Written Testimony of Tom Neely
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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 pharmaceutical 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.

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