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Hearing on "Made in America: Restoring Trust in Our Medicines"
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Opening Statement and Background

Chairman Scott, Ranking Member Gillibrand, and distinguished members of the Committee, thank you for the opportunity to testify on a matter that directly impacts the health, security, and well-being of millions of Americans, namely, our nation's growing dependence on fragile, foreign pharmaceutical supply chains and the resulting drug shortages that continue to threaten patient safety, public health, and national security.

My name is Eric Edwards. I am a physician, scientist, and co-founder of Phlow Corp., a leading American advanced pharmaceutical contract development and manufacturing organization (CDMO) and certified B-Corporation created to advance the domestic development and manufacturing of critical medicines and help reshore medicine manufacturing on U.S. soil. I also continue to serve as a volunteer paramedic in Virginia, providing care in emergency settings. These are also the settings where the consequences of drug shortages are most acutely felt.

I. The Human Cost of Drug Shortages

Drug shortages are not abstract supply-chain problems. They are real crises unfolding daily in our nation's emergency rooms, ambulances, and operating suites. Across the country, clinicians are being forced to substitute unavailable medications with less effective or unfamiliar alternatives, increasing the risk of medication errors, adverse reactions, and patient harm.

In my own clinical experience, there have been moments when critical drugs such as epinephrine for allergic emergencies, midazolam for seizures, or succinylcholine for intubating critical patients were simply unavailable. Every second counts for patients in these situations. Substituting or improvising can mean the difference between life and death.

II. Overreliance on Fragile, Foreign Supply Chains

The U.S. today relies on foreign manufacturers, primarily in China and India, for most of its active pharmaceutical ingredients (APIs) and associated precursor chemical ingredients, including pharmaceutical intermediates and key starting materials (KSMs). In many essential medicine categories, there is only one qualified source, and it is often overseas. Although drug shortages have not been primarily attributed to geopolitical conflicts in the past, the risk is significant due to growing global tensions and supply chain vulnerabilities, leading to an unacceptable strategic vulnerability.

III. The Geopolitical and National Security Dimension

Our pharmaceutical dependence is not just a public-health concern but rather a national-security threat. Rising global tensions make our fragile drug supply increasingly risky. If conflicts disrupt Asian trade routes or trigger export bans, the U.S. could lose access to essential APIs and precursor chemical ingredients needed for critical care, oncology, and infectious disease treatments. Future drug shortages may be significantly more severe, affecting a broader range of medications than we have seen in the past.

The Defense Logistics Agency and the Department of Defense Inspector General have both warned that military readiness could be severely compromised by disruptions in the medical supply chain. A purposeful adulteration or export ban on key drug ingredients could leave warfighters without vital medicines.

Over the past few years, Congress has taken significant steps to secure rare earth minerals, once 80–90% imported, including by expanding the National Defense Stockpile through actions such as the purchase of critical minerals.

That same level of urgency is required for APIs and their chemical precursors, including KSMs, which underpin every essential medicine and medical countermeasure. Just as rare earths underpin critical technologies, APIs underpin the entire pharmaceutical supply chain, and without them, we cannot make critical medicines. Yet, the U.S. still imports over 80% of APIs, primarily from China and India, creating a hidden but serious risk exposed during the COVID-19 pandemic.

Just as Congress views the rare earth critical industrial base as vital to national security, the API industrial base for key medicines and medical countermeasures should also be safeguarded as essential health infrastructure. The same bipartisan resolve that drove progress in rare earths can, and must now, be harnessed to restore America's pharmaceutical sovereignty, ensuring that the lifeblood of our healthcare system is made safely, reliably, and here at home.

IV. What Phlow Is Doing to Address the Crisis

Phlow was created to help solve this problem. In partnership with the U.S. Government, we have built a state-of-the-art advanced manufacturing campus in Virginia, designed to domestically produce APIs for medicines at both small and large scale. We share a campus with Civica Rx, which can produce the finished drug product for sterile injectable essential medicines. Our pharmaceutical campus integrates advanced manufacturing, process analytical technology, and digital quality control systems that are state-of-the-art, offering a high-quality, more efficient, and more sustainable way to make medicines entirely on U.S. Soil once again.

Through our groundbreaking partnership with the Administration for Strategic Preparedness and Response (ASPR), Phlow is developing and supplying a broad catalogue of essential APIs. For each active ingredient program, Phlow reconstructs the

chemistry, sources starting materials domestically or from allied nations if not possible to source or manufacture in the U.S., and leverages state-of-the-art development and manufacturing approaches, such as green chemistry and continuous manufacturing, to drive efficient, higher-yielding production, cost competitiveness, and a reduction of our environmental impact.

To date, we have completed five API development programs, filed four drug master files, and have a dozen additional APIs in various stages of development. Our latest program, epinephrine, is now making its way into a finished drug product, creating a product with both API and finished product manufactured in the U.S. – something that has not occurred in decades. This API was previously majority manufactured in Taiwan, highlighting the vulnerability of such a critical medicine supply chain. We are also proud to support the Department of Defense (DoD) in strengthening the warfighter supply chain through a pilot program focused on developing and manufacturing critical drug ingredients for medical countermeasures.

Phlow also co-founded the Children's Hospital Coalition, dedicated specifically to solving pediatric drug shortages. To date, we have delivered over 1.8 million doses of critical essential pediatric medicines to the Coalition to support a reliable supply of medicines that have experienced drug shortages. Furthermore, we have begun a domestic end-to-end program, from KSM to API to finished drug product, for ketamine, recently receiving the Commissioner's National Priority Review Voucher as a part of the FDA's inaugural pilot to support rapid development and approval of this critical essential medicine. Despite some misconceptions, ketamine remains vital to modern medicine as a fast-acting, versatile anesthetic that clinicians depend on for safe surgical procedures, emergency interventions, and battlefield care.

Phlow also worked with the U.S. Government to conceive of, and build, the U.S. Strategic Active Pharmaceutical Ingredient Reserve (SAPIR) program. SAPIR is designed to function as a national security buffer for medicine supply chains. Through SAPIR, we are working to maintain an inventory of end-to-end domestically produced or allied-nation-sourced KSMs, intermediates, and APIs for the most essential medicines identified by the federal government. This forward-leaning model not only allows the U.S. to secure a much larger number of critical APIs in larger quantities but also ensures that if global supply chains are disrupted, the U.S. retains the ability to rapidly convert reserve materials into finished drug products to protect Americans. Unlike traditional stockpiling, which often relies on imported finished products with limited shelf life, SAPIR focuses on the building blocks of pharmaceuticals, enabling immediate domestic surge manufacturing, longer stability windows, and far greater resilience.

V. What Is Needed for Sustainable Onshoring Success

As we discuss how to strengthen America's medicine supply chain, it is important to be clear: the goal should not be to reshore every single medicine or chemical precursor ingredient. The U.S. pharmaceutical market encompasses more than 2,000 approved

medications. Attempting to onshore everything would be economically unrealistic and strategically unfocused.

Instead, we must take a disciplined, risk-based approach, one that prioritizes medicines based on clinical criticality, population reach, and supply-chain vulnerability. Some medicines, such as certain injectables used in emergency care, have no substitutes and are essential for saving lives within minutes. Others treat millions of Americans daily, meaning any disruption would have broad population-level impacts. We are at serious risk when essential drugs depend on fragile or highly concentrated foreign supply chains that can be disrupted, or even weaponized, without warning.

A national resilience strategy must therefore begin with the right-tiered list of essential medicines, regularly updated and informed by federal agencies, healthcare systems, and manufacturers. This list should continue to identify which APIs and KSMs require domestic or allied-nation production, which can be supported through diversified global sourcing, and which pose minimal risk. By doing this, we focus on the medicines that keep Americans alive in emergencies, followed by certain medications that stabilize chronic conditions and support national preparedness in times of crisis.

Despite considerable progress, the onshoring movement remains fragile. For this transformation to succeed, certainty and sustainability are essential. No company, no matter how mission-driven, can sustain long-term domestic production without predictable demand and multi-year commitments. America must invest in domestic and allied API manufacturing capacity, particularly through shared-infrastructure ecosystems that dramatically lower production costs while enabling environmentally responsible synthesis.

For Phlow, this aligns directly with our work under ASPR and the SAPIR program: if the U.S. cannot secure these earliest building blocks of medicines, it cannot secure the medicines themselves. Strategic API manufacturing is only as strong as the weakest upstream link. Therefore, this is not a one-company solution. We need a competitive marketplace of U.S. manufacturers aligned under a national strategy for medicine security.

Several key policy enablers are required:

1. Develop a Long-term and Comprehensive Strategy

Restoring our nation’s pharmaceutical supply chain cannot be achieved through isolated, short-term interventions. To prevent future shortages and secure our supply chain, the government must create a comprehensive, long-term plan that encompasses demand forecasting, industrial base growth, research and development, workforce development, and procurement reform. Congress should support a centralized authority to align policy and funding, while bringing stability for patients and predictability for manufacturers. Developing and then executing such a strategy requires sustained, cross-functional partnership across the federal government; siloed decision-making is a vulnerability.

Given the finite time and resources available, this strategy must prioritize those essential medicines and medical countermeasures that treat life-threatening conditions and for which no suitable clinical alternatives exist. Prioritization is not optional, but rather necessary, to ensure that federal investments protect the most critical and high-risk segments of our healthcare system.

At the same time, this strategy should leverage advanced development and manufacturing technologies, such as continuous manufacturing, that improve yields, reduce costs, strengthen quality, and enable greener, more sustainable chemistry. Integrating such technologies into the federal industrial base plan will not only accelerate domestic production but also ensure it is economically viable and environmentally responsible for the long term.

2. Realign Payment and Procurement Policies with Reliability

The central obstacle in restoring the reliability of America's drug supply is not a lack of data, but rather a lack of aligned incentives. The market will not shift back to the U.S. if the buyers of essential medicines, especially hospitals, clinics, and wholesaler intermediaries, remain structurally rewarded for choosing the lowest immediate cost, even when those savings come at the expense of long-term security and patient safety. Information about quality, sourcing, or supply-chain fragility becomes little more than a "warning label" if purchasers are neither financially supported nor contractually required to act on it. To change outcomes, federal entities should adopt procurement policies valuing supply chain reliability. Strategic investment in domestic sourcing can help save lives by strengthening national health security, reducing drug shortages, and mitigating the widespread disruptions they cause.

3. Ensure Predictable, Long-Term Resourcing

To build enduring resilience, the Administration and Congress must resource these programs with multi-year contracts, similar to how we support defense and energy infrastructure. This allows U.S. manufacturers to plan, invest, and scale with confidence.

There is much to learn from the Department of Defense's long-term industrial base planning and its disciplined use of multi-year procurement, which has enabled stable domestic production of critical materials for decades. Defense contracting models demonstrate that when the government provides predictable demand signals, industry responds with sustained investment, innovation, and surge capacity.

4. Level the Playing Field

We must ensure that domestic manufacturers can compete fairly against foreign producers who benefit from heavy state subsidies, lax environmental and labor standards, weak intellectual property protections, and currency manipulation – advantages that artificially suppress prices and distort global markets. Without corrective action, U.S.-

based pharmaceutical manufacturers are forced to compete not on innovation or quality, but against foreign governments underwriting the true cost of production.

5. Close the Acetris Loophole

As previously recommended by this Committee, it is critical that Congress prioritizes work to close the Acetris loophole. This loophole breaks the connection between "Made in America" and the actual location of pharmaceutical value creation and strategic risk, enabling continued dependence on vulnerable foreign API supply chains even in federal purchasing programs intended to prioritize domestic or allied production.

Fixing the Acetris loophole is not about limiting trade or restricting competition; it is about aligning federal procurement with national security reality. APIs account for the greatest concentration of risk in the entire pharmaceutical supply chain. When the U.S. government buys drugs formulated domestically but sourced from adversarial nations upstream, it inadvertently reinforces the very dependencies we are working so hard to reduce. For essential medicines, particularly those relied upon by vulnerable patient populations, our military, and our emergency response systems, this loophole leaves the U.S. exposed to disruptions, coercion, and shortages originating far outside our borders.

Closing this gap would also give companies like Phlow the market signals needed to invest boldly in U.S. advanced manufacturing, end-to-end pharmaceutical ingredient synthesis, and strategic API reserves.

VI. Looking Ahead

If we fail to act decisively, the next crisis will not be hypothetical. The shortages our great Nation has been coping with have shown us the harm they can cause. If the United States is not adequately prepared, the repercussions could be even more severe than those seen during past shortages of saline or chemotherapy treatments. We could see dangerous situations where anesthetics are unavailable in emergency rooms, saline or antibiotics are unavailable for a sepsis patient, or the inability of our military to access life-saving countermeasures in the midst of conflict.

However, if we succeed in creating a durable, competitive, and secure domestic pharmaceutical manufacturing base, we will have restored one of the most critical pillars of national resilience. Phlow is honored to play a role in this mission, and we stand ready to partner with the U.S. Government and our fellow innovators to make medicine security a permanent reality for the American people.

Conclusion

Chairman Scott, Ranking Member Gillibrand, and members of the Committee, thank you for your leadership in shining a light on this issue. Drug shortages are not inevitable; they are the product of choices. Together, we can choose to build a safer, more resilient, and more self-reliant future for American healthcare.

Thank you, and I welcome your questions.