August 8, 2025

The Honorable H. Moran Griffith
Chairman
Subcommittee on Health
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Griffith:

I was honored and privileged to appear before the House Subcommittee on Health to discuss the enormous challenges facing American manufacturers of critical generic drugs. Your attention to this urgent matter is essential to protecting the integrity of the U.S. pharmaceutical supply chain.

As requested, I have enclosed my answers to the six additional questions for the record from Representatives Carter and Harshbarger.

Thank you again for the opportunity to tell the story of USAntibiotics, America's last domestic amoxicillin manufacturer, before your esteemed subcommittee.

Sincerely,

Patrick Cashman

Attachment

Questions for the Record from the Honorable Earl L. "Buddy" Carter

Question 1: How does the price delta for U.S.-vs-foreign origin amoxicillin compare to other sectors where the federal government already pays premiums for American-made products for national security reasons?

> **Answer**: USAntibiotics' pricing is highly competitive with other prime or subcontractors supplying amoxicillin to the federal government, as evidenced by the Federal Supply Schedule. The federal government would not have to pay significantly more to buy American-made amoxicillin because we've worked extremely hard to optimize our production processes.
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> While it's true we have lost commercial sales when outbid by 2.5 percent (a 10-cents bottle difference) from subsidized foreign competitors, even that modest premium would be wholly consistent with federal government procurement in other critical sectors. For example, the government routinely pays premiums to avoid Chinese technology solutions in favor of American alternatives for cybersecurity reasons. There's a reason that the federal government pays more for U.S.-made operating systems and computer hardware. Similarly, the Defense Department regularly pays higher prices for American-made equipment and components under Buy American requirements.
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> Essential antibiotics deserve the same treatment as computer systems, semiconductors, and defense equipment. A fractional premium for amoxicillin—the most prescribed antibiotic in America—is a small insurance policy against the catastrophic costs of supply chain failure.

Question 2: You mentioned that USAntibiotics was excluded from the $40 million Strategic National Stockpile contract because it wasn't classified as a small business for reasons of its ownership structure. Given that national security and supply chain resilience were stated priorities of the previous administration, does it make sense to prioritize small business status over domestic manufacturing capability for critical medicines?

> **Answer**: This contradiction highlights a fundamental misalignment in government priorities. While small business programs serve important economic goals, excluding the only domestic manufacturer of a critical antibiotic from Strategic National Stockpile contracts defeats the purpose of maintaining emergency medical supplies.
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> National security should take precedence over contracting categories for truly critical medicines. The irony is that even as USAntibiotics is a small business by every financial metric aside from our ownership structure, we wouldn't be able to sustain the enormous losses of the last four years unless a larger company stepped in to subsidize our operations, thereby excluding us. Any policy prioritizing business size over supply chain security for essential medicines must be re-examined.

Question 3: How would predictable, multi-year government purchasing commitments for domestic manufacturers compare in cost-effectiveness to the emergency spending required when foreign supply chains fail and the government must source alternatives at premium prices during shortages?

> **Answer:** Multi-year government purchasing commitments for domestic manufacturers would be far more cost-effective than the current cycle of emergency procurement during shortages. Predictable demand allows us to make efficient capital investments, maintain steady production, and offer competitive pricing.
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> During the 2022-2023 amoxicillin shortage, emergency sourcing cost significantly more than normal procurement. Some buyers paid 3-5 times the typical pricing for available supply. Meanwhile, USAntibiotics had untapped capacity that could have prevented the shortage entirely if we had long-term commitments that justified scaling up production beforehand.
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> This is exactly how defense procurement works—multi-year contracts provide stability for manufacturers and better pricing for taxpayers. The same approach would work for essential medicines and would be far more economical than crisis-driven emergency spending.

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Questions for the Record from the Honorable Diana Harshbarger

Question 1: Are you aware of other critical sectors where the federal government prioritizes domestic suppliers over the lowest foreign bid for national security reasons?

> **Answer**: Yes, there are numerous precedents. 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. Federal agencies routinely avoid Chinese telecommunications equipment despite lower costs. The government pays premiums for American-made vehicles, construction materials, and technology solutions.

Question 1a. How should pharmaceutical procurement policies align with these existing practices?

> **Answer**: Pharmaceutical procurement should align with these existing practices. If we won't buy Chinese routers for government networks due to security concerns, why would we fill the Strategic National Stockpile with foreign-made antibiotics that our military and emergency responders depend on? The principle is identical—critical infrastructure requires trusted, domestic sources.

Question 2: When a government agency awards a contract for strategic national stockpile antibiotics to a foreign supplier while a domestic alternative exists, what risks does this create for supply chain resilience during future emergencies?

> **Answer**: Principally, it creates supply chain vulnerability by feeding dependence on foreign sources at the expense of domestic industry. This is particularly dangerous in military or trade conflicts where exports are restricted, or a potential bacterial pandemic in which antibiotics will become highly prized commodities. Second, there are enormous quality control risks because we have less oversight and transparency in foreign manufacturing processes. Lastly, it forces domestic manufacturers to exit the market when their own government refuses to support American industry. Taken together, it undermines the very purpose of a strategic stockpile, which is supposed to provide security during emergencies, not create additional vulnerabilities.

Question 3: Mr. Cashman, you referenced a 2025 study showing Indian-made generics were 54 percent more likely to cause severe adverse events than American-made drugs. When government agencies procure pharmaceuticals, should quality metrics and regulatory oversight standards be factored into procurement decisions alongside price?

> **Answer**: Absolutely. The 2025 Ohio State study showing 54% higher rates of severe adverse events from Indian-made generics compared to American-made drugs should be a wake-up call. Quality isn't just about patient safety—it's about healthcare costs. When patients experience adverse events, it means additional medical treatment, needlessly extended hospital stays, and higher overall costs to the system.
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> Government procurement should factor in the regulatory environment where drugs are manufactured. American facilities operate under rigorous FDA oversight with regular inspections. We have transparency and accountability that's simply not possible with foreign manufacturing. When the government purchases pharmaceuticals, it should consider the total value proposition: quality, safety, oversight, and supply chain security—not just the lowest unit price.

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