

**Written Testimony of Patrick Cashman  
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**Senate Special Committee on Aging  
Hearing: "Made in America: Restoring Trust in Our Medicines"  
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Chairman Scott, Ranking Member Gillibrand, and distinguished members of the committee:

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

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

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

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

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

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

**I. The Strategic Importance of Domestic Antibiotic Manufacturing**

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

According to the Centers for Disease Control and Prevention, amoxicillin alone accounts for approximately 50 million prescriptions annually in the U.S., making it the single most prescribed

antibiotic.<sup>ii</sup> It treats a wide range of infections, particularly in children. Yet the overwhelming majority of today's U.S. amoxicillin supply is sourced from overseas, often from a small handful of producers, many of which are concentrated in India and China. Today, USAntibiotics serves approximately 5% of the U.S. market, even though we have the underutilized capacity to meet 100% of the country's demand once again.

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

Now, consider the post-operative risks when antibiotics are unavailable or of low quality. A routine hip replacement becomes a life-threatening gamble. A cardiac stent placement risks deadly infection. Cancer surgery—already traumatic—becomes even more dangerous. During the 2022 and 2023 amoxicillin shortages, hospitals across the country were forced to ration antibiotics, delay elective surgeries, and substitute less effective treatments.<sup>iv</sup> Elderly patients and children were impacted most by these shortages.

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

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

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

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

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

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

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

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

## **II. Recognition and Validation of Our Strategic Importance**

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

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

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

## **III. The Fragility of Global Antibiotic Supply Chains**

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

China produces approximately 45% of the active pharmaceutical ingredients used in amoxicillin today, and it also accounts for a majority of the global key starting material market.<sup>ix</sup> Even as India leads the world in finished form amoxicillin exports, its drugmakers are highly reliant on Chinese-made amoxicillin API. The result is that the majority of amoxicillin on pharmacy shelves today is simply Chinese chemistry with Indian finishing.

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

The concentration risk is staggering. Suppose China restricted API exports, whether for economic leverage or during a geopolitical crisis, millions of Americans could lose access to life-saving medicine within weeks. The Strategic National Stockpile would likely not sustain the country for more than a few

months in the event of a bacterial pandemic. The United States has no domestic manufacturing alternative to USAntibiotics—which is why the risk of our closure is so significant.

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

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

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

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

#### **IV. Unique Challenges to Domestic Generic Antibiotic Manufacturing**

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

##### **1. Unfair Global Competition and Market Distortions**

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

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

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

Recently, some Indian drugmakers have been selling amoxicillin at a price below our chemical costs for active pharmaceutical ingredients. That means they're offering finished products for less than we pay

just for the raw materials. Either they're selling at a loss (subsidized by their government) or they're using such substandard ingredients that quality is suspect.

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

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

## **2. Lack of Long-Term Purchasing Commitments**

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

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

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

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

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

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

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

### **3. Lack of Recognition for National Security Relevance**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

### **The Repackager Problem**

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

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

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

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

A 2023 Department of Defense review found that the country of origin for API used in 22% of essential military drugs could not be identified.<sup>xi</sup> That's not supply chain management—that's negligence.

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

### **What U.S. Manufacturers of Generic Antibiotics Need**

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

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

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

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

## **VI. How America's Allies Handle Pharmaceutical Sovereignty**

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

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

France announced a €160 million fund explicitly dedicated to rebuilding domestic pharmaceutical production.<sup>xiii</sup> The French government identified 30 essential medicines for which domestic production had been lost to Asian competitors, then offered financial incentives to pharmaceutical companies willing to reshore manufacturing.

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

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

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

These countries understand that pharmaceutical sovereignty is national security. They've moved beyond studies and reports to actual policy implementation with real funding. They've recognized that maintaining domestic pharmaceutical manufacturing capacity requires government support, not just market forces.

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

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

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

## **VII. Policy Recommendations**

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

### **1. Create Procurement Pathways for Critical Domestic Manufacturers**

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

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

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

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

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

### **2. Define "Domestic Manufacturing" to Exclude Repackagers**

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

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

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

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

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

### **3. Establish Strategic National Stockpile Domestic Purchase Requirements**

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

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

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

### **4. Incentivize Long-Term Purchasing Agreements**

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

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

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

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

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

## **5. Create a Strategic Antibiotic Manufacturing Fund**

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

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

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

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

## **6. Enforce Trade Rules to Counter Predatory Pricing**

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

We support the ongoing Section 232 investigation regarding the national security effects of imports of pharmaceuticals and pharmaceutical ingredients. Section 232 investigations have been used to address perceived national security threats from steel, aluminum, and other strategic materials imports. Pharmaceuticals deserve the same scrutiny.

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

## VIII. Conclusion

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

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

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

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

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

Respectfully submitted,

Patrick Cashman  
President, USAntibiotics  
Bristol, Tennessee

## Resources

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

<sup>ii</sup> Outpatient Antibiotic Prescriptions — United States. CDC. (2022) [https://archive.cdc.gov/www\\_cdc\\_gov/antibiotic-use/data/report-2022.html](https://archive.cdc.gov/www_cdc_gov/antibiotic-use/data/report-2022.html)

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

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

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

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