



Testimony of Patrick Cashman, President, USAntibiotics

Wednesday, June 11, 2025

Subcommittee on Health, House Committee on Energy and Commerce

Hearing: *"Made in America: Strengthening Domestic Manufacturing and Our Health Care Supply Chain"*

Chairman Carter, Ranking Member Degette, and Distinguished Members of the Subcommittee:

Thank you for the opportunity to speak before you today. 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.¹

The facility I lead has a proud history of supplying this critical medicine to American patients for more than 40 years. Until 2008, every dose of amoxicillin needed to treat life-threatening bacterial infections in this country was produced at our Bristol plant. By 2020, the U.S. had become entirely reliant on foreign-origin amoxicillin because our production lines had gone dark. After years of escalating subsidized competition from Indian and Chinese generic drugmakers, the facility's previous owners had filed for bankruptcy. USAntibiotics' new owners—its first American owners in history—stepped in and

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

stepped up in 2021 to revive the dormant facility, rehire and grow its staff, and restore confidence in America's antibiotic supply chain.²

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 because a country without access to life-saving antibiotics cannot grow its economy or defend itself from threats.

My testimony today will outline the unique challenges faced by U.S. manufacturers of critical generic medicines like amoxicillin. 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 all hinge on reliable antibiotic access.

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.³ It treats a wide range of infections, particularly in children. Yet, the overwhelming majority of the amoxicillin supply today is sourced from overseas—often from a small handful of producers,

² Wainer, D. (2024). America is running out of generic drugmakers. Another one is on the brink. The Wall Street Journal. <https://www.wsj.com/health/pharma/america-is-running-out-of-generic-drugmakers-another-one-is-on-the-brink-dbd8bb17>

³ Centers for Disease Control and Prevention. (2022). Antibiotic use in the United States, 2022 update. https://archive.cdc.gov/www_cdc_gov/antibiotic-use/data/report-2022.html

many of which are concentrated in India and China. Today, USAntibiotics serves approximately five percent of the U.S. market, even though we have the capacity to satisfy 100 percent of the country's demand.

In recent years, we've seen how fragile global supply chains can be. The COVID-19 pandemic and geopolitical tensions have exposed our vulnerability. In 2022 and again in 2023, the United States experienced severe shortages of amoxicillin, forcing doctors to substitute less effective treatments.

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 no less than five years and hundreds of millions of dollars to construct a new facility capable of producing amoxicillin. That would be five years in which this country would be entirely reliant on China and India, during which time one or both countries could restrict our access. A 2025 study found that Indian-made generics were 54% more likely to cause severe adverse events than made-in-America drugs.⁴

These are the stakes, and they drive me and my team to work as hard as humanly possible.

⁴ Medical Xpress. (2025, February). Generic drugs not equal. <https://medicalxpress.com/news/2025-02-generic-drugs-equal.html>

II. Unique Challenges to Domestic Generic Antibiotic Manufacturing

While all pharmaceutical manufacturing faces global competitive pressures, generic antibiotics like amoxicillin present a particularly difficult case. These challenges can be grouped into five key areas:

1. Unfair Global Competition and Market Distortions

Generic antibiotics are among the lowest-cost pharmaceutical products. Amoxicillin, in particular, is often sold at razor-thin margins. Indian and Chinese manufacturers benefit from significant state subsidies, lower labor costs, and less stringent environmental and regulatory standards. These advantages allow them to undercut U.S. manufacturers on price—often selling at or below the cost of production. One 2022 study found that a lack of regulatory oversight in China and India allows their drugmakers to cut as much as 25 percent off of their production costs.⁵

These price tactics sometimes resemble anti-competitive dumping practices, where foreign producers flood the market to eliminate competition. Once domestic manufacturers are driven out, prices can be raised with little oversight or recourse. Recently, some Indian drugmakers have been selling amoxicillin at a price below our chemical costs for active pharmaceutical ingredients.

On the other hand, U.S. manufacturers must comply with rigorous FDA regulations, maintain higher quality standards, and absorb higher input and operational costs. While these standards are vital for public safety, they create an uneven playing field that deters domestic investment.

⁵ Young, C. (2022, February). America's other health care crisis: Generic medicine supply chains. American Affairs Journal. <https://americanaffairsjournal.org/2022/02/americas-other-health-care-crisis-generic-medicine-supply-chains>

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. This leaves U.S. manufacturers vulnerable to market fluctuations and unable to make long-term capital investments or retain specialized labor.

Contrast this with defense or semiconductor procurement, where the federal government frequently uses multi-year contracts to ensure stability and scalability. A similar approach could transform antibiotic manufacturing.

3. Regulatory Bottlenecks

The FDA plays a vital role in ensuring the safety and efficacy of all medicines. However, the regulatory pathway for re-establishing domestic production can be time-consuming and opaque. Manufacturers seeking to bring production back to the U.S. must often navigate long approval timelines, duplicative inspections, and inconsistent guidance—especially when transitioning from an imported API to a domestically produced one.

Expedited pathways and regulatory incentives for essential medicines would greatly accelerate domestic production timelines.

4. 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.

Yet the threat posed by antibiotic shortages is just as real—and arguably more acute and more immediate. We must reclassify essential generic drugs as national security assets and build policy around that recognition.

III. USAntibiotics: A Case Study in Resilience and Risk

As this subcommittee considers legislative solutions, I submit to you one question: how could our government—which presides over the most powerful and prosperous country in history—have allowed itself to become dependent on China and India for a critical medicine that saves millions of lives annually?

In 2021, USAntibiotics was revived by private American investors who recognized not as an economic opportunity but as a U.S. national security imperative the importance of restoring domestic antibiotic production. Since then, we have brought back high-skilled jobs, invested millions into reactivating production lines, and re-entered the commercial market. But it's neither fair nor appropriate to expect the private sector to subsidize the responsibility of the U.S. government in protecting antibiotic access.

Today, my colleagues in Bristol will manufacture approximately 700,000 doses of amoxicillin before their shift ends.

But we operate on a knife's edge.

Despite our strategic importance, we receive no federal subsidies, federal prime contracts, or protection from predatory pricing. We operate in a market dominated by foreign competitors who offer below-market prices to private-sector customers like large pharmacy chains and government purchasers. In the case of government buyers, we believe there is a higher responsibility than simply selecting the lowest bid.

Since January 2023, USAntibiotics has sold approximately \$895,000 directly to government purchasers through the United States Department of Veterans Affairs and the United States Public Health Service. However, 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. So during roughly the same period in which the last remaining end-to-end 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.

We are not asking for a U.S. government subsidy or handout. But we believe that the U.S. government can and should better prioritize purchases from U.S. producers of critical, lifesaving antibiotics.

IV. Policy Recommendations

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

1. Incentivize Long-Term Purchasing Agreements

Encourage federal agencies to enter into long-term contracts with domestic producers of essential medicines. 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.

2. Implement Domestic Preference Policies, Supply Chain Visibility

A 2023 Department of Defense review found that country of origin for API used in 22% of essential military drugs could not be identified.⁶ The U.S. government should establish a "Buy American" requirement for antibiotics purchased with federal funds and a requirement for manufacturers to disclose API country origin. Just as we do for critical infrastructure and defense, our healthcare supply chain should prioritize domestic resilience over short-term savings.

3. 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.

⁶ Warren, E. (2023). FY23 NDAA section 860: Risk management for DoD pharmaceuticals. U.S. Senate. <https://www.warren.senate.gov/imo/media/doc/FY23%20NDAA%20sec%20860%20Risk%20management%20for%20DoD%20Pharmaceuticals1.pdf>

4. Modernize Regulatory Pathways

Direct the FDA to establish fast-track approval pathways for essential medicine facilities reopening or transitioning production to the U.S. Align regulatory oversight with national security priorities.

5. 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.

V. Conclusion

Rebuilding America's capacity to produce its own antibiotics is not just a matter of economics or public health. It is a matter of U.S. national security.

USAntibiotics stands ready to play our part. We have the infrastructure, the expertise, and the commitment. But we need this Congress and the U.S. administration to act—boldly and urgently. We cannot allow another crisis to catch us unprepared. We must reclaim our pharmaceutical security and independence, and we must do it now.

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