews.go.com/Blotter/story?id=5410214

APP's manufacturing capacity, supply-chain traceability, and U.S.-based sterile injectable infrastructure prevented a drug-shortage emergency from escalating into a national medical disaster.

V. Media Exposure and Public Accountability

The crisis triggered widespread public concern as national media highlighted:

- **The deaths and adverse events linked to Chinese-sourced heparin** (ABC News; *The Wall Street Journal* "China's Role in Supply of Drug Is Under Fire").
- **FDA's limited foreign-inspection capabilities**, described in hearings as "woefully insufficient."
- **The near-collapse of U.S. heparin supply**, with only APP able to fill the gap.

This coverage ultimately accelerated reforms in:

- USP testing standards
- FDA foreign inspection protocols
- Supplier qualification and traceability requirements

VI. Policy Lessons From the Crisis

1. Domestic capacity is essential for national security

APP's ability to immediately scale production was the single mitigating factor that stopped the crisis from becoming an unmanageable national emergency. The U.S. cannot rely solely on overseas API networks for mission-critical drugs.

2. Drug-shortage resilience requires redundancy

With Baxter offline, a single domestic manufacturer became the nation's sole source of heparin. Policymakers must ensure redundancy across essential injectables.

3. Regulators must anticipate economically motivated adulteration

The OSCS adulteration was a profit-driven act exploiting analytical gaps. Regulatory frameworks must evolve to detect and prevent similar risks in other biologically complex products.

4. Transparency in supply chains is critical

Traceability "down to the raw-material source"—including animal health surveillance—is not optional for biologically derived drugs.

VII. Continuing Relevance to Current U.S. Drug-Shortage Policy

The heparin crisis remains a touchstone example illustrating:

- How fragile U.S. sterile injectable supply chains remain.
- How dependent the U.S. remains on foreign API manufacturing.
- The need for domestic capacity to avoid catastrophic shortfalls.

Today's shortages of chemotherapies, antibiotics, anesthetics, and electrolytes echo the structural vulnerabilities exposed in 2008. The crisis is therefore instructive for legislators evaluating national drug security, FDA inspection authority, domestic manufacturing incentives, and strategic stockpiles.

An additional structural vulnerability emerged after the 2013 acquisition of Smithfield Foods—America's largest pork producer—by China's WH Group (formerly Shuanghui International). This transaction effectively shifted control of a substantial portion of U.S. porcine by-products, including intestinal mucosa used for crude heparin production, into a China-based supply chain. Although the United States continues to raise large numbers of hogs domestically, a significant share of the by-product stream **is now routed, processed, or priced through China-controlled channels.**

Industry analysts and congressional hearings in the years following the acquisition highlighted that this consolidation reduced the availability of U.S.-retained crude heparin material and increased the nation's dependence on imported intermediates from China—precisely the dynamic that contributed to the 2008 OSCS adulteration crisis. The Smithfield–WH Group transaction is therefore a contemporary reminder that U.S. control over biologically derived pharmaceutical inputs can erode even when livestock production remains domestic. In practice, this means the United States has **less guaranteed access to its own porcine-derived raw materials**, further magnifying the national-security risks associated with heparin dependence and underscoring the need for domestic manufacturing and vertically controlled supply chains.

VIII. Conclusion

The 2008 heparin contamination crisis was both a scientific and structural failure. It revealed vulnerabilities in global sourcing, regulatory oversight, and domestic capacity for essential medicines. One company—**American Pharmaceutical Partners (APP)**—ensured that the United States maintained access to heparin during nationwide recalls. Without its domestic infrastructure, the crisis could have resulted in thousands of delayed or canceled surgeries, dialysis interruptions, and additional loss of life.

The lessons remain urgent. The United States must treat domestic pharmaceutical manufacturing capacity—particularly sterile injectables—as a form of critical infrastructure. Reforms inspired

by the heparin crisis should serve as the foundation for a broader national strategy to secure essential medicines and protect patients from preventable supply-chain failures

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