UNITED STATES SENATE
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"Bad Medicine: Closing Loopholes that Kill American Patients"

Written Testimony of
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Senator Kirsten Gillibrand, Ranking Member
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I. Introduction

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

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

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

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

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

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

II. Background

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

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

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

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

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

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

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

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

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

independence.

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

III. America's Medical Supply Chain Vulnerabilities

Dependence on China and India

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

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

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

COVID-19 Shortages and Export Bans

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

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

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

Real-World Examples of Contamination and Death

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

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

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

A System Without a Backup Plan

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

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

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

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

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

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

IV. Policy Gaps and Regulatory Loopholes

Transparency & Procurement Reform

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

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

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

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

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

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

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

Oversight Failures

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

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

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

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

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

Financing & Market Access

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

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

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

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

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

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

Inventory Models for Crisis Readiness

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

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

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

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

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

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

V. Feasibility and Competitiveness of Domestic Manufacturing

Debunking the Cost Myth

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

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

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

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

Friend-Shoring from Allies

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

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

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

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

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

Technology and Automation Advantage

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

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

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

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

VI. Case Studies of Domestic Reshoring

Oxford Pharmaceuticals

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

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

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

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

UK-Owned Medical Device Manufacturer

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

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

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

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

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

Results: Speed, Compliance, Resilience

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

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

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

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

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

VII. Technology as a Force Multiplier

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

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

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

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

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

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

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

VIII. Legislative and Policy Recommendations

Ban Anti-Free Market Contracting Practices

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

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

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

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

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

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

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

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

Federal Procurement Reforms

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

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

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

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

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

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

Incentives for U.S. Producers

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

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

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

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

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

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

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

Trade Enforcement

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

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

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

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

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

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

IX. Human and Economic Stakes

Seniors, Soldiers, and Families

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

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

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

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

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

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

Jobs and Innovation

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

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

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

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

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

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

Health Security is National Security

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

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

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

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

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

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

X. Conclusion

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

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

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

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

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

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

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

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

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

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