Testimony for Senate Special Committee on Aging:
Bad Medicine — Closing Loopholes that Kill American Patients

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Chairman, Ranking Member, and Members of the Committee: Thank you for the opportunity to testify on the vulnerabilities in our pharmaceutical supply chain and to outline solutions to close these dangerous gaps.

American patients—especially seniors—are increasingly at risk from "bad medicine": unsafe imports, chronic shortages, and a broken market that rewards the cheapest foreign supplier over quality and safety.

These are systemic failures: fragile supply chains dominated by imports, single points of failure with no backup, collapsed pricing that has driven U.S. manufacturers out, persistent shortages, and recurring safety lapses from underregulated overseas plants. Together, they leave the United States dangerously exposed—dependent on adversarial nations for essential drugs, and unable to guarantee patients the medicines they need.

However, these problems are solvable. With the right tools, we can rebuild domestic capacity, enforce rigorous safety standards, and restore confidence in our medicines. This testimony sets out five strategic pillars that work in tandem to achieve this:

1. Protecting the domestic market through a Tariff-Rate Quota system.
2. Jumpstarting U.S. manufacturing with production and investment incentives (the PILLS Act).
3. Overhauling FDA oversight of foreign production and imports.
4. Realigning federal purchasing power and market incentives.
5. Securing U.S. biotechnology leadership through research reinvestment, strong trial standards, and protection of American talent and data.

Taken together, these reforms form a comprehensive strategy to secure our medicine supply, protect patients, and ensure that America leads in the discovery and production of future cures.

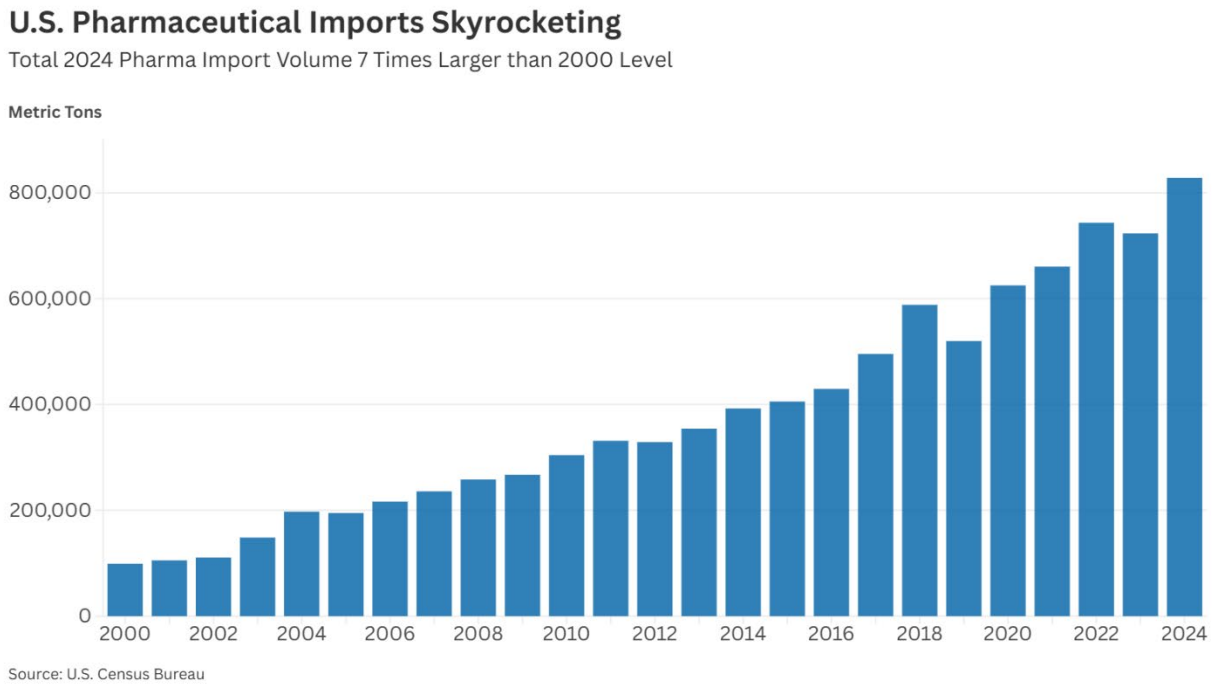
I. Key Failures of the U.S. Pharmaceutical System

Before discussing solutions, it is essential to understand how the United States arrived at this precarious moment. Over two decades of unguarded trade liberalization, relentless price pressure, and weak foreign oversight have hollowed out domestic pharmaceutical production and left our supply chain dangerously exposed and over reliant on underregulated foreign producers. What was once a resilient, U.S.-led system has devolved into one defined by foreign dependence, fragile chokepoints, chronic shortages, and unacceptable safety risks. These failures are not isolated problems. Together, they form a systemic breakdown that threatens both public health and national security.

Fragile Foreign Supply Chains — Extreme Import Dependence

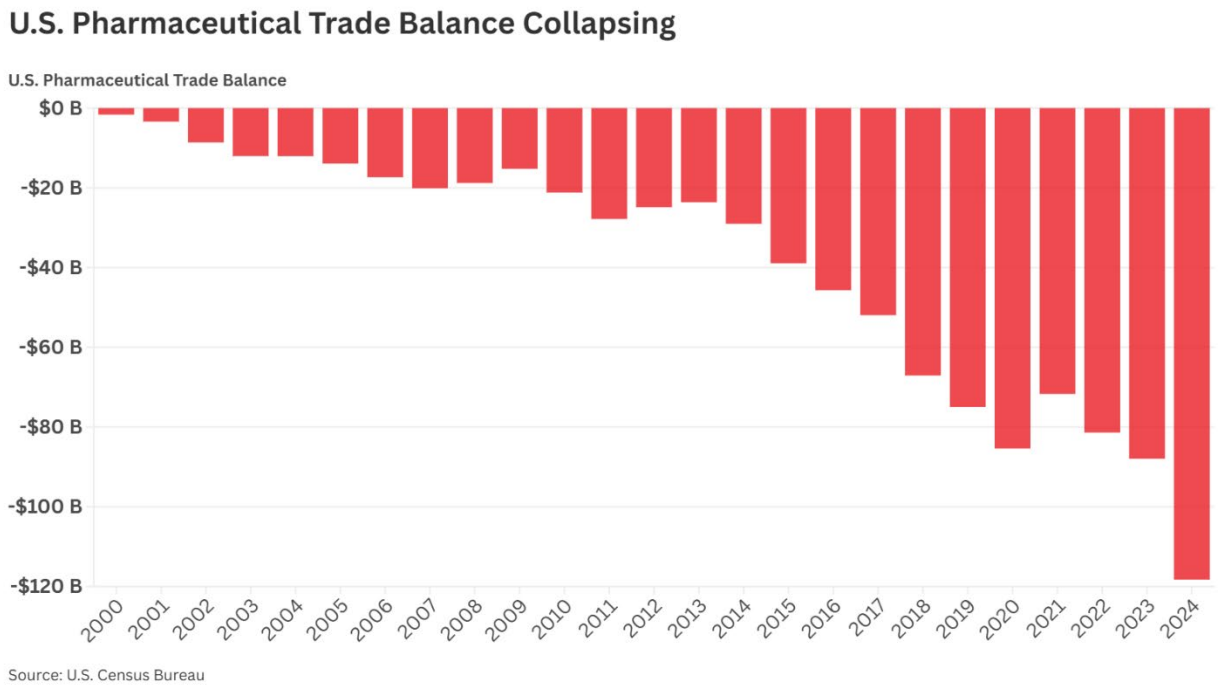
The American pharmaceutical supply chain has become dangerously dependent on imports and foreign-controlled supply chains. Over the past 20 years, the country has experienced a skyrocketing rate of pharmaceutical imports and increasing foreign reliance. In 2024 alone, the United States imported over 828,000 metric tons of pharmaceutical products—more than seven times the volume in 2000 [1].

Figure 1:



This surge doesn't reflect simple domestic demand growth but a complete surrender of U.S. production in pursuit of cheaper and riskier foreign drug alternatives. The result is not only a collapsing pharmaceutical trade balance—amounting to a record $118.3 billion pharmaceutical trade deficit in 2024 [1]—but also an erosion of U.S. sovereignty over one of its most essential industries.

Figure 2:



China and India now dominate our supply of essential drugs: China produces 80—90% of the world's key antibiotic ingredients [2], and India supplies about half of U.S. generic finished drugs, while India itself relies on China for up to 80% of their active ingredients [3]. In practical terms, the U.S. lacks a domestic source for over 80% of the active ingredients used in critical medicines [4]—if foreign shipments stop, Americans simply go without.

Such overreliance on foreign suppliers—many in geopolitically unstable or adversarial regions—is a profound strategic vulnerability. Supply vulnerabilities do not even have to be malicious. During COVID-19, for example, India banned exports of certain drugs and Chinese lockdowns disrupted shipments, triggering shortages here in the U.S. [5]. We cannot allow adversarial regimes or global upheavals to dictate whether Americans can get life-saving medicines.

Highly Concentrated Sourcing — Single Points of Failure

Our drug supply chain is not only over reliant on foreign supply, but highly concentrated in just a few sources, creating single points of failure with no backup. According to an analysis by the HHS' Office of the Assistant Secretary for Planning and Evaluation, among nearly 1,840 small molecule drugs in 2022, 43% had only one approved manufacturer in the U.S. [6]. Similarly, U.S. Food and Drug Administration (FDA) data from 2020 show that about 40% of generic drug markets are supplied by a single manufacturer [7].

Even critical medicines often depend on only one or two overseas factories. This concentration means that if one facility fails, the entire nation faces a shortage.

We are already seeing this happen: In 2023 the FDA shut down an Indian plant (Intas Pharmaceuticals) that made 50% of America's supply of the chemotherapy drug cisplatin [8]. Inspectors uncovered a "cascade of failure" in quality control—shredded and acid-doused documents meant to conceal falsified records [9]. With that single foreign plant offline and no U.S. producer to fill the gap, hospitals nationwide were forced to ration cancer treatments and delay care for thousands of patients [8].

We have seen this before with China as well. In 2016, a single factory explosion in China crippled global supplies of the critical antibiotic piperacillin-tazobactam, forcing rationing and treatment delays around the world [10]. The reason was simple: China was the only source of the active pharmaceutical ingredient. This is not an isolated case. Today, China remains the sole supplier for 20% of the active ingredients in America's most essential medicines [11]. When one plant falters, the entire chain snaps. Just as with the Intas shutdown in India, we are left exposed, with no domestic fallback and no redundancy. This is not a resilient supply chain—it's a house of cards.

Many antibiotics, sterile injectables, and other vital drugs come from only a couple of factories worldwide. A fire, a contamination, or a political decision in one country can instantly cripple America's access to an entire class of medicines. We've built a system where a single plant shutdown overseas has already caused nationwide shortages. These chokepoints are unacceptable for a nation's health security.

Collapse of Drug Pricing — U.S. Manufacturers Driven Out

Underpinning this fragile supply chain is a market failure in generic drug pricing that has allowed imports to drive U.S. producers out of the market. Generics make up 90% of U.S. prescriptions but account for only 17.5% of drug spending [12]. They

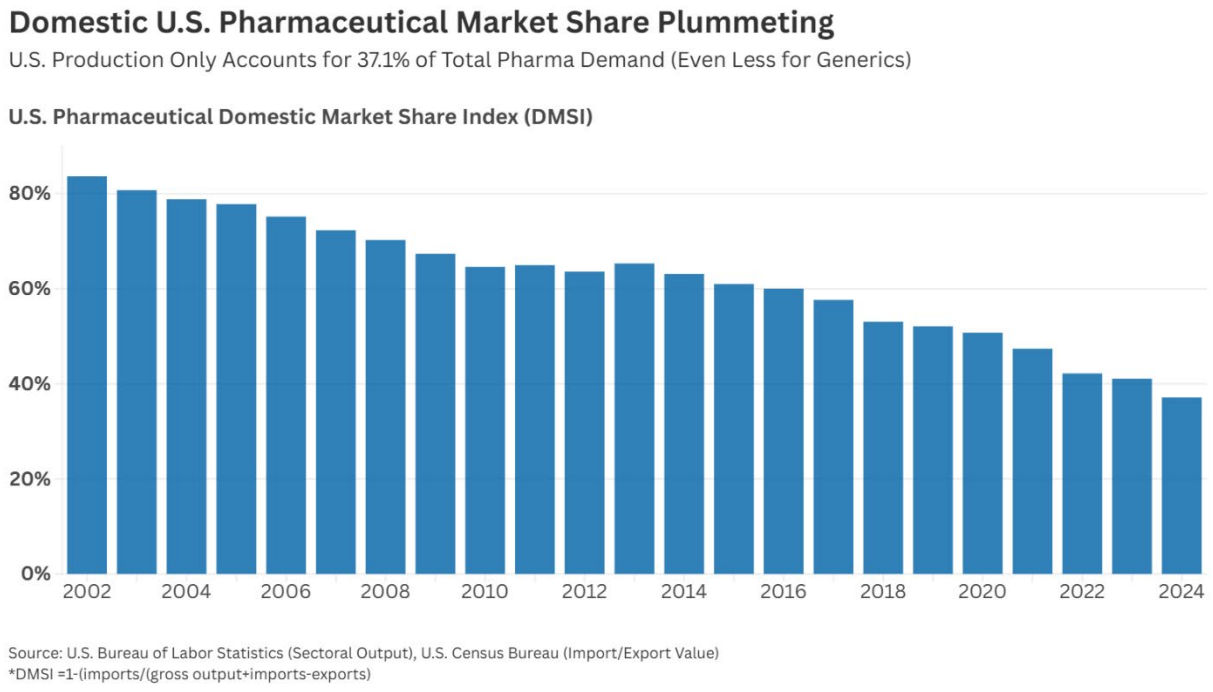
have become ultra-cheap, often just pennies per dose. Decades of unguarded free trade and foreign state subsidies have driven prices so low that U.S. companies cannot compete.

Foreign producers from China and India undercut U.S. and EU manufacturers by an estimated ~42% cost advantage [13]. But this is not through superior efficiency, but through intentional government policies in China and India. These countries have made the pharmaceutical industry a priority via government subsidies [14] [15], lower labor standards [16], lax environmental regulations [17], and corner-cutting on quality and testing [18] [19].

American firms have been squeezed out of the market as a result. As prices plunged to "rock-bottom" levels, we saw a wave of plant closures and bankruptcies among U.S. generic manufacturers [20]. For example, Akorn Pharmaceuticals, a major domestic generic producer, went bankrupt and abruptly shut all four of its U.S. plants in 2023 [21].

These closures weren't just isolated business failures. They were casualties of the gradual hollowing out of America's production base by imports. In 2002, U.S. manufacturers produced 83.7% of the pharmaceuticals consumed domestically. By 2024, that number plummeted to just 37.1%, with a corresponding $157.8 billion loss in potential domestic production value.

Figure 3:



**DMSI Calculations made using BLS Sectoral Output for Pharmaceutical and Medicine Manufacturing data [22] & Census Bureau HTS Chapter 30 Pharmaceutical Product Import/Export Value [1]*

The economic "race to the bottom" on drug prices has hollowed out our industrial base. Essential medicines are now often so cheap that no one in America is willing or able to make them. This pricing collapse also is not a victory for consumers. It is a long-term disaster.

Initially, hospitals and buyers saved money through cheap imports, but once domestic capacity disappeared, the U.S. became hostage to those foreign suppliers. The instant those suppliers have a production problem or raise prices, we have no domestic alternatives. The supposed savings of cheap imports evaporates in a crisis. Shortages force hospitals to pay exorbitant prices on the gray market, far more than any "savings" accrued by the initially cheaper imports. The U.S. pursued short-term lowest-cost drugs at the expense of long-term supply resiliency, and now we are paying the price.

Persistent Drug Shortages — A Production Crisis Endangering Patients

America is now mired in chronic drug shortages at a scale never seen before. In any given month, the United States has about 250-320 active drug shortages nationwide, spanning antibiotics, emergency sedatives, oncology drugs, cardiac medications [23]. These are staples of care in hospitals. Shortage levels hit a record high of 323 drugs in early 2024, the most in over two decades.

This is not normal volatility; it is a systemic breakdown. Over 99% of hospital pharmacists report facing drug shortages, and 85% say these shortages are critically or moderately impacting patient care [24], leading to rationed or delayed treatments. Drug shortages are disrupting frontline care—forcing oncologists to delay cancer treatments [25], hospitals to scramble for scarce medicines [26], and patients to face higher risks when doses are stretched or substituted [27]. For vulnerable and elderly patients, drug shortages can be life-threatening. Treatment delays and interruptions caused by shortages can adversely impact health and increase the risk of morbidity and mortality [28].

These shortages are not just caused by brief logistical glitches or sudden demand spikes. They stem from long-term collapse in domestic manufacturing capacity, driven by razor-thin profit margins, overreliance on foreign-sourced APIs, and insufficient incentives for U.S. firms to maintain redundant, high-quality production [29]. The drive for cheap imports actually created many of these

shortages. Up to 83% of drug shortages are in generics [30], and a primary driver is manufacturers exiting the market because prices fell below sustainable levels [29]. In other words, when foreign competitors undercut U.S. producers and force them out, no one is left to make the medicine if the import supply falters.

Hospitals have learned the hard way that free trade's "low prices" vanish in a shortage. Drug shortages drive up hospital error rates by 1—5%, create unsafe conditions in 60% of cases, and often force hospitals to pay 300—500% markups to obtain critical medicines [31]. The cheap drug from overseas turns into an expensive drug—or no drug at all—when the supply chain breaks. This shortage epidemic is a public health emergency and a national security threat.

It should be seen for what it is: a national economic breakdown with direct implications for public health, military readiness, and national security. In sum, America doesn't just have a drug shortage problem—it has a drug production problem. Without rebuilding manufacturing, the next shortage will be even worse.

Safety Risks from Substandard Imports — Loopholes in Oversight

Perhaps the most alarming loophole in our drug supply system is that Americans are often unknowingly receiving unsafe medicine. Heavy reliance on overseas factories—many in countries with weak oversight and poor compliance records—has allowed substandard and even dangerous drugs to reach U.S. patients.

The FDA has repeatedly documented widespread violations of Good Manufacturing Practices abroad, ranging from falsified test results to unsanitary conditions. These lapses have already had deadly consequences. At Glenmark Pharmaceuticals' plant in India, inspectors found repeated dissolution failures in potassium chloride capsules, poor cleaning, and inadequate investigations [32]. The company recalled more than 100 batches in 2024, and FDA records linked the product to at least eight U.S. patient deaths [32].

Other high-profile cases demonstrate the same dangers. In 2008, adulterated heparin from China killed dozens of Americans after the active ingredient was deliberately cut with a cheaper substitute, triggering fatal allergic reactions in hospitals and dialysis centers [33] [34] [35]. In 2013, Indian generic giant Ranbaxy pled guilty to felony charges and paid $500 million in penalties after admitting it manufactured adulterated drugs, falsified stability test results, and made false statements to the FDA [36]. The company knowingly submitted unreliable data and released unsafe products into the U.S. market, showing how systemic fraud abroad can directly endanger American patients.

Broader data confirms that these cases are not isolated. A recent study found that generic drugs made in India carry a 54% higher risk of severe adverse events than those made in the United States [19]—clear evidence that cut-rate overseas production often translates to cut-rate safety.

Current FDA enforcement actions reveal the same pattern. In China, inspectors cited Nuowei Chemistry for unreliable impurity testing, inadequate stability data, and a broken quality system [37]. In India, inspections at Granules India uncovered microbial contamination risks, poor cleaning and maintenance, and serious quality-control failures [38]. Even when the FDA does inspect, the process is hamstrung: until recently, nearly 90% of foreign inspections were pre-announced [39], giving plants time to conceal problems. Inspectors have found facilities literally shredding quality control records ahead of scheduled FDA inspections [40].

There is also a deep issue of a lack of transparency. Manufacturers are not required to disclose where a drug's active ingredients are made. Even FDA and GAO have acknowledged that the agency cannot determine the source country for many APIs used in U.S. medicines [41]. The Department of Defense admits that for 22% of essential medicines they cannot determine the source country at all [42]. That means hospitals, physicians, and patients have no way to know whether their base medicine ingredients were produced in a world-class facility or a high-risk plant on the other side of the world.

The consequences are sub-potent or unsafe medications, higher rates of adverse reactions, and treatment delays that erode trust in the very system meant to keep patients safe. No American should have to wonder whether their blood pressure pill or chemotherapy dose is safe, effective, and available. Yet that is where we are today. By outsourcing production, we have also outsourced oversight—surrendering control over the integrity of the medicines our patients rely on.

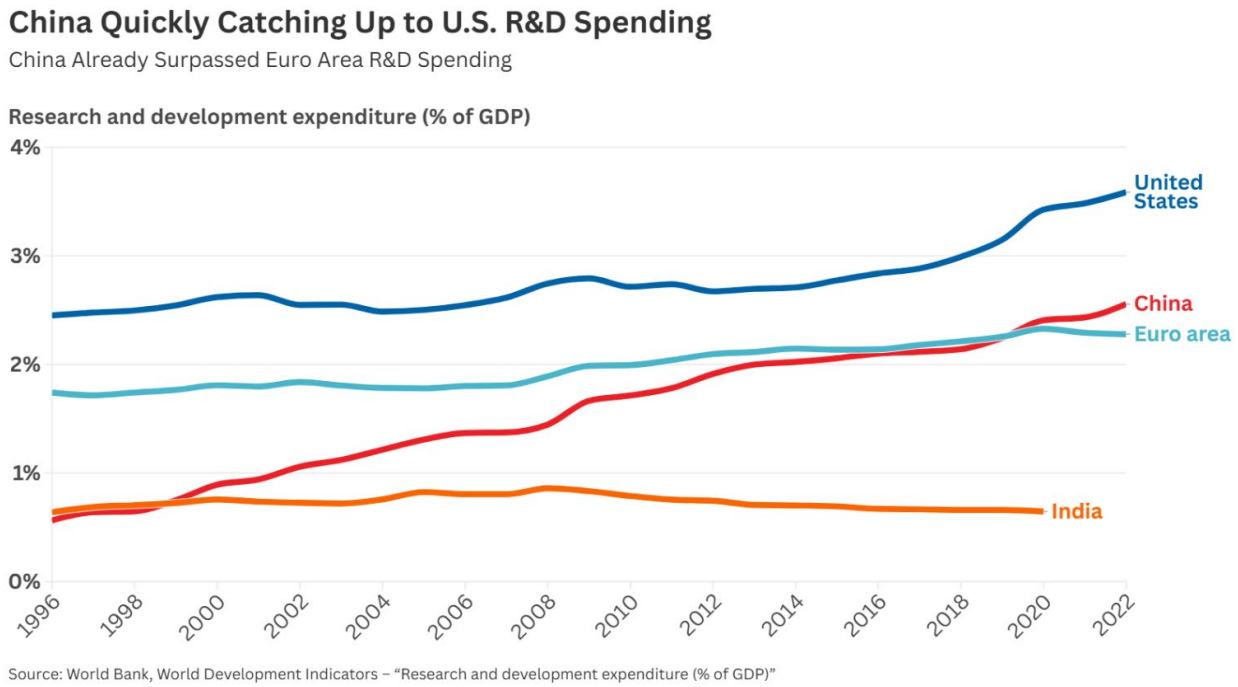
Biotechnology at Risk — How We Lost the Lead

The vulnerabilities in our drug supply extend beyond generics and APIs. America's leadership in biotechnology—once an unquestioned pillar of our medical strength—is now being eroded by a deliberate foreign strategy. Over the past two decades, the U.S. allowed core capabilities in manufacturing to move offshore, and critical research followed.

Beijing made biotech a key priority as part of *Made in China 2025* [43], resulting in billions of industrial investments and subsidies. In 2024, national R&D spending reached ¥3.6 trillion (around $500B), or 2.68% of GDP [44]—already surpassing

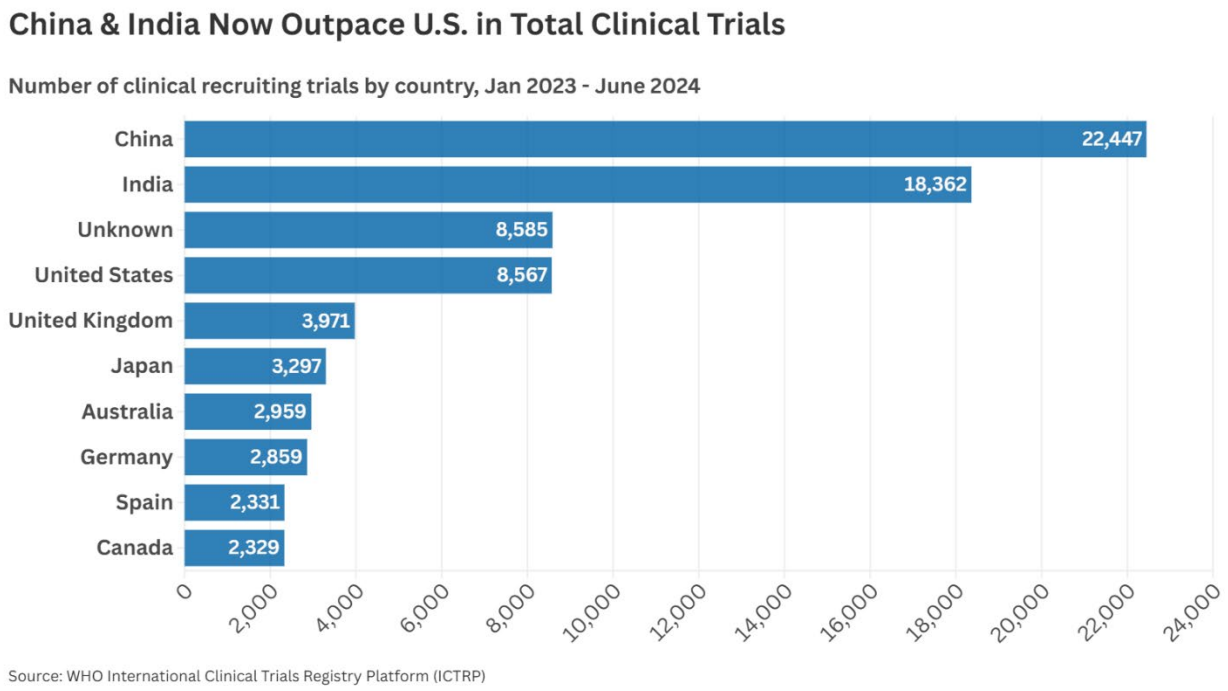
Europe's share and closing rapidly on America. China's biopharmaceutical R&D spending alone climbed to about $15 billion by 2023 [45].

Figure 4:



Driven by heavy investments in research and development, China has caught up to and in many areas surpassed the United States in critical biotechnology measures. By 2024, China logged over 7,100 registered clinical trials, surpassing the U.S. tally of around 6,000 [46]. China now accounts for about 39% of all global Phase I—IV clinical trial starts [47]—a dramatic rise over the past decade. Moreover, as shown in Figure 5, both China and India far outpace the United States in clinical recruiting trials over the past two years [48].

Figure 5:



These trials are not an end in themselves—they have fueled a broader strategy of innovation. China seized the opportunity by treating biotechnology as strategic infrastructure while the United States treated it as just another industry. This deliberate approach has translated into a rapid acceleration of discovery and commercialization. Biotech patent filings from China jumped from 119 in 2010 to 1,918 in 2023 [49], and by 2025 nearly 40% of global licensing deals involved Chinese-origin drugs [50].

This all has translated into research leadership: 7 of the world's top 10 research institutions in global research rankings are now Chinese, with Harvard as the lone U.S. entry [51].

Table 1:

Rank	Institution	Country
1	Chinese Academy of Sciences (CAS)	China
2	Harvard University	United States of America
3	University of Science and Technology of China (USTC)	China
4	Max Planck Society	Germany
5	University of Chinese Academy of Sciences (UCAS)	China
6	Peking University (PKU)	China
7	Nanjing University (NJU)	China
8	French National Centre for Scientific Research (CNRS)	France
9	Tsinghua University	China
10	Zhejiang University (ZJU)	China

Source: Springer Nature Index, Research Leaders 2024: Leading Institutions

Yet China's rapid rise has not been built on efficiency alone. Its edge comes from heavy state subsidies, tax rebates, and state-backed loans [52]—paired with low labor and safety standards [53] and weak environmental enforcement [54].

The FDA has rejected drugs like surufatinib and sintilimab [55] [56], pointing to outdated comparators, weak oversight, and homogeneous Han Chinese cohorts that do not reflect U.S. patients. Other headline therapies, such as ivonescimab, showed promising results in Chinese trials but far weaker outcomes in Western patients

[57]—demonstrating how speed-driven, low-quality designs can mislead regulators and endanger patients.

Meanwhile, NIH funding in the United States has been essentially flat. By 2024 the NIH budget was about 7% below the 2003 peak when adjusted for inflation [58], leaving our labs under-resourced just as China accelerated investment.

If America cedes biotechnology leadership, the consequences will not be limited to economics. We risk a future where the most advanced therapies are invented elsewhere, clinical trials are designed under looser standards, and our supply of lifesaving biologics and cell therapies is dictated by Beijing. This is not a theoretical risk—it is the trajectory we are on today.

II. Policy Solutions — A Five-Pillar Strategy to Secure America's Medicine Supply

The first pillar is to shield and rebuild the U.S. generic drug market using a Tariff-Rate Quota (TRQ) system. For example, Section 232 of the Trade Expansion Act empowers action when imports threaten national security [59]—and our current pharmaceutical import dependence clearly qualifies. This policy would set targeted limits on foreign generics that undermine our security, without sacrificing patient access or affordability.

National Security Rationale — Ending Dangerous Import Dependence

The TRQ is justified by the urgent need to secure our medicine supply. The Department of Commerce has already launched a Section 232 investigation into pharmaceutical imports [60], recognizing that overreliance on China and India is a national security risk. The Department of Defense reports that more than one in four essential medicines for the military are at "very high risk" of supply disruption due to foreign dependence [42].

A carefully designed TRQ directly strengthens national security by:

- **Reducing adversarial leverage.** It prevents hostile regimes from "weaponizing" drug exports to cripple our healthcare system.
- **Mitigating unintentional shocks.** COVID lockdowns in China and export bans from India showed how fragile import supply is under global upheavals.

- **Ensuring domestic fallback.** TRQ space ensures U.S. firms can scale to provide redundancy, not leave America hostage to single suppliers abroad.

Stable access to safe medicines is as fundamental to national security as an adequate defense stockpile. Trade policy is a powerful tool that Congress intended for precisely this scenario: defending the nation when imports undermine vital industries.

How a TRQ Would Work — Targeted Protection Without Shortages

Unlike across-the-board tariffs, a Tariff-Rate Quota (TRQ) allows a limited volume of product to enter the country at a low or zero tariff. Once imports exceed that quota volume limit, much higher tariffs automatically apply. This makes the TRQ a calibrated mechanism that balances security with patient access.

- **Quota setting:** Annual TRQ thresholds for critical generics and APIs would be set by the Departments of Commerce, Health and Human Services, and Defense together, based on demand, shortage data, and production capacity.
- **Quota calculation:** Allowances would equal U.S. demand minus what domestic manufacturers can supply, leaving a margin for market fluctuations. Imports within the quota face low or zero tariffs to guarantee supply of drugs not yet produced domestically.
- **Quality filter:** To qualify for quota-free treatment, both the API and finished drug must come from countries with strong regulatory systems under FDA Mutual Recognition Agreements (MRAs) [61]—such as the EU, UK, and Switzerland. This ensures only high-quality, trusted sources with equivalent safety standards are tariff-free.
- **Penalizing risky supply:** Imports from non-qualified countries (e.g., China, India, or those lacking equivalent MRA standards)—or imports above the quota—face steep tariffs (200—300% equivalent). Duties would be specific tariffs, assessed per-dose or per-kilogram, neutralizing the unfair advantage of subsidies and poor standards abroad.
- **The Need for Specific Tariffs:** One key element of the TRQ design is that duties should be assessed as specific tariffs (based on weight or dosage) rather than ad valorem percentages. In the world of ultra-cheap generics, even a 100% value tariff may add as little as a few cents per pill—far too little to change market dynamics or offset foreign subsidies. A per-dose or per-kilogram tariff structure ensures that penalties on unsafe or subsidized imports are meaningful in practice. This approach also helps guard against

invoice fraud—where exporters understate customs values to evade ad valorem duties—by tying tariff liability to physical volume rather than declared value.

- **Dynamic adjustment:** Quotas are adjusted each year to account for changes in domestic capacity and demand. As U.S. production ramps up, quotas narrow, nudging the market toward self-reliance and rewarding increased domestic supply capacity. During emergencies (pandemics, shortages), quotas can temporarily expand or tariffs be waived to keep patients supplied.
- **Strict enforcement:** Customs and FDA will require origin documentation and real-time monitoring to prevent transshipment or fraud. Any company caught falsifying data faces severe penalties or exclusion. Repeat offenders are barred outright.

In short: America will import what it needs, but on our terms—safe imports prioritized, bad actors penalized, and quotas adapted in real time.

A Proven Precedent — The U.S. Sugar TRQ

The United States already operates a long-standing TRQ system in another sensitive sector: sugar. Each year, the Department of Agriculture sets access levels of raw and refined sugar that can enter at low tariff rates, while imports above those amounts face prohibitive over-quota tariffs [84]. This system has balanced supply and price stability, ensured domestic producers a secure market, and maintained a reliable flow of imports from trusted partners. The pharmaceutical TRQ would follow the same proven model — but with far higher stakes in an even more critical sector. If TRQs can work to secure sugar, they can and must be applied to medicines essential to national health and security.

Protecting Patients — Why Tariffs Won't Raise Drug Prices

A common concern is whether TRQs and tariffs could make drugs more expensive, especially for seniors and vulnerable patients. The evidence shows they will not.

- **Middlemen capture most of the price.** Only ~36% of a generic's retail price reflects manufacturing; the other 64% goes to middlemen in the supply chain, including wholesalers, Pharmacy Benefit Managers (PBMs), pharmacies, and insurers [62]. Tariffs on manufacturers affect only a fraction of the end price at most.

- **Insurance absorbs costs.** Medicare and Medicaid already index reimbursement to acquisition costs:
    - *Medicare Part B*: pays Average Sales Price (ASP) + 6% [63], [64]. If tariffs raise costs, ASP rises, and providers are reimbursed accordingly. Patients' coinsurance stays fixed at 20% [65].
    - *Medicaid & Part D*: use Maximum Allowable Cost (MAC) and National Average Drug Acquisition Cost (NADAC) benchmarks updated weekly [66], [67], [68]. Therefore, pharmacies are compensated almost immediately. Part D's new $2,000 annual out-of-pocket cap (2025) further shields patients [69].
- **Commercial markets adjust similarly.** PBMs and insurers spread out cost upticks, and their large margins—long inflated by cheap imports—provide room to absorb modest increases.
- **Contracts already anticipate tariffs.** Most hospital GPO contracts include "change-in-law" clauses allowing modest price adjustments if tariffs apply. Drugs are so inexpensive that even doubling manufacturing costs often adds only cents to a pill.
- **TRQ reduces real costs.** By eliminating shortages that frequently cause 300—500% surge pricing [70], the TRQ saves hospitals money. Long-term stability beats dependence on a sole foreign supplier that can collapse or price-gouge.

TRQ tariffs are essentially "tariff-proof" at the pharmacy counter. Patients and hospitals are shielded by reimbursement systems, middlemen margins, and contract structures. The only losers are foreign producers and intermediaries who profit from unsafe, subsidized dumping.

Why TRQ is the Cornerstone

The Pharmaceutical TRQ system fortifies America's medicine supply by:

- Excluding unsafe, subsidized imports.
- Resetting the playing field so U.S. firms can compete on quality, not against state-backed dumping.
- Maintaining stable patient access through flexible quotas.
- Ensuring enforcement is adjustable, traceable, and enforceable.

- Doing all this without raising drug prices or causing shortages.

The TRQ is the cornerstone of reform. Trade tools exist to defend U.S. national security, including public health. American lives now depend on using them.

Pillar 2: Jumpstarting U.S. Pharmaceutical Manufacturing — The PILLS Act (Production & Investment Incentives)

The second pillar tackles the other side of the equation: we cannot just curb bad imports; we must actively rebuild the U.S. pharmaceutical base. That requires strong production and investment incentives to make domestic manufacturing economically viable again, and quickly.

The PILLS Act Framework

The Producing Incentives for Lifesaving Medicines Supply (PILLS) Act [71] is modeled on successful manufacturing incentives such as the CHIPS Act. It would provide targeted tax credits that directly address the cost disadvantages that drove production offshore.

Production Tax Credit (PTC).

- 35% tax credit on sales of U.S.-made finished generics, APIs, and licensed biosimilars.
- 30% credit for U.S.-made inputs such as intermediates, excipients, sterile diluents, packaging, and testing materials.
- A "domestic content bonus" worth up to 20%. The more of a company's supply chain that is U.S.-sourced, the larger the bonus. For example, if 80% of a drug's ingredients, packaging, and components are made in America, the manufacturer would qualify for an additional 16% tax credit on top of the base credit. Firms that fully source domestically could receive the full 20% bonus.
- Together, credits could offset up to half of costs, erasing much or all the foreign cost advantage.

Investment Tax Credit (ITC).

- 25% credit for building or upgrading pharmaceutical facilities and equipment.

- Covers new API plants, sterile injectable lines, and modernized fill-finish capacity.
- Structured as direct-pay or transferable to benefit startups as well as incumbents.
- Lowers the upfront barrier that often pushes investment overseas.

Both credits would phase down gradually between 2030—2033 to give firms planning certainty while preventing long-term dependency.

Why It Matters

The PTC makes U.S. production profitable where it currently operates at slim margins or even a loss, while the ITC lowers capital costs to build capacity. Together, they neutralize foreign subsidies, environmental and labor cost arbitrage, and quality-cutting advantages in China and India.

This is not abstract—it matters for critical U.S. firms like Coherus Biosciences, one of the few U.S. players in biosimilars. Coherus has brought important products such as *Udenyca* (for cancer patients) [72] and *Cimerli* (for vision loss) [73], but like other U.S. biosimilar firms it faces relentless pricing pressure from subsidized imports. Razor-thin margins leave little room for reinvestment or expansion. With a Production Tax Credit and investment incentives, companies like Coherus would finally have the foundation to expand capacity, hire American scientists, and secure a U.S. foothold in a sector we cannot afford to lose.

The Synergy with TRQ

The TRQ and PILLS Act are designed to work together. Tariffs create market space by curbing predatory imports; incentives make it attractive for U.S. firms to fill that space with real production. One without the other risks failure. Together, they form a classic industrial strategy: demand protection and supply stimulation. Within a few years, this combination could put new U.S. plants online making the medicines Americans need—under high standards, with American workers.

Pillar 3: Overhauling FDA Oversight of Foreign Manufacturing — Ensuring Safety for Imports

Even as we rebuild domestic capacity, the reality is we will continue to import some pharmaceuticals in the near term. To protect patients, we must close the regulatory loopholes that have allowed unsafe and substandard imports into the U.S. market. The U.S. must strengthen FDA oversight so that any drug sold in America meets the same gold-standard requirements as if it were made here.

Unannounced, Frequent Inspections

Foreign plants must face the same scrutiny as U.S. facilities. Today, many overseas facilities have gone five years or more without inspection [74], and until recently nearly 90% of those inspections were announced in advance [75]—giving companies time to conceal violations, as some have been caught doing [76]. Surprise visits should become the norm. Congress should provide FDA the resources for more inspectors abroad and mandate inspection frequency on par with domestic plants. Countries that refuse unannounced inspections should see their shipments restricted until compliance is restored.

Independent Batch Testing

The U.S. also needs to verify the safety of imported medicines, not just trust manufacturer paperwork. Each batch—or a statistically valid sample—of critical imports should be tested in certified U.S. labs for identity, potency, and impurities. This closes the loophole that allowed dangerous contaminants like NDMA in blood pressure drugs [77] to be discovered only after patients had already taken them. In the European Union, routine batch release testing by certified labs is standard [78], giving patients assurance that unsafe products are caught before reaching pharmacies. U.S. patients deserve no less. Independent testing can be financed through modest importer fees and would cost far less than the billions lost in recalls, shortages, and adverse events.

Tougher Enforcement for Repeat Offenders

Serial violators cannot be allowed to treat FDA warnings as a cost of doing business. If a manufacturer has multiple major violations—falsified data, contamination, or unsafe practices—FDA should be required to act swiftly. A “two strikes” rule could automatically suspend imports for a year, and a third violation

would trigger a five-year or permanent ban. Repeat offenders would also lose tariff-free access under the TRQ system and potentially face total exclusion from the U.S. market. Enforcement must have teeth—firms that cheat should lose the privilege of supplying the world's largest medicine market.

Supply Chain Transparency

A glaring weakness today is opacity. Hospitals and regulators often cannot determine where drugs or their active ingredients are produced. Congress should require full disclosure: API country-of-origin on labels, finished-drug site information, and a public FDA database tracking supply chains. Transparency allows buyers to avoid risky sole sources and enables policymakers to anticipate vulnerabilities before they trigger shortages. It is a low-cost reform that delivers accountability and security.

These reforms ensure that even as we import, those imports are held to U.S. standards. Stronger inspections, independent testing, strict enforcement, and transparency will restore trust in the drug supply. Safety can no longer be an afterthought—it must be embedded in the system.

Pillar 4: Realigning Federal Purchasing Power and Market Incentives — Putting Quality and Security First

The final pillar recognizes that the U.S. market itself—especially the largest buyers—must be part of the solution. The federal government, through Medicare, Medicaid, Veterans Affairs, Defense Department, and the Strategic National Stockpile, is the single largest purchaser of medicines [79]. Meanwhile, a handful of private buying groups—Group Purchasing Organizations (GPOs) and Pharmacy Benefit Managers (PBMs)—dominate hospital and pharmacy contracts. For too long, these buyers have rewarded only the lowest price, inadvertently reinforcing offshoring, squeezing out domestic firms, and leaving America dangerously exposed. The U.S. must realign incentives so that both federal programs and private intermediaries reward quality, redundancy, and security—not just pennies-per-pill.

Buy American in Federal Programs

- Medicare, Medicaid, DoD, and VA should explicitly favor U.S.-made or allied-sourced drugs.
- The Centers for Medicare & Medicaid Services (CMS) could provide enhanced reimbursement for U.S.-made generics, modeled on the COVID-era add-on for American-made N95 masks [80].
- DoD and VA should use TRICARE and procurement contracts to prioritize U.S.-sourced medicines vital to military readiness.
- Pilot programs in Medicare Part D, Medicaid formularies, and DoD acquisition can test domestic preference rules.
- Even a modest preference margin (5—10%) could tip contracts away from imports, sending a strong demand signal to U.S. producers.

Strategic Stockpiles and Anchor Contracts

- Expand the Strategic National Stockpile from a narrow reserve into a tool that anchors domestic production.
- Establish a Strategic API Reserve (SAPIR) and expand finished drug reserves sourced from U.S. plants.
- Use long-term federal procurement contracts to guarantee demand—making the government a buyer of first resort.
- The Defense Production Act (DPA) showed during COVID that federal purchasing can jumpstart capacity [81]; this should be institutionalized.
- Stockpiling also saves money: shortages cost hospitals hundreds of millions annually in labor and substitutes.

Reforming GPOs and PBMs

- Three Group Purchasing Organizations (GPOs)—Vizient, Premier, and HealthTrust—control ~90% of hospital generic contracting [82]. Moreover, ~90% of retail generic purchasing is concentrated in three PBM-aligned alliances—AmerisourceBergen, Cardinal, and McKesson [83].
- This concentration gives a handful of buyers overwhelming leverage in drug contracting. To win access to those contracts, manufacturers must accept rock-bottom prices. Subsidized imports from China and India can sustain

those margins, but U.S. producers cannot—and are driven out of the market. Once domestic firms exit, the only suppliers left are the foreign manufacturers, leaving hospitals dependent on single overseas sources.

- Congress should revisit the anti-kickback safe harbor that allows GPOs to collect vendor fees (42 C.F.R. §1001.952(j)), which biases contracts toward large incumbents.
- Require contracts to weigh FDA compliance history, redundancy of supply, and domestic sourcing—not just price.
- Encourage dual sourcing and shorter contract terms to avoid lock-in.
- The FTC and DOJ should investigate exclusionary practices—from bundled rebates to monopsony (buyer-side monopoly) power—that block new domestic entrants.

By harnessing the immense purchasing power of the federal government and the dominant leverage of GPOs and PBMs, the U.S. can reset incentives across the system. If Medicare, Medicaid, DoD, VA, and major buyers all prioritize secure supply, the entire market will follow. Hospitals will know that choosing the safer supplier is financially viable. Manufacturers will finally have customers willing to pay a fair price for reliable medicines. This ensures that the way America buys its drugs supports resilience, not collapse.

Pillar 5: Securing U.S. Biotechnology Leadership — Research, Trials, and Talent

Protecting today's medicine supply is essential, but the U.S. must also secure long-term leadership. The next frontier is biotechnology: advanced biologics, innovative therapies, and cutting-edge clinical research. China has treated biotech as strategic infrastructure, pairing subsidies with loose standards to seize global market share. Meanwhile, U.S. investment has stagnated and our research base risks erosion. The U.S. must ensure that it is not playing catch up to China—it must lead.

Strengthening Clinical Standards

- Require multi-regional trial data with diverse patient cohorts and modern comparators before FDA approval, ensuring U.S. patients are not exposed to therapies validated only on narrow overseas populations.
- Expand FDA capacity to monitor foreign trials and manufacturing sites with advanced analytics and risk-based inspections if these products seek U.S. approval.
- Mandate independent verification of site quality and data integrity to prevent shortcuts and systemic fraud in overseas studies.

Reinvesting in Research and Talent

- Reverse NIH stagnation by restoring real growth in research budgets, especially for early-stage discovery.
- Direct a share of federal R&D funding to biotech startups and translational research, using matching grants, loan guarantees, and dedicated commercialization funds to bridge the gap between university discoveries and market-ready therapies.
- Retain U.S.-trained PhDs and postdocs with competitive fellowships and permanent opportunities, while selectively recruiting top global scientists to ensure the most advanced cures are discovered and made in the United States.

Protecting U.S. Biological Assets

- Prohibit export of U.S. patient cells, genomic data, and biological samples to adversary countries without consent, traceability, and federal oversight.
- Establish penalties for unauthorized transfers and require transparent review of partnerships involving sensitive biological material.

These policies secure America's future edge in biotechnology by tightening trial standards, rebuilding research capacity, investing in startups and talent, and protecting patient data. Without these steps, tomorrow's cures may be discovered and manufactured in Beijing—not in Boston, San Diego, or North Carolina's Research Triangle. With them, the U.S. ensures that innovation, safety, and supply resilience remain firmly in American hands.

Conclusion

America's medicine supply chain is failing patients. We have built a system that prioritizes the cheapest offshore pill over secure access and quality. The result has been chronic shortages, shuttered U.S. plants, dangerous dependence on adversarial suppliers, and repeated safety lapses that cost lives. Today, 80% of essential medicines have no U.S.-based source, and many rely on a single foreign factory. When that chain snaps—whether by contamination, political decision, or accident—Americans go without care. This is not a temporary problem; it is a systemic breakdown with direct consequences for public health, seniors' care, and national security.

But this crisis is solvable. This testimony outlines five interlocking pillars that together can close the loopholes that kill American patients:

- **Protecting the Domestic Market (TRQ):** A Section 232 Tariff-Rate Quota system will end the flood of unsafe, subsidized imports while ensuring patients still have access to trusted allies' supply. It creates breathing room for U.S. firms to re-enter the market.
- **Jumpstarting Manufacturing (PILLS Act):** Production and Investment Tax Credits will make it profitable to manufacture generics, APIs, and biosimilars in America again, backed by a clear planning horizon that would catalyze capacity investments.
- **Overhauling Oversight (FDA Reform):** Independent batch testing, unannounced inspections, tougher enforcement, and supply chain transparency will ensure that any imports Americans do take meet our gold-standard safety expectations.
- **Realigning Purchasing (Federal Power & GPO/PBM Reform):** By directing Medicare, Medicaid, DoD, and VA to prioritize resilient domestic supply, and by reforming distorted GPO and PBM contracting, we can reset the market so it rewards reliability and quality, not just the lowest foreign bidder.
- **Securing Biotechnology Leadership:** By raising trial standards, reinvesting in NIH and biotech startups, protecting research talent, and safeguarding U.S. biological data, we ensure the cures of tomorrow are discovered and manufactured in the United States—not dictated from Beijing.

Taken together, these pillars rebuild both today's supply of generics and tomorrow's pipeline of advanced therapies. They are designed to reinforce one another: trade tools create the market space, incentives fill it, oversight guarantees safety, purchasing power sustains it, and biotech leadership secures the future.

Importantly, these reforms do not raise costs for patients. In fact, they lower them over time by eliminating shortages, preventing gray-market price spikes, and avoiding the hidden costs of unsafe imports. Seniors on Medicare and patients on Medicaid will remain protected, while hospitals will save from greater stability and fewer emergency markups.

We are at a historic inflection point. Congress now has the chance to transform supply security before the next crisis costs lives. With bipartisan leadership, we can move from a fragile, import-dependent system to one where every American can trust that their medicine is safe, available, and made under standards worthy of this country.

Let us act now. By enacting these five pillars, Congress can save lives, restore American manufacturing, revive research leadership, and ensure that our seniors—and every patient—never again suffer from "bad medicine."

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