**STATEMENT OF**

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**ON BEHALF OF**
**THE COUNCIL ON STRATEGIC RISKS (CSR), BLUZONE BIO, AND SECURING AMERICA'S MEDICINES AND SUPPLY (SAMS)**

**BEFORE THE**

**U.S. SENATE COMMITTEE ON ARMED SERVICES**
**SUBCOMMITTEE ON PERSONNEL**

**TO RECEIVE TESTIMONY ON THE DEPARTMENT OF DEFENSE'S EFFORTS TO ENSURE SERVICEMEMBERS' ACCESS TO SAFE, HIGH-QUALITY PHARMACEUTICALS**

# THE DEPARTMENT OF DEFENSE'S EFFORTS TO ENSURE SERVICEMEMBERS' ACCESS TO SAFE, HIGH-QUALITY PHARMACEUTICALS

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## I – Opening Remarks

Chairwoman Warren, Ranking Member Scott, and distinguished members of the Committee, thank you for the opportunity to speak with you today. My name is Vic Suarez, and I am the Founder and Principal Growth Partner of Blu Zone Bioscience & Supply Chain Solutions, LLC. Blu Zone Bio assists biotechnology and life science supply chain organizations accelerate growth and expand domestic biomanufacturing through effective public and private partnerships, strategic alliances, and business development. In addition to my role at Blu Zone, I serve as a visiting Senior Fellow for The Council on Strategic Risks (CSR). CSR is a nonprofit, non-partisan security policy institute devoted to anticipating, analyzing, and addressing core systemic risks to security in the 21st century, with special examination of the ways in which these risks intersect and exacerbate one another, and finding novel ways to mitigate those risks. I am also a Senior Advisor to the Securing America's Medicines and Supply (SAMS) coalition, a multi-industry coalition of companies with the mission to strengthen the security of the medical supply chain in the United States.

My story is one of public service, the product of a family who fled Vietnam during the Fall of Saigon in April 1975 and driven by the promise of the American dream and the idea that no U.S. citizen should live in fear or without freedom. This idea drove me to a career of service in the U.S. Army, where I quickly learned that one of the most significant risks was those that affected our warfighters' health and well-being. After two active-duty combat tours as a medical company and battalion commander, I returned, competed for, and was selected to serve as the Joint Product Manager of the Joint Vaccine Acquisition Program (JVAP), a biodefense advanced development vaccine program where my team helped rapidly accelerate the advanced development and eventual delivery of both FDA licensed Ebola and Mpox vaccines with industry and interagency partners. I was then chosen early to attend the Army War College and serve in a unique capacity at the Milken Institute School of Public Health, George Washington University, DC, as a Senior Service College Fellow, researching new ways and means to improve the health and readiness of the force by studying successful corporate health & wellbeing programs and making policy recommendations to senior Army leadership and Congressional Staffs. Following this unique opportunity, I was hired to be the Chief of Staff at Walter Reed Army Institute of Research (WRAIR), the Department of Defense's (DoD) largest biomedical research laboratory headquartered in Silver Spring, MD, and here, I saw firsthand the power of global biomedical innovation in both infectious diseases, but also in neuroscience and the ability for the U.S. military to work with the interagency partners, industry, and allied nations to help prevent the proliferation of HIV/AIDS through the President's Emergency Plan for AIDS Relief or PEPFAR.

When COVID-19 struck our country, I was called to service again and had the great honor of serving in a role among many fine men and women in Operation Warp Speed (OWS) as the lead Vaccine Program Manager for the Moderna COVID-19 Vaccine. COVID-19 exposed our reliance on foreign, fragile supply chains for essential pharmaceuticals and personal protective equipment (PPE), but this vulnerability predates the pandemic. **Put simply, chronic drug shortages and overseas manufacturing in adversarial nations represents an existential public health threat to our citizens, our warfighters, and our entire healthcare system.**

I finished my formal career in the DoD exploring how to mitigate these threats, serving as a Colonel level commander of a globally relevant medical logistics command at Fort Detrick, Maryland, where we supported each geographic combatant command area of responsibility, including operating the medical supply chain in the Middle East through 21 years of perpetual deployments, perhaps the most continuously deployed medical unit in the entire DOD. I saw firsthand the specific vulnerabilities in the global supply chain of essential medicines.
In the last several months of my service after completing my two-year command tour, I served as a Senior Medical Acquisition Consultant to the U.S. Army Medical Research and Development Command's (MRDC) Tech Transfer, IP/Patent, and Business Development Office at Fort Detrick, MD where I decided to leverage my new team's assistance and establish a Cooperative Research and Development Agreement (CRADA) to explore a new pathway for us to better assess the quality and underlying risks of the medicines the DOD was buying from the commercial marketplace, especially one that was more globally manufactured than ever before.

As I mentioned, these issues are not new. They represent a growing, existential public health threat to the United States. Today, I wish to offer specific recommendations on how to ensure the health, well-being, and readiness of our warfighters, ways we can equip the DoD with the resources necessary to serve as a trusted federal partner in a "whole-of-government" response to drug shortages, and ways to foster innovation to create robust, resilient, and quality domestic biomanufacturing.

In drafting my testimony today, I realized *how* acute this problem is. I sincerely appreciate the actions of many members of Congress in highlighting this issue. Most recently, the US House Select Committee on China released a December report highlighting the dependence of our pharmaceutical supply chain on China.[1] However, a shortage of any drug – whether it be oncology medications, antibiotics, or over-the-counter pain medications – affects one key group: ***patients***. I was reminded of an article I read last year: the story of a schoolteacher who, after beating pancreatic cancer, learned that he "*didn't make the cut"* for his final round of chemotherapy.[2] Imagine the struggle, the willpower needed to fight such a deadly disease, only to learn that the one medicine that could *literally* save your life is subject to factors out of your control. It's a story that deeply resonates with me and a struggle that is equally pronounced for our warfighters. I pray the day never comes when men and women in combat face a threat – chemical, biological, radiological, or nuclear – and are without the drugs needed to save their lives and bring their medical conditions under control.

This is the threat we're up against, and unfortunately, this nightmare is starting to become a reality. During my final year in the DoD, I conducted stakeholder interviews with some of our military operational units and discovered some troubling findings. One example I wish to highlight is ketamine injections, which are commonly used for sedation and analgesia during deployment operations.[3] During most of 2023, I learned that many of our operational units could not get appropriate allocation for primary injections.

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[1] The U.S. House of Representatives, House Select Committee Report on the CCP, December 12, 2023.
[2] C. Jewett. New York Times. 17 May 2023. https://www.nytimes.com/2023/05/17/health/drug-shortages-cancer.html
[3] Victor A. Suarez first-hand experience with customer and stakeholder inquiries, June 2023.

There is hope, though. I'm reminded how quickly our nation can heed the call to action when an urgent threat is present. This premise has been tested throughout history, and our Nation has responded when our safety has been threatened. During World War II, for example, America's steel, chemical, and automotive manufacturing plants produced thousands of tanks, airplanes, ships, and explosives, an industrial base critical for our success. And I'd be remiss if I did not mention the response from our pharmaceutical industry during that time, where we saw a dramatic response to the need for critical medicines such as penicillin, sulfa drugs, and other life-saving medical supplies.[4]

America's pharmaceutical industrial base is synonymous with the *entire* defense industrial base and, from a preparedness standpoint, stands on equal footing with semiconductors, chemical production, and other critical materials needed to ensure our Nation's safety during peacetime or crisis. Today, I wish to provide recommendations on how the DoD can serve as a trusted partner, in combination with other federal agencies and the private sector, in delivering the response we owe to our warfighters to ensure they're never without the drugs they need on the frontline. In many ways, my recommendations resonate with calls for a "CHIPS-style" program for our medical supply chain. One difference between overseas reliance on essential medicines and semiconductors is that should there be a severe drug shortage or an embargo due to geopolitical reasons, people will unnecessarily die due to not having their essential medicines, and health systems will fail to deliver quality care. The risks of the status quo could be even more pronounced if these first-order effects occur when systems are already strained by conflict or other conditions. I hope my recommendations today could serve a small part in a whole-of-government effort to secure America's medicines and supplies.

## II. Background

The COVID-19 pandemic revealed the critical need for a resilient and secure pharmaceutical supply chain. However, these problems have long pre-dated the pandemic. Today, China is the sole source of about 20% of our most vital medicines' active pharmaceutical ingredients (API).[5] More dangerously, China's overwhelming global dominance of the key starting materials (KSM) required to produce these essential medicines cannot be readily substituted due to the current levels of market concentration: approximately 45% of KSMs, a vital subcategory of API, are solely sourced from China.[6]

In 2023, drug shortages in the nation's healthcare system consistently affected approximately 300 medicines, 100 more than at the same time five years ago.[7] These drugs are generic medicines, including sterile injectables (SIs). Without any distinguishing product differentiation, these specific drugs face immense downward cost reduction trends, triggering what many experts call a ***'race to the bottom.'*** This pricing squeeze reduces generic manufacturers' margins and,

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[4] Roswell Quinn, "Rethinking Antibiotic Research and Development: World War II and the Penicillin Collaborative," American Journal of Public Health 103, no. 3 (2013): 426-434, accessed February 7, 2024.
[5] USP and Center for Analytics and Business Insight, Olin Business School at Washington Louis University, October 13, 2023.
[6] Ibid.
[7] Erin Fox, "National Drug Shortages Active Shortages by Quarter – 10 Year Trend," University of Utah Drug Information Service.

ultimately, degrades the economic viability of the manufacturing supply base. It's also been a contributing factor to the offshoring of pharmaceutical production, given the high costs of labor and current good manufacturing practices (cGMP) in the United States. In other words, these pricing pressures create a fragile economic system for generic drugs. The passage of the Hatch Waxman Act, which created the scenario for generics to enter the market, was one of the most successful bills ever passed by Congress. However, it did not contemplate sustainability for these drugs, and that is the problem we're seeing now that a drug can be launched and can bring the price of the drug down significantly. Without sustainability measures in place to make it economically viable for generics to continue to produce some of these drugs, we now face a scenario where these drugs are driven into shortage.

A 2022 study by the API Innovation Center – a St. Louis, Missouri based non-profit dedicated to enabling the delivery of market-competitive commercial supply of U.S.-made APIs – investigated the U.S. generic pharmaceutical manufacturing plant capacity. The study found that despite an approximate 10% growth in demand for medicines from 2016-2021, *"these sites are producing at just half of their production capacity, with an aggregate excess capacity of nearly 50%."*[8] This average, being 30% below the U.S. total industry capacity utilization rate average of approximately 80% means that, unlike many other commodity markets in the U.S., the generic pharmaceutical industry's underutilization places domestic drug manufacturers at significant risk of additional plant closures, further market concentration, and acquisition by foreign entities. It also perversely incentivizes more offshore buying activities, generally in countries with access to cheap labor, which often struggle to produce consistently high-quality medicines.

As a result of these cost pressures, there has been a massive displacement of drug manufacturing to foreign adversaries over the past three decades, creating a perfect storm for any dysfunctional marketplace, which includes opaqueness in supply origins, product quality issues, and lack of pricing trade-offs. A subsequent concern is a significant backlog in FDA inspections and many documented cases of poor manufacturing controls. This, unfortunately, provides an enormous incentive to grow global market share in these countries due to less regulatory and environmental oversight, cheap manufacturing, sourcing of KSM and API, and underinvestment in quality manufacturing technologies. These combined factors place the strategic risk of reliably sustaining pharmaceuticals in America squarely upstream in the supply chain. This multi-component downward spiraling of the above factors will lead to more drug shortages, mainly as a byproduct resulting from quality manufacturing issues driving plant closures—an expected outcome of less frequent and episodic regulatory plant inspections.[9]

In a recent white paper I published for CSR, I recommend stockpiling as an approach the United States has commonly taken to mitigate such risks. An additional and often overlooked aspect of having a national strategic KSM and API reserve is to ensure our military can rapidly build up their medical supply stocks as quickly as possible. In addition to the deterrence value of robust preparedness, a significant gap exists in the DoD's demand for these items in case of war, which would surge significantly more (per person basis) than any demand from the civilian healthcare

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[8] Anthony Sardella, "U.S. Generic Pharmaceutical Manufacturing Available Capacity Research Survey," Washington University Olin School of Business Center for Analytics and Business Insights, September 30, 2022.
[9] US Government Accountability Office, "DRUG SAFETY: FDA Should Take Additional Steps to Improve Its Foreign Inspection Program," January 2022.

system. One of the solutions I wish to explore is a proposed national KSM and API "safety stock" capability that would enable an industrial base that can mobilize effectively during a crisis or war and is complementary to a series of foundational industrial capabilities and investments that can ultimately help deter aggression on our allies or our Nation.

Lastly, I wish to call attention to the DoD's interim Pharmaceutical Supply Chain Risk Assessment. A significant finding was that 54% of the national drug codes (NDCs) sourced by the DOD came from countries not compliant with the Trade Agreement Act (TAA). Not only does this recent finding present a clear and present danger for national security, it also compels us to explore other legal and trade policies that erode rather than strengthen our economic and health security, such as those addressed in the controversial Acetris Health, LLC v. United States case from February 2020. In this case, the U.S. Court of Appeals for the Federal Circuit overruled a long-standing precedent regarding the origin of a drug by ruling that a drug could be "manufactured" in the U.S. even if its API and all its components were derived from TAA-banned countries.[10] This loophole exacerbates national security and known drug quality risks.

Finally, I want to applaud the Department of Defense's efforts to assess these strategic risks through both the assessment of the origins of this supply chain at the Defense Logistics Agency as well as the Uniformed Services University's Pharmaceutical Assessment of Quality Pilot Study (PhaQS) as both of these efforts will provide more transparency and potentially enable millions of our servicemen and women, their families and other TRICARE retirees like me confidence that when they go to a military treatment facility in the US or combat, that they will always have access to the highest quality medicines at the most affordable prices—something that is possible if we're willing to disrupt the status quo.

Thank you for your attention as I raise these significant considerations concerning our Nation's overreliance on non-Trade Agreement Act nations for our pharmaceuticals and encourage Congress and this committee, in particular, to closely monitor and support the DOD's efforts to care for our warfighters, their families, and retired military.

My hope for today is that this committee views the collective expertise of this panel as a "call to action" to address drug shortages, the safety, reliability, and quality of these drugs, and a menu of specific recommendations for the DoD.

## III. Recommendations

The US House Select Committee on China Report issued in December 2023 recommends that Congress considers the following near-term actions (A). It requires the FDA to develop an expanded list of key pharmaceutical products widely used in the U.S. and maintain a database to track their supply chain. (B) Authorize the U.S. Trade Representative to negotiate trade agreements to reduce U.S. dependencies on People's Republic of China medical and pharmaceutical goods. (C) Direct a Buy American program for federal entities that purchase pharmaceuticals and medical devices.

[10] API Innovation Center, Addressing the Acetris "Loophole," Aug 2023

With respect to these overarching points, I wish to offer the following specific recommendations for the DoD:

1. ***Adherence to Berry Amendment Requirements***

The DoD health system and, potentially, the Veteran Health Administration (VHA) should be required to adhere to the intent of the Berry Amendment through legislation. The amendment was enacted in 1941 to promote the purchase of certain US goods (notably food and textiles) for national security and domestic trade purposes. We should also now include language in legislation requiring the purchase of essential medicines and medical supplies. This idea is backed by an HHS 2022 report titled "Essential Medicines and Manufacturing Resilience Assessment." The Administration for Strategic Preparedness and Response (ASPR) proposed two primary supply chain recommendations: "Leverage the federal government's collective buying power to reform procurement protocols" and "revise purchasing models to increase emphasis on product quality and supply chain resilience, not simply lowest cost."11

2. ***Expansion of Quality Testing Program***

As reported in the media in 2023, the Department of Defense initiated a pilot study to assess the quality of pharmaceuticals independently in an independent ISO-17025 accredited laboratory in response to the FY2023 NDAA Section 860 and concern from the Joint Staff Surgeon, Combatant Command Surgeons, and the ASD Health Affairs that the DOD was over-reliant on overseas derived pharmaceuticals and that some had unknown countries of origin and were of suspect quality-a significant risk to national security and the health of military health beneficiaries and its warfighters. This pilot project in September 2023 was expanded to a 2-year-long study at the Uniformed Services University of the Health Sciences, Bethesda, MD, to evaluate the approximately 44 DOD's essential medicines (about 1000 National Drug Codes). Initial interim data presented during the 4 April 2024 USU State of the Science Symposium demonstrates some wide variability in drug product quality, notably in drug dissolution curves and API dosage purity for critical narrow therapeutic index drugs. I recommend that Congress continue to monitor this landmark study as it evolves and encourages the DOD, the VA, and other federal health providers to leverage this data for better drug product procurement methods and patient care and to establish a new path to incentivizing industry to make high-quality medicines at affordable prices by making quality a key metric in product selection, other than just cost alone.

3. ***Establishment of Supply Chain Resilience within DoD***

The Assistant Secretary of Defense (ASD) for Acquisition and Sustainment and in partnership with the Assistant Secretary of Defense (ASD) for Health Affairs, following the interim report directed by the FY23 NDAA, should work to ensure a safe, high-quality, and resilient pharmaceutical supply chain of domestic and allied nations for the following subset of drugs:

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[11]Administration for Strategic Preparedness and Response, Essential Medicines and Manufacturing Resilience Assessment (2022) (https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf)

A. All drugs that DOD currently sources or are derived from China or non-TAA compliant nations (inclusive of API as a metric for country of origin)
B. All drugs on the DoD Essential Medicines List, and
C. All drugs on the ASHP and FDA Drug Shortage List that would have a readiness impact (e.g., albuterol)
D. All drugs on the FDA's Essential Medicines List

For procurement, DoD should prioritize domestic procurement when there are two or more domestic suppliers; when there are not, prioritize sources from TAA-compliant nations, except life-saving drugs (oncology, etc.) that are "only made" in non-TAA-compliant nations and explore ways and means to help U.S. based pharmaceutical companies to technically transfer manufacturing domestically or through near-shore friendly, allied nation and high-quality options.

4. **Expansion of Procurement Strategies to Military Health System**

Direct the ASD for Health Affairs to develop policies that the Defense Health Agency (DHA), in conjunction with the Defense Logistics Agency, would execute to implement the above procurement strategies within the Military Health System, including operational and deployment medical forces worldwide. Procurement contracts and day-to-day prescriptions would enable an additional metric of quality and reliability of the actual product and its associated supply chain so that our Warfighters, their families, and military retirees would always have access to the highest quality medicines at the most affordable prices, a goal within reach with these new pharmaceutical quality and origin risk assessment programs.