

S. HRG. 118–709

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

HEARING

BEFORE THE

SUBCOMMITTEE ON PERSONNEL

OF THE

COMMITTEE ON ARMED SERVICES
UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

SECOND SESSION

APRIL 30, 2024

Printed for the use of the Committee on Armed Services



Available via: <http://www.govinfo.gov>

U.S. GOVERNMENT PUBLISHING OFFICE

61–558 PDF

WASHINGTON : 2025

COMMITTEE ON ARMED SERVICES

JACK REED, Rhode Island, *Chairman*

JEANNE SHAHEEN, New Hampshire	ROGER F. WICKER, Mississippi
KIRSTEN E. GILLIBRAND, New York	DEB FISCHER, Nebraska
RICHARD BLUMENTHAL, Connecticut	TOM COTTON, Arkansas
MAZIE K. HIRONO, Hawaii	MIKE ROUNDS, South Dakota
TIM Kaine, Virginia	JONI ERNST, Iowa
ANGUS S. KING, Jr., Maine	DAN SULLIVAN, Alaska
ELIZABETH WARREN, Massachusetts	KEVIN CRAMER, North Dakota
GARY C. PETERS, Michigan	RICK SCOTT, Florida
JOE MANCHIN III, West Virginia	TOMMY TUBERVILLE, Alabama
TAMMY DUCKWORTH, Illinois	MARKWAYNE MULLIN, Oklahoma
JACKY ROSEN, Nevada	TED BUDD, North Carolina
MARK KELLY, Arizona	ERIC SCHMITT, Missouri

ELIZABETH L. KING, *Staff Director*

JOHN P. KEAST, *Minority Staff Director*

SUBCOMMITTEE ON PERSONNEL

ELIZABETH WARREN, Massachusetts, *Chairman*

RICHARD BLUMENTHAL, Connecticut	RICK SCOTT, Florida
MAZIE K. HIRONO, Hawaii	MIKE ROUNDS, South Dakota
TIM Kaine, Virginia	DAN SULLIVAN, Alaska
TAMMY DUCKWORTH, Illinois	TED BUDD, North Carolina

CONTENTS

APRIL 30, 2024

	Page
THE DEPARTMENT OF DEFENSE'S EFFORTS TO ENSURE SERVICEMEMBERS' ACCESS TO SAFE, HIGH-QUALITY PHARMACEUTICALS	1
MEMBERS STATEMENTS	
Statement of Senator Elizabeth Warren	1
Statement of Senator Rick Scott	3
WITNESS STATEMENTS	
<i>Joint statement of:</i>	
Martínez-López, Hon. Lester, Assistant Secretary of Defense for Health Affairs, Department of Defense	5
Smith, David J., M.D., Deputy Assistant Secretary of Defense for Health Readiness Policy and Oversight, Department of Defense	5
Dertzbaugh, Mark, M.D., Principal Assistant for Research and Technology, United States Army Medical Research and Development Command	5
Beebe, Matthew R., Director of Acquisition (J7), Defense Logistics Agency	8
Barber, Melissa, Ph.D., Postdoctoral Fellow	20
Mendez, Bryce H.P. Specialist in Defense Health Care Policy, Congressional Research Service	53
Suarez, Colonel Victor A., USA (Ret.), Founder and Principal Growth Partner, Blu Zone Bioscience & Supply Chain Solutions, LLC	66
Questions for the Record	86
APPENDIX A	
References of Dr. Dr. Melissa Barber	102
Supportive articles submitted by Mr. Victor A. Suarez	
White House Plan to Curb Drug Shortages Doesn't Address Generics' Quality	103
The National Security Rationale for Stockpiling Key Pharmaceutical Ingredients	110
The Pentagon Wants to Root Out Shoddy Drugs	121

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

TUESDAY, APRIL 30, 2024

UNITED STATES SENATE,
SUBCOMMITTEE ON PERSONNEL,
COMMITTEE ON ARMED SERVICES,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:30 p.m. in room SR-232A, Russell Senate Office Building, Senator Elizabeth Warren (Chairman of the Subcommittee) presiding.

Committee Members present: Warren, Kaine, and Scott.

OPENING STATEMENT OF SENATOR ELIZABETH WARREN

Senator WARREN. This hearing will come to order.

We welcome everyone to today's hearing to receive testimony on the efforts of the Department of Defense to ensure servicemembers' access to prescription drugs that are safe, high quality, and effective.

We owe our servicemembers and their families the best possible health care. This is a morale issue, it is a recruiting issue, and ultimately, it is a national security issue.

DOD spends about \$5 billion every year on pharmaceuticals. That is about 2 percent of the entire U.S. commercial pharmaceutical market. Now to make these purchases, DOD must navigate many of the same challenges as civilian health systems.

For example, according to the FDA, almost half of the drugs on DOD's operational medicines list—a list that contains drugs necessary for warfighting that are essential for meeting the medical needs of servicemembers—about half those drugs are in shortage. This includes the blood thinner heparin, a common anesthesia drug called midazolam, and morphine for pain management. The impact of these drug shortages can be devastating. A shortage could mean using a drug with worse side effects, or it could mean having to use the second-or third-line treatment for an illness, rather than the treatment that is most effective.

While there are many factors that can cause shortages from spikes in demand to natural disasters to inspection failures—most drugs in shortage share a common feature: they are generics. That means they are no longer protected by patents, and they can be made by any manufacturer with approval from the FDA. Despite this, most generic drugs have very little competition. In fact, 40

percent of the generic drugs sold in the United States have just one manufacturer.

Why? Because the profit margin for some generic drugs is so low that American manufacturers just are not interested in making them. As a result, more of DOD's generic drug supply is coming from foreign manufacturers who can produce the drugs at even lower costs.

DOD's reliance on overseas manufacturers is not limited to finished drug products. The ingredients used to make the medicines, called active pharmaceutical ingredients, or APIs, and the ingredients used to make APIs, known as key starting materials, or KSMs, are also increasingly sourced from abroad.

The COVID-19 pandemic exposed the risks we face by importing more and more of our commercial drug supply overall. DOD relies on those imported drugs and that gives potential adversaries the power to restrict DOD's access, which can result in harm to our servicemembers, to their families, and to our national security. In addition, the U.S. has less and less visibility into and oversight of foreign manufacturers and their manufacturing practices, and that is particularly true with China.

These problems have concerned me for a long time, and that is why I partnered with Senator Rubio to secure language in the fiscal year 2023 NDAA requiring DOD to develop guidance for risk management of the Department's pharmaceutical supply chain, to report on supply chain vulnerabilities, and to establish a working group to develop policies for allocating scarce pharmaceutical resources.

When a drug does not work properly it can have serious consequences for servicemembers. Bloomberg reported last year that an outside lab tested tacrolimus, an immunosuppressant used to treat soldiers who have lost limbs in combat. The results revealed that some generic versions of the drug might not work. Worse yet, they could cause kidney failure or seizures.

So last summer, in accordance with Senator Rubio's and my provision, DOD entered into a cooperative agreement with an independent lab to conduct a pilot study to test the quality of 12 finished drugs in the military drug supply. In November, DOD revealed that 27 percent of the drugs on the FDA's Essential Medicines List are at, quote, "Very High Risk" because they are either dependent on Chinese manufacturers using Chinese ingredients or were derived from unknown sources.

So we are holding this hearing today to learn more about these challenges and to discuss DOD's capacity to address them.

I want to thank Ranking Member Scott for his commitment to improve the quality of life for our servicemembers and for their families, and to our witnesses, I say welcome and thank you for appearing today.

We will have two panels. The first panel consists of officials from the Department of Defense who will explain how DOD is currently addressing drug shortages and DOD's existing capabilities for biomedical research and development. I am pleased to have the opportunity to introduce them, which I will do in just a minute, but I want to see if Senator Scott has any remarks he would like to make first.

STATEMENT OF SENATOR RICK SCOTT

Senator SCOTT. Sure. First I want to thank Chair Warren for doing this. I think this is a very important issue. I think any of us that would have a health issue, we would want to make that our kids and our grandkids, that they had the best medicine out there, and it sure does not seem like we are doing that.

For several years I have raised concerns over the pharmaceutical supply chain in this country. The COVID pandemic exposed the vulnerabilities in our supply chains and the dangers of continuing to be reliant on Communist China for medicines and other critical products. I do not know if anybody, logically, would ever want to be dependent on Communist China for anything.

While the pandemic is over, these problems continue. America is far too dependent on Communist China and other foreign producers, and our supply chains will be massively disrupted when Xi decides to invade Taiwan. I do not think it is a question of if. I think it is a question of when.

If we do not take action to fix this now, the supply chain disruption that will occur when Communist China strikes Taiwan will be extreme and cause unbearable pain for the United States and every American family. No one will be safe from the impact of supply chain disruption if we continue down our current path. Prices will skyrocket even higher; product shortages will be widespread and severe. I mean, I just cannot imagine that we are buying essential items like medicines, technology, household goods, you name it. Everything is going to be affected, and I do not know why we buy anything from Communist China.

But today we want to focus on medicine and the pharmaceutical supply chains that our military depends on. I am glad we have this opportunity to discuss how pharmaceutical safety, quality, and supply chain issues affect our warfighters. I think we all agree that America's dependence on Communist China and other foreign producers for medicines is a significant problem, and it does not appear to be addressed.

I have been fighting for legislation to get this fixed. My American Drugs Act will create a strong incentive for companies to invest in domestic pharmaceutical production, address the ongoing drug shortages, and work to prevent future ones, and shift away from reliance on Communist China. The American Drugs Act seeks to fix this problem by leveraging the buying power of the Federal Government and requiring Federal health programs to purchase American-manufactured generic drugs if there are two or more manufacturers of a generic drug. I think this bill is needed, given the issues we face today, and as the Chair said, it is not a little bit of money that our defense industry is buying. It is billions of dollars every year.

The Department of Defense recently conducted a pharmaceutical supply chain study, as required by 860 of the fiscal year 2020 National Defense Authorization Act, and I want to thank Chair Warren for leading that effort. This study revealed the Department has a high dependence on foreign material and foreign trade agreements to maintain current pharmaceutical capabilities. I do not know anybody in their right mind who trusts anything made in China. The report shows that 54 percent of the pharmaceutical in-

redients that encompassed the products on the FDA's Essential Medicines List, being the critical pharmaceuticals that the Department should have access to, are from sources that are at a high risk of disruption. Who would do that? Only a quarter of the drugs on the list have domestic manufacturers.

As I mentioned earlier, during COVID we learned the hard way that relying on non-allied countries for our medical supply chain poses a real danger. For that reason it is imperative that we work to ensure DOD's supply chains are independent from non-allied nations for necessary pharmaceutical treatments. In the future these supply chains could easily cease to exist, and I assume they will when China invades Taiwan.

I am also working on legislation that would have the DOD work with manufacturers to buildup our domestic pharmaceutical manufacturing base. If we have a drug shortage of antibiotics, where about 90 percent of the key inputs to make those drugs come from China, it becomes a readiness issue because our strength comes from a ready and health warfighter.

About 90 percent of the drugs dispensed at the pharmacy are generic drugs, but a country like China-controlled generic drug manufacturing makes us more dependent as we ramp up for possible conflict.

Today I look forward to hearing from both the Defense Logistics Agency and the Department of Defense Health Agency to discuss the findings of the Department's pharmaceutical supply chain study and their ongoing work to study and secure these supply chains.

In addition to focusing on pharmaceutical supply chains' security we must address the specific medical countermeasure needs of the warfighter. The Walter Reed Army Institute of Research has a Pilot Bioproduction Facility that can aid the transition phase from research and development to early stage clinical trials for warfighter-specific vaccines and biologics. While this effort is small in scale, it is important that we discuss the success that General Bailey and his team have found in keeping our warfighter healthy and combat ready.

History shows us that infectious diseases have a high morbidity rate in theaters of war. As we look toward the pacing threat in the Pacific I would like to understand the medical challenges that our troops will face, what innovative tools and improve medical countermeasures in advance of a contingency.

Last, we will discuss the ongoing pilot program on quality and safety of pharmaceuticals. The Department of Defense Uniformed Services University of the Health Sciences is leading a pilot program to assess pharmaceutical product quality in the military health system pharmaceutical supply chain. While this pilot program is in the early stages, we utilize the military health system as a representative example to conduct a thorough review of the pharmaceutical supply chain to include a risk assessment analysis of our domestic manufacturing capacity and analytical testing of drug products from various suppliers.

I am deeply concerned by our lack of resiliency and transparency in this area. I look forward to hearing the results of this study over the coming years. I want to thank all of you for being here, and

I simply do not understand how we ever got ourselves dependent on China and why we are not doing more to get it done.

Senator WARREN. Thank you very much. Thank you, Senator Scott.

As I said, our first panel is going to be about drug shortages and R&D for the Department of Defense. From my left to my right we have Dr. Mark Dertzbaugh, Principal Assistant for Research and Technology for the U.S. Army Medical Research and Development Command; we have with us Dr. Martínez-López—it is good to see you—Hon. Dr. Lester Martínez-López, Assistant Secretary of Defense for Health Affairs at the Department of Defense—welcome; Dr. David Smith, Deputy Assistant Secretary of Defense for Health Readiness, Policy and Oversight at the Department of Defense; and Mr. Matthew R. Beebe, who is Legislative Affairs Director at the Defense Logistics Agency.

I understand, Dr. Lester Martínez-López, that you are going to give a joint statement to get us started?

Dr. Martínez-López and Mr. Beebe, as well.

Senator WARREN. All right, and then Mr. Beebe will speak. Thank you. You are recognized, Dr. Lester Martínez-López.

JOINT STATEMENT OF HON. LESTER MARTÍNEZ-LÓPEZ, ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, DEPARTMENT OF DEFENSE; DAVID J. SMITH, M.D., DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR HEALTH READINESS POLICY AND OVERSIGHT, DEPARTMENT OF DEFENSE; AND MARK DERTZBAUGH, M.D., PRINCIPAL ASSISTANT FOR RESEARCH AND TECHNOLOGY, UNITED STATES ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND

Dr. MARTÍNEZ-LÓPEZ. Chairwoman Warren, Ranking Member Scott, and distinguished Members of the Senate Armed Services Committee, I am pleased to represent the Office of the Secretary of Defense to discuss the Department of Defense's commitment to ensure access to safe and effective pharmaceutical products we procure and use in the Military Health System.

In this testimony we will inform the Committee about the Department's initiative to maintain a secure pharmaceutical supply chain, assuring our MHS beneficiaries receive the highest quality pharmaceutical products available.

Over the past few decades, production of most American generic drugs, and particularly the ingredients needed to make them, has moved overseas. With this movement, national security supply chain concerns arise. Similar to civilian health care groups and other parts of the U.S. Government, the Department's core areas of concern are unstable sourcing of pharmaceutical and/or active pharmaceutical ingredients and the availability of domestic manufacturing for contingency scenarios.

Consistent with the National Biodefense Strategy, Section 3.5, "Guidance on Agile Therapeutic Development and production," and Executive Order 14017, "America's Supply Chains," the Department is taking a range of actions to address these vulnerabilities. Specifically reference to the MHS policy efforts, the Department's pharmacy and medical logistics teams established a Pharmacy Supply Chain Risk Management Working Group. This group leverage

existing and new assessments of all aspects of the supply chain, with focal areas on the critical pharmaceuticals for beneficiary care that are on the Joint Deployment Formulary. We have begun the development of policies and procedures based on this effort to enable allocation of resources in the case of supply chain disruption.

Another effort to generate insights, led by the Uniformed Services University of the Health Sciences, we are evaluating aspects of the MHS pharmaceutical supply chain, to include domestic manufacturing capability, documentation of the supply chain, and supply chain security and resilience. Our objective, through our research initiative, is to generate meaningful and actionable information on drug and active pharmaceutical ingredient supply chain resiliency. Using the MHS as a representative example, this study will conduct a thorough environmental scan of the pharmaceutical supply landscape, including a risk assessment, analysis of the domestic manufacturing capacity, and examination of the pharmaceutical supply chain, analytical testing of drug products from various suppliers, and study of proposed scoring systems and the associated policy considerations. Through this study the MHS will gain insights into which manufacturers, and associated supply chains meet reliability essential to the Department's Joint Deployment Formulary.

In addition to the USU-led work, the Defense Health Agency Research and Development focuses on developing novel solutions at Walter Reed Institute of Research. At WRAIR, structural and computational biologists harness the latest generation in electron microscopy, the next generation in sequencing, monoclonal antibody generation, machine learning technologies and novel adjuvants in design of the next-generation vaccine candidates, which are then tested in preclinical models.

Through a range of efforts evaluating the supply chain vulnerability and resiliency we hope to drive more effective care while preparing for any potential shortfalls in supply chain.

In conclusion, I would like to sincerely thank you for your continued support of military medicine and for inviting me here to discuss the important issues surrounding the health of our warfighters and our DOD beneficiaries. I look forward to your questions.

[The prepared statement of Dr. Martínez-López follows:]

PREPARED STATEMENT BY DR. LESTER MARTÍNEZ-LÓPEZ, ASSISTANT SECRETARY OF
DEFENSE (HEALTH AFFAIRS)

Chairwoman Warren, Ranking Member Scott, distinguished Members of the Senate Armed Services Committee, I am pleased to represent the Office of the Secretary of Defense to discuss the Department of Defense's (DOD's) commitment to ensure access to safe and effective pharmaceutical products we procure and use in the Military Health System (MHS). We are honored to represent the dedicated military and civilian medical professionals in the MHS, providing direct support to our combatant commanders and delivering or arranging health care for our 9.6 million beneficiaries.

The Department's primary mission is to defend the Nation. As codified in DOD policy on supply chain management,¹ we focus on identifying, monitoring, and assessing the security risks and potential disruptions within and outside of the DOD supply chain to mitigate the risk to supply chain operations that may impact avail-

¹DODI 4140.01, March 6, 2019 (whs.mil)

ability or quality of material solutions. As it relates to the pharmaceutical supply chain, fulfilling this mission means our MHS beneficiaries, including our warfighters, have ready access to quality pharmaceutical products to ensure their best health outcomes and to optimize the health readiness of the Force. Considering pharmaceutical supply chain vulnerabilities, and in line with our mission of maintaining a ready medical force, we have a responsibility to identify and evaluate these emerging threats and develop data informed solutions to mitigate them.

In this testimony, we will inform the Committee about the Department's initiatives to maintain a secure pharmaceutical supply chain assuring our MHS beneficiaries receive the highest quality pharmaceutical products available. We will specifically focus on opportunities to enhance security of the supply chain, generate information necessary for contingency planning and response, and the potential for financial savings to the MHS.

Over the past few decades, production of most of America's generic drugs and particularly, the ingredients needed to make them, has moved overseas. With this movement, National Security supply chain concerns arise. Similar to civilian healthcare groups and other parts of the U.S. Government, the Department's core areas of concern are unstable sourcing of pharmaceuticals or active pharmaceutical ingredients and availability of domestic manufacturing for contingency scenarios.

Consistent with the National Biodefense Strategy section 3.5, "Guidance on Agile Therapeutic Development and Production," and Executive Order 14017, "America's Supply Chains," the Department is taking a range of actions to address vulnerabilities. Specifically to the MHS efforts, my office has several efforts. The Department's pharmacy and medical logistics teams established a Pharmacy Supply Chain Risk Management Working Group. This group leverages existing and new assessments of all aspects of the supply chain, with focal areas on the critical pharmaceuticals for beneficiary care that are on the on the Joint Deployment Formulary. We have begun the development policies and procedures based on this effort to enable allocation of resources in the case of supply chain disruption.

Another effort to generate insights, led by the Uniformed Services University of the Health Sciences (USU), is evaluating six aspects of the MHS pharmaceutical supply chain, to include: domestic manufacturing capability, documentation of the supply chain, and supply chain security and resilience. Our objective, through our research initiative, is to generate meaningful and actionable information on drug and active pharmaceutical ingredient (API) supply chain resiliency. Using the MHS as a representative example, this study will conduct a thorough environmental scan of the pharmaceutical supply landscape, including a risk assessment, analysis of the domestic manufacturing capacity, and examination of the pharmaceutical supply chain, analytical testing of drug products from various suppliers, and study of scoring systems and the associated policy considerations. This pilot study will generate data pertaining to essential drugs for military operations. Through this study the MHS will gain insights into which manufacturers, and associated supply chains meet reliability essential to the Department's Joint Deployment Formulary. By creating more transparent information concerning supply chains that are able to consistently deliver quality medications, this study may enable manufacturers to be able to better compete and allow major purchasers of drugs, like the DOD, to direct our purchasing to best value manufacturers.

USU has begun work on the first part of the study, "A Comparison of Essential Medicines Lists from Three Agencies," that will compare the publicly available essential medicines lists of the DOD, the FDA, and the World Health Organization. Future studies will include evaluation and risk assessment of the DOD drug supply chain, an analysis of domestic drug manufacturing capability, and study of a proposed scoring tools for drug quality.

In addition to the USU led work evaluating existing products, the Defense Health Agency Research and Development (DHA R&D) focuses on developing novel solutions. DHA R&D has a long history of researching and developing new medical technologies in support of readiness and health care for servicemembers from accession, through training, deployment, and medical treatment on the battlefield. This research and development also led to new technologies and vaccines that have saved countless lives across the world. The committee has asked for more information on the capabilities at the DHA's Walter Reed Army Institute of Research (WRAIR).

WRAIR is one of our premier laboratories at the center of researching and developing such new technologies and vaccines.

The WRAIR conducts vaccine research in partnership with industry, other US government partners academic, and international research partners. At WRAIR, structural and computational biologists harness the latest generation in electron microscopy, the next generation in sequencing, monoclonal antibody generation, ma-

chine learning technologies and novel adjuvants to design innovative next-generation vaccine candidates, which are then tested in preclinical models.

WRAIR's Pilot Bioproduction Facility, or PBF, manufactures test batches of vaccines of military relevance for use in human clinical phase 1 and early phase 2 trials. Vaccine candidates manufactured at the PBF can then transition to the WRAIR Clinical Trials Center, and subsequent expanded field testing. Through WRAIR's forward deployed directorates centered in Thailand, Kenya, and the Republic of Georgia, WRAIR maintains enduring relationships with clinical research centers in over 10 countries around the globe. WRAIR has led pivotal trials for dengue, malaria, chikungunya, Lassa, Ebola, and HIV vaccine products. Additionally, WRAIR has developed intellectual property behind two Shigella vaccine candidates currently in phase 2 clinical trials.

Through a range of efforts evaluating the supply chain vulnerability and resiliency we hope to drive more effective care while preparing for any potential shortfalls in supply chain. In parallel, we seek to contribute along with our USG, academic, and industry partners to develop novel solutions to future health threats from capability to delivery.

In conclusion, I would like to sincerely thank you for your continued support of military medicine and for inviting me to be here with you today to discuss the important issues surrounding the health of our warfighters and our DOD beneficiaries. I look forward to your questions.

Senator WARREN. Thank you, Mr. Secretary. Mr. Beebe?

**STATEMENT OF MATTHEW R. BEEBE, DIRECTOR OF
ACQUISITION (J7), DEFENSE LOGISTICS AGENCY**

Mr. BEEBE. Good afternoon, Madam Chair, Ranking Member Scott, and distinguished Members of the Senate Armed Services Personnel Subcommittee. Thank you for the opportunity to testify today. My name is Matt Beebe. I am the Senior Procurement Executive for the Defense Logistics Agency, or DLA, a Department of Defense combat support agency. I am grateful to have the chance to speak to you today about some of the work DLA is doing to improve visibility and transparency within the DOD pharmaceutical supply chain and ensure that our military servicemembers have access to safe, high quality pharmaceuticals.

DLA's mission is to deliver readiness and lethality to the warfighter always, and support our nation through quality, proactive, global logistics. In support of that mission, DLA manages the full spectrum of pharmaceuticals for the military and their dependents all over the world, to include supply to military hospitals.

Although our military customers set pharmaceutical requirements based upon the needs of today's warfighters, it is DLA who purchases those products and manages critical end-to-end supply chain logistics to ensure that military servicemembers get the pharmaceuticals they need, when they need them. We accomplish this by leveraging commercial capabilities and contracting with commercial distribution companies who use their global networks of sources to deliver FDA-approved medicines to servicemembers at military treatment centers or wherever they are located throughout the world.

In line with our logistics mission and to better serve our customers and the warfighter, DLA is always seeking to improve our ability to identify, manage, and mitigate logistical and supply chain risks, including those impacting pharmaceutical supply chains.

One area of focus in this issue is foreign dependency of pharmaceuticals. A 2021 report by the DOD inspector general identified that due to the dependency of the U.S. commercial pharmaceutical market on ingredients from foreign suppliers, a disruption of the

supply chain of those ingredients to domestic manufacturers had the potential to cause drug shortages, which could ultimately compromise the standards of care for military servicemembers.

Similarly, in November 2023, DOD submitted a report in response to Section 860 of the National Defense Authorization Act for fiscal year 2023, regarding risks in DOD pharmaceutical supply chains. In that report, DOD identified the defense supply chain for pharmaceuticals is highly dependent upon foreign or unknown sources, in large part due to the global nature of the pharmaceutical supply chain for both finished products and active pharmaceutical ingredients, or APIs.

DOD identified several pervasive information gaps that hinder its ability to obtain visibility and transparency in these supply chains, particularly the lack of readily available and authoritative data on the sources of finished generic drugs, their APIs, and other key ingredients. Having this information would significantly improve our ability to illuminate the complex pharmaceutical supply chain and help DOD ensure that our military servicemembers continue to have access to safe, high-quality pharmaceuticals.

As the provider of critical pharmaceutical products to our Nation's warfighters, we are steadfastly committed to working with the Department, other Federal agencies, and Congress to strengthen our collective ability to identify, mitigate, and prevent risks in the pharmaceutical supply chain.

DOD and the Department sincerely appreciate your interest in these issues. I look forward to addressing your questions.

[The prepared statement of Mr. Beebe follows:]

PREPARED STATEMENT BY MATTHEW R. BEEBE

Thank you for the opportunity to testify before the Senate Armed Services Personnel Subcommittee. As the Senior Procurement Executive for the Defense Logistics Agency (DLA), I am here to discuss the report submitted by the Department of Defense in November 2023 pursuant to Section 860 National Defense Authorization Act (NDAA) for fiscal year 2023 regarding risks in DOD pharmaceutical supply chains.

DLA is a combat support agency. We manage end-to-end, global supply chain logistics in support of the services and Combatant Commands. DLA's mission is to deliver readiness and lethality to the Warfighter Always and support our Nation through quality, proactive global logistics. As part of that mission, DLA procures and manages the full spectrum of pharmaceuticals for the military and their dependents all over the world, to include supply to military hospitals. DLA is DOD's largest purchaser of these products, acquiring \$5.3 billion of pharmaceutical products in Fiscal Year 2023. In addition, DLA comprises approximately 23 percent of the total Federal demand. Other major Federal Government purchasers include the U.S. Departments of Veterans Affairs and Health and Human Services, for a total of \$22.9 billion in fiscal year 2023 for the entire Federal Government. Although the total Federal Government spend is considerable, it represents a very small percentage of global demand.

DLA's pharmaceutical purchases are driven by the needs of its defense customers, primarily the Defense Health Agency (DHA). DLA executes its defense supply mission through the pharmaceutical prime vendor program, which leverages commercial capabilities and efficiencies to meet DOD needs. DLA contracts with commercial manufacturers and distributors to satisfy customer requirements for pharmaceutical products through integration with commercial supply chains.

The Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services (HHS) regulates the U.S. commercial medical products, including pharmaceuticals. DOD leverages commercial pharmaceutical supply chain capabilities. DOD is supported by the commercial medical industrial base and provides medical treatment and care for the U.S. Military. Within DOD, DHA manages the personnel, facilities, treatment protocols, and requirements of the military

healthcare system. In turn, DLA supports DHA and other defense customers by procuring the pharmaceutical supplies and services needed by the Department, based upon the requirements and specifications defined by its customers.

The issue of foreign dependency in pharmaceuticals has been a recognized risk for some years. A 2021 DOD Inspector General report, “Evaluation of the Department of Defense’s Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain,” found that “[a] disruption of the supply of foreign-made APIs to domestic manufacturers could cause a drug shortage that affects every level of the U.S. health care system. Since the DOD is a consumer of the U.S. commercial pharmaceutical market, which is dependent on ingredients from foreign suppliers, these potential drug shortages could ultimately compromise the standard of care for military servicemembers and DOD beneficiaries. Implementing measures to mitigate the risks of a pharmaceutical supply disruption would provide a defensive capability and mitigate public health and national security risks.”

In recognition of these risks, DLA began developing the Pharmaceutical Provenance Solution (PPS) in 2021, a cloud-based software solution that uses various data bases, including the publicly available, Food and Drug Administration Drug Shortage Data base, to help provide visibility and analytics of the country of origin and sources of supply of finished drugs, active pharmaceutical ingredients (APIs), and excipients. PPS provides insight into a variety of factors related to pharmaceutical supply chain risks.

The Section 860 report primarily focused on foreign dependence on active pharmaceutical ingredients (API), which is one of a variety of potential risks and vulnerabilities within pharmaceutical supply chains. As referenced in the report, DOD is in process of developing the Supply Chain Risk Management (SCRM) Framework and Taxonomy with implementation guidance, as well as the SCRM governance process. The Department utilized the PPS when creating the Section 860 report to help identify sources of supply risks. The report findings are based upon the results of an initial DOD pharmaceutical supply chain analysis examining 1,744 drug families, which equates to 12,917 specific drugs, identified by national drug codes, or about 10 percent of the total drugs available in the U.S. marketplace.

As referenced in the report, based upon this initial supply chain analysis, DOD identified a high dependence on foreign material and trade agreements to maintain current pharmaceutical capabilities. Although 28 percent of the APIs are sourced from North America and are considered at least moderately secure, 5 percent are sourced from China, and 22 percent are unknown. In total, DOD identified that 54 percent of the DOD pharmaceutical supply chain is considered either high or very high risk, with dependency on non-Trade Agreements Act (TAA) compliant suppliers, as defined in the Section 860 report, sourcing from China and India, or unknown.

In addition to identifying the degree of overall foreign dependency for DOD procured products, the section 860 report identifies the following mitigations and recommendations in consideration of mitigating risk on foreign dependence:

- Work with the Military Services and other DOD Components regarding transition to TAA-compliant viable therapeutic API alternatives.
- Pursue efforts to validate sources of supplies/production capacity from industry.
- Enhance PPS capabilities.
- Engage suppliers of pharmaceuticals with Unknown country of origin to determine source of API and update in PPS data base.
- Work with relevant Federal stakeholders to support domestic production of finished generic drugs, APIs, and key ingredients.
- Focus on utilization of secure ingredient sources following DLA’s sourcing hierarchy.
- Partner with the FDA and other Federal stakeholders to facilitate provision of the necessary business intelligence to determine the source for the finished drug, API and key ingredients acquired by the Federal Government.

The information provided by PPS has enhanced DLA’s ability to share information with customers and other stakeholders to develop risk mitigations and actions to address potential shortages and issues of availability. Additionally, DOD participates in the HHS Joint Supply Chain Resilience Working Group. The formal Working Group operates under the authority of the Critical Infrastructure Partnership Advisory Council and facilitates engagements between government representatives at the Federal, State, local, tribal, and territorial levels and representatives from critical infrastructure owners and operators to conduct deliberations and form consensus positions to assist the Federal Government in developing resiliency.

Going forward, DOD anticipates that insight into pharmaceutical supply chain risks will improve as additional information is gathered and risk assessment capabilities are further refined; however, pervasive information gaps remain. The Department identified the lack of authoritative data on the sources of finished generic drugs, their APIs, and other key ingredients as a critical DOD information gap. In the report, DOD recommended that manufacturers of pharmaceuticals sold in the U.S. provide definitive information on the production location of all their finished drugs and the source of all APIs and key ingredients, and the percentages of APIs and key ingredients coming from each source, for each lot produced. The current lack of manufacturer production and sourcing data for generic drugs hinders DOD's ability to obtain visibility and transparency within the supply chain. That in turn makes it more difficult for DOD to identify areas of risk. Obtaining this information and having it available to Federal stakeholders responsible for assessing and mitigating vulnerabilities to our Nation's pharmaceutical supply chain would increase our collective readiness and facilitate development of solutions to address foreign dependencies.

I want to thank you for your interest in this important topic and the important work the DLA is doing to bring greater visibility and transparency to the DOD pharmaceutical supply chain. As the provider of critical pharmaceutical products to our Nation's warfighters, we are steadfastly committed to working with the Department, other Federal Departments and agencies, and Congress to strengthen our collective ability to identify, mitigate and prevent risks in the pharmaceutical supply chain.

Senator WARREN. Thank you, Mr. Beebe.

I am going to start with the first round of questions. The Defense Health Agency provides care for about 9 million people in the military health system, and that includes by dispensing prescription drugs to servicemembers and to their families.

Earlier this month, the American Society of Health System Pharmacists announced that there were a record 323 active drug shortages during the first quarter of 2024. That is an all-time high in the United States.

Dr. Martinez, you are in charge of ensuring the health and safety of our servicemembers. When DHA cannot get a critical drug because it is in shortage, can you just explain to everyone what options you have to ensure that servicemembers and their families are receiving the care they need?

Dr. MARTÍNEZ-LÓPEZ. Chairwoman, thank you for the question. You know, the health of our beneficiaries is of most importance to all of us, and when you face the issue of not having the drug, the right drug for that patient then your choices are to go and look at alternate drugs that may not be exactly the same one for that condition or for that patient. It may have a different side effect profile.

So let me give you an example. Amoxicillin may be a drug. It is an antibiotic, made overseas, and used everywhere for basic infections. But let's say I do not have it. Now I have to take other antibiotic, and at the same time I am trying to combat resistance of antibiotic. I am using an antibiotic that is not indicated for that condition. So there I lose twice, once because I am not giving the right antibiotic to my patients but on top of that I am losing ground on my fight against antibiotic resistance.

In other events, like in an epinephrine injection, that can be life or death. We do not have hours to decide what the alternate is. So that may translate into a life, right on the spot.

So this creates a conundrum for all health care professionals, and it is not just us. It is across the Nation we are facing this.

Senator WARREN. Okay. So worse health outcomes for the patient and worse health outcomes for the system overall, is what I am hearing you say.

According to the FDA, one of the leading factors contributing to drug shortages is quality issues. For example, an FDA inspection of a manufacturing plant in India revealed a, quote, “cascade of failure” at the plant’s quality control unit. Investigators found problems with systems to prevent microbial contamination, to keep processing areas sterile, and to protect critical production documents, including they found a trash bag full of records that had been torn and doused in acid. The plant temporarily closed, resulting in widespread shortages of common chemotherapy drugs across the United States, affecting both civilian and servicemembers.

As more of our drug supply chain moves overseas, these kinds of quality concerns are going to become even more common. So last summer, DOD launched a pilot with an independent lab to test drug products for safety and effectiveness. For example, it will test whether the drug contains any contaminants, whether it contains the correct dosage, and whether it has the expected potency.

The pilot study is going to look at 12 drugs on DOD Operational Medicines List, which includes drugs that are necessary for warfighting, and its Predeployment Medicines List, which includes drugs that help servicemembers control chronic conditions to meet standards for deployment. Together the pilot will test medicines needed to stabilize wounds, alleviate pain, and treat infections.

Dr. Smith, can you share why DOD thought it was necessary to conduct this pilot study?

Dr. SMITH. Thank you for the question, Senator Warren. As we have noted, we are most concerned about ensuring the access to safe and effective drugs, and as you noted we are doing a number of studies. The 860 study that we have referred to and then also the study for the Uniformed Services University, that is evaluating, in particular, a quality scoring tool by DeBastiani, that was published in the Journal of the American Pharmacy Association just last year as an additional factor for us to consider as we purchase medications on the market, and you pointed out the various FDA recalls and the issues that have been coming up.

Additionally, we have heard that within the generics, where there are multiple manufacturers using the same API, that there may be a variance in those generics. So we thought with all of those factors it would be useful to conduct this pilot study that you referred to, that ultimately will look at 42 drugs from our Joint Deployment Formulary, to see if we can differentiate between the generics and make us actually a better buyer and actually reward manufacturers that produce the product that is spot on. Over.

Senator WARREN. Good. So you are talking about a study that you are doing because you hear a lot of problems out there, and also this may help you figure out how to respond to those going forward. Is that a fair summary?

Dr. SMITH. I think that is fair.

Senator WARREN. Good. Good. So when DOD is making decisions about purchasing drugs, price is often the most important consideration, but it should not be the only consideration. Whether a drug is made by a reliable manufacturer or whether its active ingredi-

ents are made, and where they are made should also inform purchasing decisions.

The Defense Logistics Agency is responsible for procuring pharmaceuticals on behalf of the Military Health System, but DHA can put requirements on the purchases. Dr. Martinez, if DOD identifies significant risks to the safety of its drug supply chain will DHA add requirements on drug quality to ensure that we are buying effective, safe, the best drugs for our servicemembers?

Dr. MARTÍNEZ-LÓPEZ. Senator, based on the information the pilots give us, I think we will be in a position to, if that is indicated, to make it so.

Senator WARREN. Okay. So you can put that into your requirements, and you are telling me that if you are concerned about quality you will put it into your requirements.

Dr. MARTÍNEZ-LÓPEZ. Yes.

Senator WARREN. For the drug. Good. That is what I want to hear. You know, I am glad that DOD has taken steps to evaluate drug quality, and the Department should be prepared to use this information to improve quality and accessibility of the prescription drugs that our servicemembers need. Thank you.

Senator SCOTT?

Senator SCOTT. Thank you. Mr. Beebe, how many different drugs do you buy in a year? How many different ones?

Mr. Mr. BEEBE. Well, our catalog probably is in the tens of thousands of items. Of course, that is not all different drugs. In some cases it is dosage differences, application differences.

Senator SCOTT. Okay. Tens of thousands. All right. Do you personally believe that we should not buy things from Communist China?

Mr. Mr. BEEBE. I agree basically, or in reality we follow existing regulation on how and where to buy materials, whether it be pharmaceuticals or other items.

Senator SCOTT. Sure. But do you believe that we should not buy from Communist China?

Mr. Mr. BEEBE. I agree, sir.

Senator SCOTT. Okay. So in the last 12 months, how many drugs have we stopped buying from Communist China?

Mr. Mr. BEEBE. When we buy pharmaceuticals we buy with a preference toward domestic or safe, assured sources, although in many cases we do not know where the sources are. Normally we buy from domestic or our trading partners, but we do not always have visibility of where the ingredients of those pharmaceuticals come from, which is why it was so important for us initiate the study and identify where we believe the sources of the ingredients are.

Senator SCOTT. But today you could just say, "I am not going to buy anything that has an ingredient that comes from Communist China. You could say, "I am not going to buy anything that has an ingredient from Communist China. I am not going to buy anything that is packaged in Communist China. I am not going to buy anything that is in any way in the supply chain impacted in Communist China." You could do that today, right?

Mr. Mr. BEEBE. Actually, I do not believe the regulation actually supports that, in that very often the final product is manufactured

domestically or from an ally, and if it is substantially transformed in those countries it is in accordance with trade agreements in the Buy American Act.

Senator SCOTT. So what is the limitation? Why can you not make that decision today?

Mr. Mr. BEEBE. Because often the final product is manufactured either domestically or with an ally—

Senator SCOTT. But you could set that as a standard and then it is a requirement—you could set the standard that whatever you buy can have nothing, anywhere in the supply chain, comes from Communist China. You could decide that today.

Mr. Mr. BEEBE. If that standard exists, yes, but that is not for DLA to decide. We have to follow existing regulations and policy and—

Senator SCOTT. Who set regulations that said you could not—the Secretary of Defense testified the other day that we should not buy anything from Communist China. So what regulation would it be?

Mr. Mr. BEEBE. That would establish that?

Senator SCOTT. Yes. What regulation would stop you from being able to do it today?

Mr. Mr. BEEBE. I cannot say what that regulation would be, but I certainly support being part of the discussion with the Department of Defense.

Senator SCOTT. Why don't you just do it. Just do it and see what happens. Why don't you just say tomorrow, you just do it. Like I am a business guy. I negotiated contracts with people. I ran the largest hospital company in the country. I was the biggest buyer of pretty much everything in health care on the provider side, and once I signed a contract I said our hospitals could not buy anything that day. They said, like that, and we are not going to buy those gloves, that drug, that device. Why don't you just do it?

Mr. Mr. BEEBE. We do not buy end products from China unless it is the only source available and we can justify the waiver.

Senator SCOTT. So you believe that if there is a product that there is a supplier in the United States today, you do not buy anything made in China if there is supplier of that product today?

Mr. Mr. BEEBE. If the end product is available domestically, that is where we will buy it, yes.

Senator SCOTT. Do all of you believe that? So if come back and tell you that there are suppliers here that compete with China, that cannot get contracts with you, you will be shocked.

Mr. Mr. BEEBE. If we are talking about the end product, yes.

Senator SCOTT. What is the difference?

Mr. Mr. BEEBE. Well, much of what we are talking about is the active pharmaceutical ingredients that originate from China that get molded into a final product. When we buy the final product we are buying it from the United States or a domestic trading partner, and we cannot, until recently, see whether or not there were some ingredients from China or other country of concern. It was not visible, and we are working to make it visible.

Senator SCOTT. But why don't you just say, starting today you will not contract, just put it out there, you are not going to contract with anybody if anything—not just the active ingredients—there is no part of the process where Communist China is involved in it.

There is none. Or Russia, Iran, but primarily Communist China. Why don't you just do it right now?

Mr. Mr. BEEBE. If we made that absolute then we would be creating a sufficient amount of non-availability for our health professionals.

Senator SCOTT. But if you do not do it today, when are you going to do it? I mean, if you do not start today, I mean, when are you going to do it? If you do 10,000, why don't you start off with 1,000 and see how bad it is? I mean, I am just a business guy, and I did not buy from my competition. This is not competition. These people are trying to kill us. Oh, they are killing us. I mean, Chinese precursors are killing 70,000 people with fentanyl a year. So why don't you just do it?

What I am trying to understand is, I think all of you agree Communist China wants to destroy our way of life. I think we all would, right? Does anybody disagree?

[No response.]

Senator SCOTT. Nobody disagrees. So let's do it today. What I do not understand is why don't we do it today? I just do not get it. Can somebody explain to me why we do not?

Dr. SMITH. Sir, there are some of the APIs that only originate from China, that are critical to medications that we use on a daily basis, and so that would be one of the impediments that needs to be resolved to be able to go that direction, sir.

Senator SCOTT. So, Dr. Smith, how many is that?

Dr. SMITH. I am aware on the Joint Deployment Formulary, and this is specifically China, and as Mr. Beebe pointed out we have an issue with provenance on a fair percentage of our Joint Deployment, but I am aware, I believe—and I can take it for the record—27 drugs that the APIs are specifically only sourced from China.

Senator SCOTT. Have we put out a bid for Americans to say, will somebody do it, on those, those 27?

Dr. SMITH. As part of our work on 860, it is part of what we are going through to confirm and work solutions to this issue. But we are well aware that there is a substantial amount of the APIs, the active pharmaceutical ingredients, that are coming from Mainland China. Over.

Senator SCOTT. So that is not 27 out of 10,000, right?

Dr. SMITH. I should probably take it for the record, sir, and we can give you the information. But I think it is 27 out of 920, or so.

Senator SCOTT. Okay. I am sorry.

Senator WARREN. No, no. That is fine.

Senator SCOTT. I just want to understand why we do not do it today. I mean, in business we would just say, guys, we had a nice meeting. We found out that these people are trying to destroy it, and we just say, okay, guys. We all decide, as of today, we will not do business with them. We do that in business all the time. I do not know why we just do not do that. I do not know what the limitation is. If there is a limitation, I want to all—the Secretary of Defense has told me he does not want to buy anything from China.

Dr. MARTÍNEZ-LÓPEZ. Sir, if I may, the main limitation we have right now, like Dr. Smith said, is that some of these drugs, the API is only made in China, and that is in the global market. So if we decide not to buy Chinese, I mean, I think the number is around 5

percent of it, that we know of, of all the drugs in the formulary, that the API comes from China, and we do not know about 20-something percent of them where the API comes from. So that creates a conundrum. So if we could source it some other place, that would be great.

Senator SCOTT. Okay. So why would we not do this. There are all these different options. Number one, what I would do is just say I am not going to do it, and everybody has to sign a contract that they will not do it, and let's see what happens. I guess they will come back and tell us, right. Or we could say you have got 90 days to tell us where all your ingredients come from, and then we could make a decision. But, I mean, in my business life I would not say, "Let's do a study." I would say, "No, I am not going to do it."

I am just trying to figure out, if there is an impediment, just tell me what it is. Are you in the same position I am?

Senator WARREN. Yes, and I want to followup on your point. Okay, I just want to followup on this about the risks we run from having overseas manufacturing that is either in China or some other nation that is not an allied nation, because they all pose this risk and we need to worry about it.

I mentioned in my opening remarks that Senator Rubio and I got a provision in the fiscal year 2023 NDAA for DOD to put together a report, and it came out last November, about drug supply chain risks in military, and evaluated 211 drugs. It found that half of those were either at high or very high risk because the active pharmaceutical ingredients, the APIs, for those drugs are sourced from China or non-Trade Agreement Act countries, or are just simply unknown, nobody knows where they are coming from.

So you identified, Mr. Beebe, that 27 APIs are sourced exclusively from China, but I would just point out that is only a little over 10 percent of the drugs. It is not half the drug we are talking about here. We have got a lot more drugs that if you right that it is only 27, then we have got a lot of other drugs that are being sourced overseas, that we think there is a substantial risk.

So the question becomes whether or not we should bring that manufacturing back to the United States. Is that in our national defense?

So let me put that question to you, Mr. Beebe. Should we be manufacturing these drugs domestically, and what is the risk if we keep running these manufacturing facilities overseas for China or non-Trade Agreement Act countries?

Mr. Mr. BEEBE. So yes, ma'am. First of all, Dr. Smith is the one that made reference to the 27—

Senator WARREN. Sorry. Sorry.

Mr. Mr. BEEBE.—but I will go ahead and address the question first. So yes, we studied the FDA Essential Medicine List, and that is what was the basis for the report that identified a high amount of APIs sourced in China or other non-TA countries. Since then we have doubled that population, adding some of the highest volume pharmaceuticals that are purchased by our medical treatment facilities, as well as the overlap with the Joint Deployment Formulary, to expand the amount that we have reviewed, and the results are essentially the same, by percentage, as in same percentage of those coming from countries of high risk as well as the same

percentage of unknown, which is, to me, equally troubling that I do not even know how to characterize the risk.

Do I support bringing more domestic capacity? Absolutely. I mean, not only does domestic capacity mean that we have better access, but it also means that the government can better influence prioritization when there needs to be decisions of priority.

Senator WARREN. Okay.

Mr. Mr. BEEBE. That is very important too. Yes, ma'am.

Senator WARREN. So let's talk a little bit about what is involved in increasing domestic manufacturing of these pharmaceuticals. Last summer, DOD released its inaugural DOD Biodefense Posture Review. This outlined the Department's capabilities to counter biothreats and identify domestic manufacturing as a priority reform initiative. According to the Posture Review, we have reduced drug manufacturing here in the United States so much that we simply do not have the commercial capacity to manufacture what our troops need, and because the Department's, quote, "unique biodefense demands" are small and not commercial competitive, reliable domestic manufacturing partners are actually hard to find.

But that is not the end of the story. DOD has its own manufacturing capabilities, capabilities with a proven track record of success. In 2017, DOD's Advanced Development and Manufacturing Biopharmaceutical Facility to help manufacture medical countermeasures became fully operational. DOD has a second biomanufacturing facility at the Walter Reed Army Institute for Research, WRAIR. The Walter Reed facility has developed many vaccines that DOD relies on today to protect our troops from a number of diseases, including Zika, Ebola, and adenoviruses.

Dr. Dertzbaugh, you help oversee WRAIR, and WRAIR has developed many essential products that both servicemembers and civilian populations use today. Can you explain why WRAIR was the best place to develop these discoveries rather than just leaving it to private industry?

Mr. DERTZBAUGH. Thank you, Chairwoman, for the question. I appreciate the opportunity to talk about DHA R&D's infectious disease research capabilities. Our two laboratories, the Walter Reed Army Institute of Research and then the U.S. Army Medical Research Institute of Infectious Diseases, have the capabilities and the subject matter experts to get after these infectious disease threats that our servicemembers might encounter when they are deployed overseas or fighting an adversary or even in training. So those capabilities help us find countermeasures for solutions to medical infectious disease threats that are not commercially viable in the U.S. because there is no market for this. There is no threat to the U.S. population, in general.

Senator WARREN. All right. That is very helpful. Thank you. Because WRAIR's Pilot Biopharmaceutical Facility has been crucial in addressing these potential threats and keeping our servicemembers safe, especially when private sector is not in a position to fulfill that role.

As DOD considers how to implement the recommendations it has identified on domestic manufacturing, the Department should also think about how to replicate the capabilities at facilities like

WRAIR to strengthen supply chain resilience and to keep our members safe and bring that manufacturing home. Thank you.

Senator Kaine?

Senator KAINE. Thank you, Madam Chair and Ranking Member Scott, and I appreciate the witnesses being here. I have two questions that I would like to ask. While reliance on APIs from foreign countries that are adversaries presents significant threats, the good news in this challenge is that we are not alone. Not every other country is an adversary. We have networks of alliances, unlike any of our adversaries.

I wonder whether, and maybe I will start with you Mr. Secretary, have we discussed this challenge with nations with whom we have close economic, military, diplomatic ties, and explored ways we can deal with those challenges in a joint way?

Dr. MARTÍNEZ-LÓPEZ. Thank you for the question, Senator. The answer is yes. Actually, we talked with a couple of allies, trying to figure out their ability to produce all the drugs that could use, and to their amazement and my amazement—

[Audio interruption.]

Dr. MARTÍNEZ-LÓPEZ.—we have to have a secure chain of supply. I owe it to my servicemembers—

[Audio interruption.]

Senator KAINE.—within the DOD, from antidepressants to—

Dr. SMITH. It is a wide range. Yes, sir.

Senator KAINE. What are we expecting to learn from this, and I suspect that if we do learn something from this data, the application is not just the military application. This would be good information in the civilian space, whether it is Medicare or civilian. It would be really good to have that.

Dr. SMITH. Yes sir, and I think as I had mentioned, we are looking at this quality tool that was actually proffered by a group of academic pharmacists last year to see whether or not, indeed, we can differentiate by manufacturer. So we are looking at all the in a particular drug and then doing this additional—I mean, clearly looking at all of the good work that FDA and the regulatory piece does, but then adding onto it testing, looking at potency, looking at the dose, and also looking at contaminants that may be used as fillers, et cetera, in the product.

Then if we find anything we have also contracted with three other academic institutions to do validation of that work. If it pans out, we think it will help us direct our buying toward those manufacturers that produce what we would define as the highest quality products. But it is a pilot, and that is why we have characterized it that way, because we do not know, and I do not think this has ever been tested, if you will.

Senator KAINE. I am talking about the timing of the pilot and when do you expect it to start, you know, getting good information back?

Dr. SMITH. It is to run 2 years. We started the actual work in November. They have just finished contracting with the—or I believe it is finished, but they are in the process with these third-party or additional partners. So we should start seeing beginning information. As Senator Warren said and you have, we are doing the first 12 right now. But our intention is to do about 42 different

drugs. So I would anticipate that clearly by early next year we will start flowing in, but the whole project is scheduled over a 2-year period.

Senator WARREN. Thank you. Senator Scott?

Senator SCOTT. Secretary, let's think about—because I think you are right, what you were talking about how we can use this whole buying power idea. So let's think about it. I have checked with the Chair to see if she would be okay with this. But could you prepare a letter that we would send out to basically all of the health care community—you know, we could do it through like the hospital association, pharmaceutical, everybody—and say this is the problem, you guys have the buying power, we believe we ought to create a domestic market, and so everybody starts doing their part.

So, the way I would think about doing it is, number one, if the Chair is okay with this, we would do it with you, and send a letter out to the entire health care community. I think they would probably read it if it came from you and from us, and talk about what you are doing, the concern that you have addressed today. Then maybe wait 30 or 60 days, and then invite all the associations together on a conference call to answer their questions, and get ideas from them about what we could do to help build a domestic market.

Dr. MARTÍNEZ-LÓPEZ. Senator, that is a very intriguing proposition. I have not thought about it. But really I would like to be part of it, but it has to be really the whole government. So ask for help from HHS and other agencies. HHS has the lead for the country in this particular issue, and obviously I would have to clear it with the Secretary to make sure that it is appropriate, and if it is, we will pursue it.

Senator SCOTT. So let's do this. If it is okay with the Chair, let's start with us. If we can get other people to sign on, HHS, all these people, that is great. If they do not, let's go forward if we can. If not, we can do it, if the Chair is okay with it, and then after that let's do a call and tell them why this does not work.

Dr. MARTÍNEZ-LÓPEZ. Senator, you may well know, we need to ask, but if I get that from my Secretary then I will be more than glad to lead the effort.

Senator SCOTT. Let me know, because he said in testimony that he did not want to buy anything from Communist China.

Then, Mr. Beebe, I think we all would like to have something happen. So could you come back, maybe—I do not know what is appropriate, whatever you think is appropriate—and maybe meet with the Chair and me and our staff and just say, okay, what is the limitation and what can we do today. If you tell us there is a limitation, then I think at least the three of us that are here, I think we are all on the same page—and it is just crazy that we are doing this to ourselves, and being dependent on China—we are all on Armed Services, and we will work hard to get it affixed to the NDAA. I do not know if that makes sense to you. Is that doable? Thirty or 60 days, is that realistic?

Mr. Mr. BEEBE. Yes, sir. I mean, absolutely, we want to be part of the solution. The illumination we are doing to try to identify the sources is the beginning of having some information to use toward that dialog, to figure out how we can move the market or adjust the market. I will be glad to respond.

Senator SCOTT. Let's try to do it in 30 days. The NDAA is coming up this year pretty quick now, because it is May 1 tomorrow, right. But the faster you can do it, the three of us will work with you.

Mr. Mr. BEEBE. I would offer that because that is very much a policy discussion that we would want to include the other stakeholders from the Department.

Senator SCOTT. Sure. But, I mean, we have Paul on our team, and I know you have great people on your team. We will work with you. But the faster we do it, there is a greater chance the three of us can get it in the NDAA this year.

Senator WARREN. Let's make sure we have got Mr. Dertzbaugh on this, as well, since I see WRAIR is the model for when the market has a complete breakdown and cannot produce what it is that our military needs.

Mr. DERTZBAUGH. Ma'am, if I may speak, that is true to a point, I would say. We certainly have the ability in our production facility to make small quantities of vaccines. It does not have the ability to make any drug products, though. We are still reliant on commercial manufacturers to produce large quantities of those materials if we are going to use them.

Senator WARREN. I understand that you are small, but successful. But I also understand, and I hope you are hearing here, all of you are hearing, how committed we are to redomesticating our pharmaceutical supply chain and production. I think you are going to be part of that, as well. Good. We good? Senator Kaine, you good?

Senator KAINE. I am good.

Senator WARREN. All right. Thank you all. I appreciate you being here today, and I ask for Panel 2 to come in. Thank you.

[Pause.]

Senator WARREN. Thank you. Thank you for being with us. The second panel will feature testimony that clarifies DHA's existing authorities to insulate servicemembers from drug shortages and offers additional solutions.

We have with us today, again from my left, Dr. Melissa Barber, a postdoctoral fellow at the Yale Collaboration for Regulatory Rigor, Integrity, and Transparency; Dr. Bryce H.P. Mendez, a Specialist in Defense Health Care Policy at the congressional Research Service; and Mr. Victor A. Suarez, a retired U.S. Army colonel, and Founder and Principal Growth Partner of Blu Zone Bioscience & Supply Chain Solutions, LLC.

So I will start the first round of questioning here.

Most of the time, DOD will continue to purchase drugs from the commercial drug market.

Oh, I am so sorry. I am so eager to get to them. I apologize. If we could we still start with our testimony. Dr. Barber, would you like to start us, please?

STATEMENT OF MELISSA BARBER, PH.D., POSTDOCTORAL FELLOW

Dr. BARBER. Chair Warren, Ranking Member Scott, and Members of the Subcommittee, thank you for the invitation to testify today. I am a postdoctoral fellow at Yale University, researching pharmaceutical markets.

Both here and in my written testimony I will endeavor to report, as precisely and honestly as I can, evidence from the academic and policy literature on drug market failures and other remedies. My remarks today reflect my own views, not the view of my employer or any other organization.

No one here today disputes that the military faces challenges in ensuring a reliable supply of safe, high-quality pharmaceuticals. No one here today disputes the unacceptable risks this creates for the health and well-being of servicemembers and their families, as well as operational readiness. So the task before us then is to unravel the root causes of challenges in the supply chain and to develop solutions.

First, military procurement of medicines is exposed to many of the problems seen in broader commercial markets for medicines, including increasing costs and supply and stability. Supply chains for many drugs are vulnerable to interruption. We do not even know the scale of the problem. A recent report by DOD noted that they could not determine the API source of 22 percent of drugs. But within the academic literature we find that approximately one-third of generic active pharmaceutical ingredients produced for use in U.S. markets were manufactured by a single facility, and an additional third were manufactured by only two or three facilities.

This Committee may not have jurisdiction over industrial policy, but it still must reckon with the downstream results of decades of policy decisions that have resulted in the concentration and offshoring of most pharmaceutical production.

Second, economists widely agree that markets for medicines do not always behave like typical markets and are far from being few or competitive. We should leave our idealized, orderly supply and demand curves in the cloakroom. They will not be of much use to us this afternoon as theoretical lenses. We have to instead understand these markets on their own terms and through rigorous analysis of empirical data.

Markets for medicines for military use are even more unusual. One factor is many are national monopolies and monopsonies because they involve hyper-specialized goods, often produced in quantities too small to be manufactured cost-effectively by more than one company. A review of DOD contracts shows many such hyper-specialized products, all the way from anthrax vaccines, battlefield-suitable analgesic auto-injector kits and nerve agent antidotes, to the specialized medicines used by California sea lions that the U.S. Navy trains for defense purposes. When there is only one buyer and seller, the DOD is not bidding in a competitive market. The DOD is the market, and that demands that we think about market problems and market solutions in a nuanced, context-specific way.

Third, for some drugs there is an irreconcilable mismatch between commercial incentives and defense needs, which cannot be solved with purely market-based solutions. Pharmaceutical companies are incentivized to manufacture a drug if it gives them a good return on investment. A supply line that manufactures an expensive cancer drug that serves a wide market is just more profitable than manufacturing drugs with small markets, like anthrax vaccines or drugs with low margins, like off-patent antibiotics.

In contrast, the military is conscious of costs but is ultimately incentivized to purchase drugs that meet operational needs and protect the health of servicemembers. Sometimes, but not always, these incentives overlap, and when they do not, one often-tried solution to bridge that gap is to pay pharmaceutical companies enough that it becomes worth their while to manufacture the drugs the military needs. For products used mostly or only by the military, we have seen time and time again that the expected demand has not been sufficient to generate a healthy number of bidders.

We therefore have to be realistic about when the DOD will be able to buy itself out of market failures. The DOD just does not have the spending power to fundamentally change the incentives that govern the commercial market to serve defense needs. DOD spending, as many have spoken today, accounts for less than 2 percent of overall spend in the United States.

These limitations of using commercial markets to ensure a resilient supply chain for military needs bring me to my final point. When it comes to medicines for military use, we live, and have always lived, in a mixed economy. By this I mean that the public and private sectors have both played an important role in developing, manufacturing, and supplying medicines in the United States for over 160 years. The private sector has efficiently supplied DOD with many needed medicines.

However, for many other medicines where the military is the sole market, or the commercial market has struggled to meet military needs, the military has brought manufacturing in house. The history of the military producing medicine stretches back to at least the Civil War, when pharmaceutical manufacturing facilities were established in Philadelphia and Astoria to stabilize supply chains for the Union army, with many other examples outlined in my written testimony.

The public sector, more generally, has solved puzzles that the private sector was not incentivized to explore, like how to manufacture penicillin, and the public sector in the United States continues to successfully manage products as complex as vaccines and monoclonal antibodies today.

We cannot afford to hold onto the hope that markets will always sort themselves out. At present, government creation of manufacturing capacity is usually done reactively, with initiatives created in response to particular crises. As one example, it took over 10 years and \$100 million for DOD to bring adenovirus vaccine manufacturing back online after Wyeth, the sole supplier, held DOD to ransom, to renovate the facility at excessive cost.

I bring up this history to dispel any misconceptions about military drug production as a new idea, rather than as an idea older than the Department of Defense itself. In my written testimony I detail independent review after independent review, recommending that the military build on past successes and existing capacity and bring the manufacturing of priority products back in house. I also detail decades of bipartisan support for this from the congressional Record.

Today I echo their conclusions in recommending that Congress introduce legislation establishing clear options for creating a gov-

ernment-owned facility to manufacture priority health products to meet unmet DOD needs. Thank you.

[The prepared statement of Dr. Barber follows:]

PUBLIC PRODUCTION AND PUBLIC HEALTH

Written statement of Melissa Barber, Ph.D.

Postdoctoral Fellow

Yale School of Medicine, Yale Law School, and

Yale Collaboration for Regulatory Rigor, Integrity, and Transparency (CRRIT)

U.S. Senate Committee on Armed Services, Subcommittee on Personnel Hearing:
The Department of Defense's efforts to ensure servicemembers' access to safe,
high-quality pharmaceuticals

Tuesday, April 30, 2024, 2:30 PM

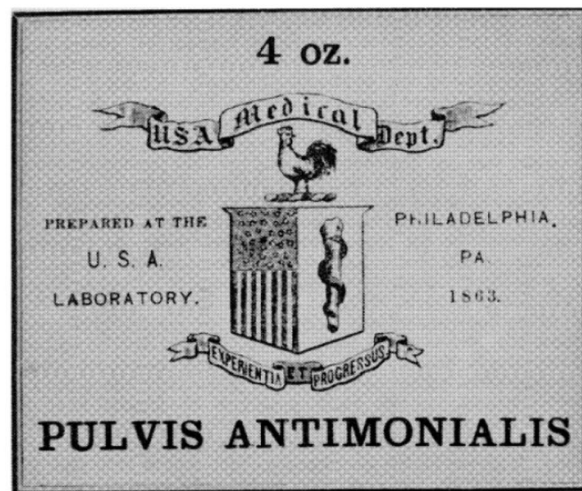


Figure 1. Label for a drug manufactured for defense medical use at one of the earliest known government-owned, government operated (GOGO) facilities. Philadelphia, 1863.¹

OUTLINE OF WRITTEN TESTIMONY

1. The availability and affordability of drugs is a pressing challenge faced by the Department of Defense.

- 1.1 The root causes and proximate determinants of shortages are complex and heterogeneous. Any solution will require a long-term collaborative strategy by many government departments.
- 1.2 The Department of Defense's ability to provide quality healthcare has been compromised by pharmaceutical supply issues.
- 1.3 At the same time, the Department of Defense is facing increases in prescription drug costs, which have outpaced inflation.
- 1.4 The increasing market concentration of key starting material (KSM) and active pharmaceutical ingredient (API) manufacturing is an important driver of shortages. Reversing this trend will require long-term strategies and investment to diversify supply and increase domestic capacity.
- 1.5 Increasing the prices paid for drugs is neither an efficient nor effective strategy to prevent future shortages, unless tied to conditionalities requiring manufacturers to demonstrate investments that address the underlying causes of shortages (e.g., improving risk management practices, diversifying supply sources, investing in back-up manufacturing capabilities, and other reforms to improve supply chain robustness.)

2. Meeting defense health needs in a mixed economy: past lessons and future directions.

- 2.1 Public sector R&D has yielded breakthroughs of immense military (and wider public health) significance.
- 2.2 However, the public sector does not just undertake R&D: there is a long history of the public sector also stepping in to manufacture drugs for military use.
- 2.3 Contractor-owned, contractor operated (COCO) facilities have sometime been characterized as cost-saving and lower risk compared to government-owned, contractor-operated (GOCO) or government-owned, government operated (GOGO) alternatives. However, COCO models have not always resulted in the desired efficiencies, and have in some cases resulted in preventable morbidity and mortality among people serving in the military.
- 2.4 GOGO and/or GOCO facilities have been recommended for decades as a solution to DOD supply challenges and pursued on a bipartisan basis.
- 2.5 Congress should consider introducing legislation establishing clear options for creating a government-owned facility to manufacture priority health products to meet DOD needs. Such a facility would ensure reliable access to quality drugs for servicemembers, as well as generate significant cost savings.

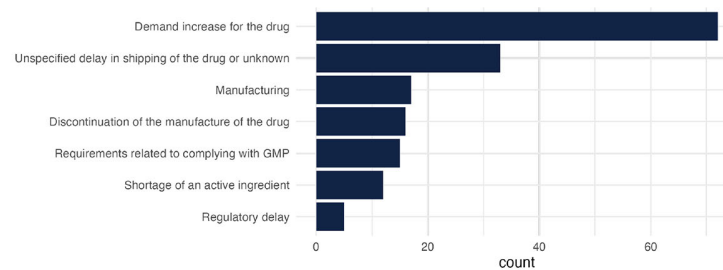
1. The availability and affordability of drugs is a pressing challenge faced by the Department of Defense (DOD).

1.1 The root causes and proximate determinants of shortages are complex and heterogeneous. Any solution will require a long-term collaborative strategy by many government departments.

Both academics and US government bodies, including the FDA and Government Accountability Office (GAO), have studied the causes of shortages, but analyses are limited by incomplete data. As of April 2024, there were 131 drugs reported to the US Food and Drug Administration (FDA) to be in shortage.²¹

Manufacturers report shortages to the FDA, but there are no standardized shortage reporting codes, nor are manufacturers obligated to give detailed information on the cause(s) of the shortage. The accuracy and diligence in shortage reporting is not audited by the FDA. A quarter of current reported shortages (April 2024) did not have a declared cause (Figure 2).² Among those with a reported cause, the majority (53%) were due to increased demand, followed by discontinuation of manufacture (12%), manufacturing delays or other issues (12%), good manufacturing practices (GMP) issues (11%), shortage of active pharmaceutical ingredient (API) (9%), and regulatory delays (4%) (Figure 2).²

Figure 2. Current shortages reported to the FDA by declared cause²



While some shortages are resolved quickly, others last years (Figure 3). At least 9 drugs have been in shortage since 2016, of which 6 have been in shortage since 2012 (Table 1).²

¹ Number of drugs counted as based on unique generic name or active ingredient, as reported by FDA. Data as downloaded 12 April 2024.

Figure 3. Current shortages reported to the FDA by year the shortage was first reported²

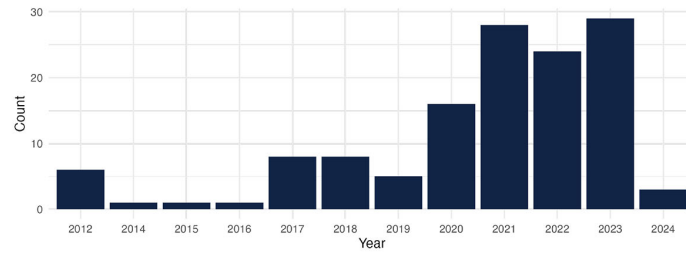


Table 1. Drugs with unresolved drug shortages reported to the FDA: subset with initial shortage reported 2012-2016.

Drug and formulation	Reported cause of shortage	Year first reported
Atropine Sulfate Injection	Manufacturing; Requirements related to complying with GMP	2012
Epinephrine Bitartrate, Lidocaine Hydrochloride Injection	Demand increase for the drug; unspecified “delay in shipping of the drug” (2016)	2012
Epinephrine Injection, Syringes	Manufacturing; Demand increase for the drug	2012
Fentanyl Citrate Injection	Discontinued	2012
Leucovorin Calcium Injection	Demand increase for the drug	2012
Lidocaine Hydrochloride Injection	Demand increase for the drug	2012
Cefotetan Disodium Injection	Unspecified delay in shipping of the drug, discontinued (2015)	2014
Cefotaxime Sodium Injection	Demand increase for the drug	2015
Sodium Acetate Injection	Manufacturing	2016

In 2021, the Department of Health and Human Services (DHHS) conducted a review of API and pharmaceutical supply chains, as part of a 100-day review under Executive Order 14017 on America’s Supply Chains.³ The report identified five factors contributing to risk in the supply chain, including:

- “1) The complexity, vastness, and multinational nature of drug supply chains and the corresponding overdependence on foreign entities who may prioritize national interests above trade in an emergency.
 2) Reduced incentives for existing manufacturers to invest in upgrading equipment, improving supply chains, or expanding capacity.
 3) Lack of redundant capacity in manufacturing.
 4) Just-in-time inventory management practices that limit inventory and reduce the ability to respond to surges in demand.
 5) Geographic concentration of manufacturers that puts production at risk from natural disasters or climate change that can quickly affect an entire region.”³

1.2 The Department of Defense’s ability to provide quality healthcare has been compromised by pharmaceutical supply issues.

The Defense Health Agency (DHA) is subject to similar market forces as wider commercial markets.

The 2023 *Report on the Department of Defense Pharmaceutical Supply Chain Risks* by the Office of the Under Secretary of Defense for Acquisition and Sustainment reported that the Defense Logistics Agency (DLA) spent \$5.4 billion per year on pharmaceuticals, accounting for 2% of the total US commercial market.⁴ Similarly, the 2023 Biodefense Posture Review concluded that “compared to the global market, DoD’s unique biodefense demands are small and not commercially competitive.”⁵

In testimony to the U.S.-China Economic and Security Review Commission hearing on *Exploring the Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products*, Christopher Priest (Principal Deputy, Deputy Assistant Director of Healthcare Operations at the Defense Health Agency) described DOD’s reliance on the commercial market, and the limitations of its relatively small buying power in shaping markets:

“DoD is wholly dependent upon the consumer market to produce and distribute the pharmaceutical products it requires to ensure the health, safety and wellbeing of the DoD personnel and beneficiaries who require them... Given its relatively small footprint in the commercial marketplace, DoD must work within the constraints of the commercial sector and the market forces that drive and shape it. Depending on the commercial sector, it is a two-edge sword. While it enables DoD to reap the efficiencies of the competitive commercial marketplace, it also makes DoD totally dependent on the sources that competition produces. These sources are increasingly foreign and non-compliant with the Buy American Act, as amended by the Trade Agreements Act of 1979. DoD’s compliance with these acts drives up DoD pharmaceutical costs while having little or no effect on the primary production arc of the commercial sector, which is bending toward foreign production sources.” (emphasis added).⁶

Challenges reported by DOD also extend to limited visibility in mapping API capacity and supply sourcing: the DOD reported to the Senate Committee on Homeland Security and Governmental Affairs that it lacks “authoritative data” on the sources of drugs purchased from the private sector.⁷ The same report noted that the DLA was “unable to determine with certainty if any of the drugs it purchases rely solely on sources in China or India”, with the exception of three drugs.⁷

One recent examples of shortages in the commercial market impacting members of the military and their families is penicillin G benzathine. Pfizer first reported a shortage of penicillin G benzathine injections in June 2023.² According to the FDA, penicillin G benzathine has been on the shortages list since at least 2012.² The FDA reports that the drug is still in shortage as of April 2024.² Penicillin G benzathine is given prophylactically to military recruits during boot camp.⁸ The drug is also used for syphilis and various streptococcal infections, including in the treatment of rheumatic fever to prevent the development of rheumatic heart disease. Pfizer has stated that they anticipate shortages of the pediatric formulation because the pediatric supply line has been repurposed to manufacture the adult formulation.⁸

TRICARE publishes its formulary; however, I am not aware of a public, current database of DOD direct pharmaceutical purchases.⁹ I have instead reviewed all pharmaceutical contracts available on the System for Award Management (SAM.gov) and cross-checked them against drugs currently listed as “in shortage” by the FDA (as of April 2024).² See Table 2.

Another challenge of DOD’s reliance on commercial markets is markets for some health products are small, and in some cases DOD is a monopsony purchaser. Recent DOD contracts with sole source notices (as required by U.S.C. 2304 (c)) include TPOXX (tecovirimat for orthopoxviruses such as smallpox and mpox), pre-mixed intravenous IV fluids, and neonatal pediatric inhaled nitric oxide gas. Review of recent DOD health purchase contracts also highlights DOD health product needs unlikely to be found in commercial markets, for example contracts for battlefield-suitable analgesic autoinjectors, nerve agent treatment autoinjectors, and medicines used by US Navy Marine Mammal Program-trained California sea lions and bottlenose dolphins.

Table 2. Current drug shortages and year of confirmed last DoD purchase

Drug currently in shortage (FDA, April 2024)	Last known purchase by DOD (sam.gov)
Albuterol Sulfate Solution ^a	2003
Amoxicillin Powder, For Suspension ^b	2015
Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Tablet ^c	current
Atropine Sulfate Injection ^d	current
Azacitidine Injection	2021
Bupivacaine Hydrochloride Injection ^e	2018
Bupivacaine Hydrochloride, Epinephrine Bitartrate Injection	2011
Cefotaxime Sodium Injection	2018
Dexamethasone Sodium Phosphate Injection	2018
Dexmedetomidine Hydrochloride Injection	2020
Dopamine Hydrochloride Injection ^f	2005
Epinephrine Injection, Syringes ^g	2020
Erythromycin Ointment	2011
Etomidate Injection	2011
Fentanyl Citrate Injection	2020
Furosemide Injection	2005
Heparin Sodium Injection	2012
Hydromorphone Hydrochloride Injection	2020
Ketamine Hydrochloride Injection	2023
Lidocaine Hydrochloride Injection	2020
Lidocaine Hydrochloride Solution	2020
Methotrexate Sodium Injection	2021
Midazolam Hydrochloride Injection	2018
Morphine Sulfate Injection	2020
Parathyroid Hormone Injection	2004
Penicillin G Benzathine Injection	2012
Promethazine Hydrochloride Injection	2011
Rocuronium Bromide Injection	2023
Ropivacaine Hydrochloride Injection	2020
Sodium Chloride 0.9% Injection ^h	2018
Sodium Chloride 0.9% Irrigation	2018
Sodium Phosphate, Dibasic, Anhydrous, Sodium Phosphate, Monobasic, Monohydrate Injection	2014
Sucralfate Tablet	2012
Sufentanil Citrate Injection ^h	2020
Technetium TC-99M Pyrophosphate Kit Injection ⁱ	2014

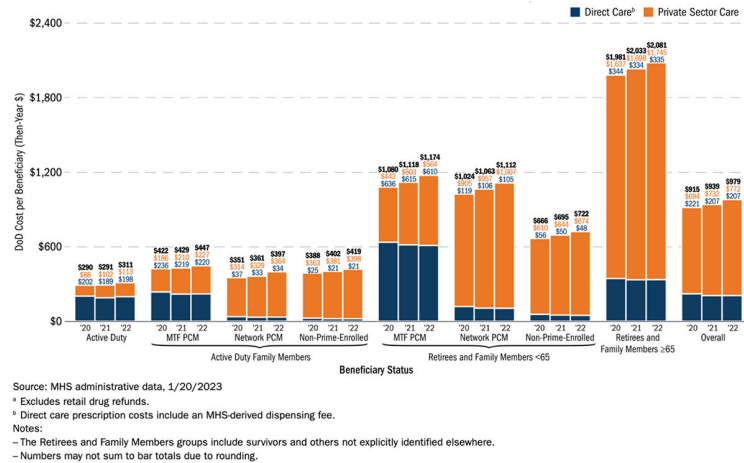
^a Albuterol 90 µg CFC and HFA formulations; ^b Amoxicillin 400 MG/5 ML SUSP 100ML;

^c Dextroamphetamine/ Amphetamine; ^d Antidote treatment, nerve agent, Automatic, Dual-Chamber, Pralidoxime Chloride Injection, 300 mg per mL, 2 mL, and Atropine Injection, 2.99 mg per mL, 0.7 mL; ^e Bupivacaine .25% Plain 50ML VT, 1, VT; ^f More recent contracts may exist but ambiguous descriptions of formulation mean this cannot be confirmed. This listing is the most direct description match; ^g Sodium Chloride .9% 100 ML, 96 in each case, NDC 00338004903 or Equal^h Sufentanil NanoTab. Intended for battlefield use.

1.3 At the same time, the Department of Defense is facing increases in prescription drug costs, which have outpaced inflation.

The 2023 Evaluation of the TRICARE Program found increases in overall per-capita prescription drug costs in every beneficiary group (Figure 4).¹⁰ Annual increases in all groups outpaced inflation, by a margin ranging between +5% for retirees and family members aged 65 and older and +13% for active duty family members with a network primary care manager.³ Average annual DOD prescription costs per beneficiary remained relatively steady 2020–2022 when delivered directly, but have increased in private-sector care covered by DOD.

Figure 4. Average Annual DoD Prescription Costs per Beneficiary, Fiscal Years 2020–2022.³



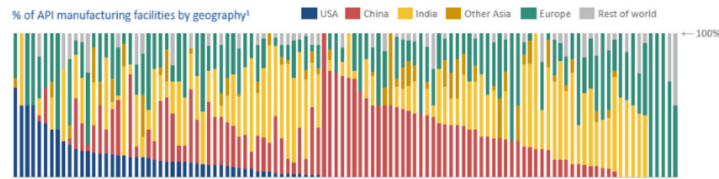
1.4 The increasing market concentration of key starting material (KSM) and active pharmaceutical ingredient (API) manufacturing is an important driver of shortages. Reversing this trend will require long-term strategies and investment to diversity supply and increase domestic capacity.

Some drugs are only manufactured by one or two suppliers, rendering them especially vulnerable to supply disruptions and/or demand shocks. A 2023 study in *Health Affairs* found that approximately one-third of generic APIs produced for use in the United States

market between 2020 and 2021 were manufactured by a single facility; an additional third was manufactured by two or three facilities.¹¹ The same study found that “23.0 percent of markets had upstream vulnerabilities to the supply chain because a robust level of competition among finished drug manufacturers obscured a fundamentally uncompetitive market of three or fewer API producers.”¹¹

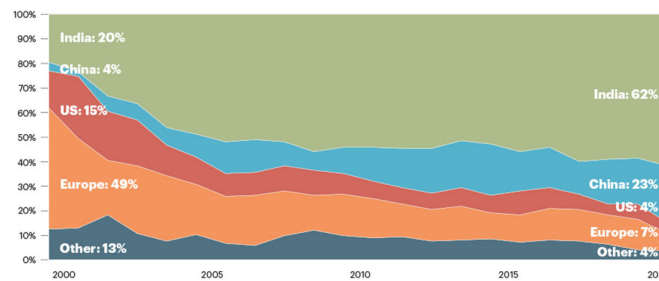
The Senate Committee on Homeland Security and Governmental Affairs issued a report in 2023 noting that “90 to 95 percent of generic sterile injectable drugs for critical acute care in the U.S. rely on key starting materials and drug substances from China and India.”⁷ The report concluded that “the lack of robust domestic manufacturing capacity and diversification of suppliers for critical generic drugs prone to shortage, leaves the U.S. vulnerable to a variety of threats.”⁷ Estimates of reliance on supply from China are likely underestimates, as they generally measure transfers of API, but exclude the chemicals used to manufacture API. There is no systematic monitoring of API transactions, but some have estimated that as much of 70% of India’s API uses chemicals sourced from China.³ Using commercial (Clarivate) data, the report documented that roughly half of 118 essential medicines (as defined by FDA) have domestic API manufacturing sites (Figure 5).⁷

Figure 5. Percentage of API Manufacturing Facilities by Geography for 118 Critical Medicines.¹²



India and China have increased their market share over 2000–2020 (Figure 5), with India now estimated to account for 62% of API drug master files and China 23%. In the same period, the number of API Drug Master Files attributed to US-based manufacturers has decreased from 15% to 4%, and the number of those attributed to Europe-based manufacturers, from 49% to 7%.

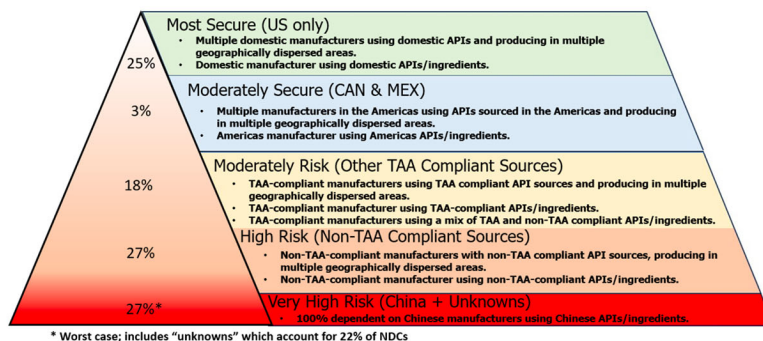
Figure 6. Active API Drug Master Files, by year of filing and country of manufacture¹³



In testimony to the U.S.-China Economic and Security Review Commission hearing *Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products*, Christopher Priest (Principal Deputy, Deputy Assistant Director of Healthcare Operations at the Defense Health Agency) described the strategic implications of gaps in API data, noting that “concerns about any situation where foreign actors, such as China, control substantial access to critical warfighting materiel and potential serious risk of interruptions in the supply chain or posed by contaminated APIs...is compounded by the fact that there is no required registry for API sources making it extremely difficult to gauge the extent of the risk.”⁶

Recognizing the strategic and health importance of ensuring secure, diversified supply chains, the Office of the Under Secretary of Defense for Acquisition and Sustainment analyzed API sources of 12,917 drugs (10% of the US marketplace).⁴ The report concluded that “DoD has a high dependence on foreign material and trade agreements to maintain current pharmaceutical capabilities” and characterized “54% of the DoD pharmaceutical supply chain [as] considered either high or very high risk, with dependency on non-Trade Agreements Act (TAA)² compliant suppliers, sourcing from China and India, or unknown.”⁴ A summary of the API risk assessment for the 12,917 drugs (10% of US commercial market) analyzed is reproduced as Figure 7.⁴

² The Office of the Under Secretary of Defense for Acquisition and Sustainment 2023 report defined TAA-compliant and TAA non-compliant as follows: “For the purposes of this report [2023 *Report on the Department of Defense Pharmaceutical Supply Chain Risks*], the term “TAA Compliant” means that the sources of both finished pharmaceuticals and APIs or key ingredients are U.S. -made or a qualifying country or designated country item API. The term “TAA Non-Compliant” for purposes of this report does not include application of the definition of U.S.-made end product as defined in Defense Federal Acquisition Regulation Supplement (DFARS) clause 252.225-7021. If the API or key ingredients have not been substantially transformed in the U.S., a qualifying country, or designated country, then the item is “TAA Non-compliant” for the purposes of this report.”⁴

Figure 7. DLA hierarchy of drug security.⁴

Analyses of global API distribution and flows are impeded by data gaps. In some cases, multiple suppliers of a given final drug will use the same API supplier. This means that drugs that appear to have a robust multi-source supply chain may in fact be reliant, upstream, on one or a few API manufacturers and may thus be less resilient than is apparent. This structure also has the effect of obscuring the relative volumes and ultimate source for raw materials: approved drug applications must disclose the sources of supply, but FDA does not know whether supply is split evenly across facilities, or if, for example, one facility produces 99% of product while another produces just 1%.

In its analysis of DOD supply chains, DLA noted that even “with all its specialized expertise, available databases, and IT support tools and capabilities”, they were unable to identify source of 22% of APIs.⁴ Mending the deep cracks in the information ecology around API sourcing will require more than merely increasing required disclosure by manufacturers – these efforts, while important, at best only address drugs currently registered in the United States. Any risk mapping requires an understanding of API production globally, and will require investments in improving data collection to realize.

1.5 Increasing the prices paid for drugs is neither an efficient nor effective strategy to prevent future shortages, unless tied to conditionalities requiring manufacturers to demonstrate investments addressing the underlying causes of shortages (e.g., improving risk management practices, diversifying supply sources, investing in back-up manufacturing capabilities, and other reforms to improve supply chain robustness.)

Shortages for some medicines have been attributed by some to prices that are too low. Price is always a factor in questions of supply, and an FDA analysis on the “root cause of

shortages” estimated that half of the 163 drugs that went into shortage from 2013-2017 “may have had inadequate financial incentives to market the product or invest in ensuring manufacturing capability and capacity prior to the shortage.”¹⁴ However, studies of shortages of generic sterile injectables suggest that manufacturing issues, rather than price declines, are more predictive of shortages. Research undertaken by the FDA analyzing shortages found that supply disruptions for drugs in shortage persist even after some price increases.¹⁴

A 2016 analysis of shortages of sterile injectable drugs undertaken by the Government Accountability Office (GAO) concluded that the two most strongly predictive factors of shortages were a) a decline in the number of suppliers and b) the failure of at least one manufacturer to comply with manufacturing standards, resulting in an FDA warning letter. Sales of a generic version were also predictive, but price decline was not found to be statistically correlated with shortages of drugs in this study (See Table 3). The ongoing penicillin G benzathine shortage (see 1.3) also points to a more complex relationship between price and availability. According to the FDA, the drug has been in shortage since at least 2012. Since 2013, the price has increased 275% to \$470 per 4 mL syringe.⁸

Table 3. Estimated Percentage Point Increase in Probability of a Drug Shortage in the Presence of Certain Factors, for Sterile Injectable Anti-infective and Cardiovascular Drugs, 2012-2014¹⁵

The estimated mean probability of a shortage predicted for all drugs in our study by the model is 60.7 percent.

Factors	Estimated percentage point increase in the probability of a shortage ^a
Decrease in suppliers, previous 2 years	16.8**
Sales of a generic version, previous year	12.3**
Failure to comply with manufacturing standards resulting in a warning letter, previous 2 years	8.1**
Price decline, previous 2 years	0.7

Source: GAO analysis of data from IMS Health, the Food and Drug Administration, and the University of Utah Drug Information Service. | GAO-16-595.

Notes: Our multivariate logistic regression model uses a 3-year panel data file that contains shortage measures for 118 sterile injectable anti-infective and cardiovascular drugs from 2012 through 2014 and measures of market structure (whether there was a decrease in suppliers), compliance with FDA manufacturing standards (whether there was a failure to comply with manufacturing standards resulting in a warning letter for at least one establishment that manufactured the drug), drug characteristics (whether sales of a generic version), and price and volume of sales (whether the price declined) from 2010 through 2013.

^aThe estimated percentage point increase in the probability of a shortage is calculated as the difference between (1) the probability of a shortage if the factor is present for all drugs and the other three factors remain unchanged and (2) the mean probability of a shortage predicted for all drugs in our study by the model (60.7 percent). To compute the predicted probability of a shortage when the characteristic is present, we set the value of the variable to one, left the values of the other explanatory variables unchanged, and then calculated the probability using the coefficients estimated from our 3-year repeated measures logistic regression model. To compute the mean probability of a shortage predicted for all drugs in our study by the model, we first computed the predicted probability of a shortage for every drug and every year in our study by using the estimated coefficients from the model and the data for each drug. We then computed the mean of the 354 predicted values (118 drugs and 3 years), which was 0.607, or 60.7 percent.

** indicates that the estimated probability is based on a coefficient estimate that was significant at a level of 0.01 or better, based on our logistic regression model results.

2. Meeting defense health needs in a mixed economy: past lessons and future directions.

2.1 Public sector R&D has yielded breakthroughs of immense military (and wider public health) significance.

The military has developed health products for specific combat missions: the botulinum toxoid vaccine was developed for D-Day because of concerns regarding a bioweapon attack using the toxin, and the Japanese encephalitis vaccine was developed for an anticipated ground invasion of Japan.⁴

Still more important are military investments to research, develop, and manufacture health products for infectious diseases. Preventing infectious disease as a key defense priority predates the establishment of the United States: George Washington famously insisted that his army be variolated against smallpox.¹⁶

The 2023 Biodefense Posture Review emphasized the critical importance of health in defense strategy, noting that “the most likely infectious disease threats to deployed U.S. forces come from endemic diseases (i.e., diseases that regularly occur in a particular population or area). Respiratory diseases (e.g., tuberculosis, seasonal influenza), food and waterborne diseases (e.g., typhoid, cholera), and vector-borne diseases (e.g., malaria, dengue fever) may cause local or regional epidemics.”⁵

Most of these diseases receive very limited private sector research and development (R&D) investments.¹⁷ The private sector has not historically engaged in significant R&D for health conditions with limited commercial markets. Public investments and public labs have been instrumental in developing treatments and vaccines that have saved countless lives and improved military readiness. A summary of some of accomplishments in vaccine research was compiled in a 2002 report by the Institute of Medicine (IOM) of the National Academies (Appendix A).⁸

Penicillin, perhaps the most important therapeutic advance of the twentieth century, would have likely been delayed by years, if not decades, without public investments in improving manufacturing processes. Penicillin was discovered in 1928, but manufacturing technologies at the time could only produce minuscule supplies: supply was so scarce that penicillin was extracted from patients’ urine and re-used.¹⁸ The US Office of Scientific Research and Development’s Committee on Medical Research (OSRD / CMR) and the U.S. Department of Agriculture’s Northern Regional Research Laboratory (NRRL) played a key role in developing production processes that allowed the drug to be mass-produced, leading to sufficient quantities being available for routine military use by 1944.¹⁹ OSRD was established

by FDR in 1941 to mobilize and coordinate research undertaken in both civilian and military spheres for defense purposes.²⁰

The production technology used and improved through public research – a fermentation process – was considered by the private sector to be far more expensive than manufacture through chemical synthesis; commercial firms preferred to wait until synthesis became possible.¹⁹ However, chemical synthesis of penicillin was not developed until 1959, and even then, was not as efficient as fermentation methods until 1992.¹⁹ The case of penicillin highlights the perils of the military relying on commercial markets to meet defense needs: without public investments aimed at addressing military health needs, widespread availability of the antibiotic may have been delayed by almost three decades.

Maintaining readiness requires the development of vaccines and other products that prevent illness, not just treatments. For some diseases, the existence of a treatment has made markets for preventative products less attractive to the sector. One example is the pneumococcal capsular polysaccharide vaccine. *Streptococcus pneumoniae* (or ‘pneumococcus’) causes pneumonia and, less frequently, meningitis – both of which can be serious or fatal. Though prevention is always preferable to curing disease after infection, private sector interest in developing a vaccine dissipated after an effective treatment (sulphonamide antibiotics) was discovered. Respiratory diseases are easily transmitted in military barracks, resulting in antibiotic use that exceeds typical civilian use. By 1944 antibiotic resistance was observed at a Sioux Falls, South Dakota Air Force base.²¹ Because sulphonamides were generally still effective in the wider population, military needs for a vaccine preceded the market sizes that might have incentivized the private sector to engage in R&D.²¹ As noted by Hoyt, “[a]ll efforts to develop a new vaccine to induce active immunity would likely have come to a halt if the military did not have an enduring interest in population-based preventive measures.”²¹ The Board for the Investigation and Control of Influenza and other Epidemic Diseases (BICIED, later renamed the Army Epidemiology Board) carried out research and identified the most common pneumococcus strains prevalent among military personnel, allowing the development of a vaccine, with confirmatory clinical testing conducted by the US Army Medical corps.²¹

The military has also undertaken R&D to improve upon products offered by the private sector. Improvements to the tetanus vaccine are the result of the Army finding that earlier tetanus vaccinations caused a high number of adverse effects.²¹ Research by the Preventive Medicine Division identified a key driver of these adverse effects (peptones in the nutrient media used to grow the bacteria), and an improved vaccine without these side effects was developed.²¹

2.2 However, the public sector does not just undertake R&D: there is a long history of the public sector also stepping in to manufacture drugs for military use.

The often-cited ‘division of labor’ between the public and private sectors, wherein the public sector undertakes R&D through national labs like Walter Reed Army Institute of Research (WRAIR) and the National Institutes of Health (NIH), and the private sector takes over manufacturing, were the result of policy choices rather than any intrinsic necessity. The division largely dates to the aftermath of WWII, when the Secretary of War directed that military production be shifted “to the maximum practicable extent” to the private sector.²¹ However, this division was not absolute, and the public sector has continued to be, in some cases, the only manufacturer of key health technologies. The cases below – while far from comprehensive – highlight government-owned, government operated (GOGO) and/or government-owned, contractor-operated (GOCO) initiatives for health product manufacturing that have played an important role in US military history.

US Civil War: The first industrial-scale manufacturing of medicines by the United States military of which I am aware occurred during the Civil War. Reliable access to medicines was decisive in some battles: historians attribute the failure of the first siege of Vicksburg to shortages of quinine, a medicine used for malaria prevention.^{22,23} The military investigated the cost of production of some needed medicines and found that in-house manufacturing would likely be cost effective.¹ Subsequently, the US Army invested \$200,000 (about \$6 million in 2024 dollars) in setting up facilities for government manufacture of medicines in Astoria and Philadelphia.¹ In terms of governance, these facilities were operated out of the military Medical and Hospital Department funds rather than the War Office.¹ Eventually these early GOGO facilities would manufacture more than 100 different tinctures, extracts, powders, and pills.²⁴ Reviews of the initiative found that the drugs they produced were of good quality, and that the effort was important in stabilizing supply.¹

In addition to stabilizing supply chains – a key defense priority – the establishment of manufacturing facilities had a secondary consequence of substantial cost savings.

First, savings were achieved through decreased direct expenditures. Even accounting for capital investments and start-up costs, the Philadelphia facility alone was estimated to have saved the US government \$766,019 (\$24 million in 2024 dollars).²⁵

Second, government facilities indirectly reduced overall expenditures by curbing the worst excesses of firms abusing their dominant market position to increase drug prices. Quinine was of especial strategic importance, as malaria was endemic in many spheres of battle. Military purchasers contended with sharp price increases: quinine prices increased by seventy percent, from \$2.10 per ounce in 1861 to \$3.60 in 1863 (\$89 in 2024 dollars).¹ These price increases were the result of abuse of market power, rather than an increase in the cost of

doing business, with the New York Times reporting that “[quinine] is speculated in, in the same manner as Gold.”²⁶ The mere announcement of the government’s intention to manufacture its own quinine resulted in price decreases of more than thirty percent in a single day, and by the end of the week, private manufacturers were offering \$0.70 discounts.²⁶

WWII: Penicillin was discovered in 1928, but insufficient quantities were able to be produced with existing technologies (see 2.1). The US Office of Scientific Research and Development’s Committee on Medical Research (OSRD / CMR) and the U.S. Department of Agriculture’s Northern Regional Research Laboratory (NRRL) played a key role in developing production processes that allowed the drug to be mass-produced for military use. But the public’s role was not restricted to R&D: the War Production Board also constructed penicillin production facilities.¹⁹

The US Army Medical Department also identified dengue serotypes in response to high (up to 12%) infection rates among troops stationed in Melanesia during WWII,^{27,28} and the Walter Reed Army Institute of Research (WRAIR) later developed a live-attenuated, tetravalent dengue virus vaccine candidate, which was manufactured at the WRAIR Pilot Bioproduction Facility.²⁸

MassBiologics: In the mid-1930s-40s, MassBiologics (at this time, “the State Biologic Laboratories”), Harvard Medical School, the U.S. Navy, and the American Red Cross collaborated to extract and distribute over 10,000 grams of gamma-globulin antibodies to address the measles outbreaks.²⁹ The Laboratories signed a contract with the U.S. Navy to bring nearly 2 million doses of the antibody to soldiers and the public.²⁹ Produced between 1934-1944, these measles antibodies were the first human blood-derived products to be distributed by the Biologic Laboratories.²⁹

Michigan Department of Health: The Michigan State Department of Health manufactured the anthrax vaccine for the Pentagon from 1964 to 1995.³⁴ The US Army provided necessary expertise and equipment to the Michigan State Department of Health to develop and produce the anthrax vaccine to serve DoD requirements.³⁴

2.3 Contractor-owned, contractor operated (COCO) facilities have sometime been characterized as cost-saving and lower risk compared to government-owned, contractor-operated (GOCO) or government-owned, government operated (GOGO) alternatives. However, COCO models have not always resulted in the desired efficiencies, and have in some cases resulted in preventable morbidity and mortality among people serving in the military.

Policy efforts to encourage the private sector to engage in markets serving military needs have been unsuccessful in certain key areas. In 1991, the GAO (then named General Accounting Office) conducted a review analyzing whether the Army's only option for developing and producing needed vaccines was with the non-profit Salk Institute, or if there were opportunities for greater private sector involvement. After speaking with several commercial vaccine manufacturers, the GAO concluded that there was no commercial market.³⁵ More recently, in 2021, a GAO (now the Government Accountability Office) study found that the "lack of [domestic] surge capacity is caused partially by the reluctance of vaccine manufacturers in the private sector to invest in the high cost of maintaining excess, idle capacity in anticipation of unknown future vaccine."³⁶

The cases of the anthrax, plague, and adenovirus vaccines offer illustrative examples of the risks of a lack of public oversight and control over the production and control of drugs essential for military use.

Anthrax: The Michigan State Department of Health was the sole manufacturer of the anthrax vaccine for the Pentagon during 1964–1995 (see 2.3).³⁴ The facility and license to manufacture the anthrax vaccine was transferred from public ownership to BioPort Corporation for \$25 million in 1998. This transfer was done with significant underwriting of risk by the public sector: BioPort only paid \$3.3 million in cash, and the state of Michigan provided the rest of the \$25 million in financing.³⁷ BioPort was then in turn provided \$15 million for capital investments to expand production and over \$60 million in Pentagon contracts to continue providing needed anthrax vaccines.³⁸ DOD also agreed to pay up to 75% of the cost of the vaccine, whether or not BioPort succeeded in securing a license for use.³⁷

One year later, BioPort increased the price per dose agreed at the time of the sale from \$4.36/dose to \$10.64/dose.³⁹ The Defense Contract Auditing Agency (DCAA) found BioPort's price increase to be "overstated" and recommended that accounts be carefully reviewed before any price increases were approved.⁴⁰ A report issued by the Committee on Government Reform described BioPort as "not [to] be a reliable financial partner in the vaccine enterprise."⁴¹ An expert witness testifying in a 2004 hearing of the Select Committee on Homeland Security described DOD's position as one wherein "threats to stop production render[ed] DOD unable to resist demands for extraordinary financial relief and pressure to permit the use of publicly funded improvements to monopolize the private domestic and foreign markets as well."⁴²

Despite significant investments from the Pentagon, BioPort was unable to produce any vaccine for four years, and failed FDA inspections during the first 2 years of operation.^{38,43} In reviewing the supply challenges, GAO concluded that "if we are relying upon this vaccine as part of the backbone of our defensive biological program, the question of vulnerability to

a single site becomes an issue.”⁴⁴ BioPort’s record was described in a 2000 Senate Armed Services Committee hearing as “an unmitigated disaster... costing the American taxpayer millions and millions of dollars and jeopardizing the safety of our troops who we’re not able to provide that anthrax vaccination.”⁴³

Adenovirus: An adenovirus vaccine was developed by the military (see Appendix A), but the sole manufacturer was Wyeth Laboratories. In 1996, Wyeth Laboratories requested funding from the Pentagon to make facility improvements.⁴⁵ Wyeth refused to invest in the facility themselves, and wound down adenovirus production. No other private sector manufacturer filled the gap, and supply ran out by 1999.⁴⁵

Without vaccination, “adenovirus illness reemerged as a major cause of illness and hospitalization among new trainees” by 2002.⁴⁶ Medical services were interrupted, with at least three basic training facilities becoming overwhelmed after outbreaks, resulting in medical staffing challenges and requiring some bases to convert barracks to infirmaries.⁴⁶ At least two recruits died.⁴⁶ The number of recruits having to repeat basic training due to days lost to illness increased by as much as 20-fold.⁴⁶ It took 10 years and \$100 million for DOD to be able to re-introduce adenovirus vaccination among military trainees.⁴⁷ Cost-effectiveness analysis undertaken in 1998 estimated that without vaccination, adenoviral acute respiratory disease (ARD) outbreaks resulted in over twelve thousand cases of ARD hospitalization and cost the Army \$26.4 million.⁴⁸

Plague: Greer Laboratories, the only manufacturer of the plague vaccine, received a warning letter from the FDA, and subsequently the business decision was made to discontinue the vaccine in 1998. No private sector provider was found, and to date there is no licensed vaccine available.^{46,49}

2.4. Government-owned, government operated (GOGO) and/or Government-owned, Contractor-operated (GOCO) facilities have been recommended for decades as a solution to DOD supply challenges and pursued on a bipartisan basis. DOD should act on these recommendations and establish a GOGO facility for priority health products. Such a facility would ensure reliable access to quality drugs to meet DOD needs, as well as generate significant cost savings.

GOGO and GOCO models have been successful in ensuring reliable access to drugs on a cost-effective basis (Sections 2.1 – 2.2). A range of government reviews in recent decades have recommended GOGO and GOCO models to address military drug production needs.

The DOD commissioned a special task force (“Project Badger”) in the 1990s to assess whether or not commercial markets could serve defense needs.⁴² After making inquiries to all commercial manufacturers as to their interest and ability to manufacture needed vaccines,

the task force concluded that “the best option appeared to be a facility that was government owned (and funded).”⁴² The proposed model was a government-owned, contractor-operated (GOCO) model, where the government would own and construct a facility as a “national asset”, but a contractor would staff production.⁴² In the mid-1990s, a GOCO vaccine facility was included within a DOD budget request but “was subsequently withdrawn in favor of an approach that relies upon private industry to meet the vaccine needs of the DOD.”⁴²

Separately, a GAO report recommended in 1991 that “the Army could improve and expand its in-house vaccine production facilities to meet its needs.”³⁵ Walter Reed Army Institute of Research (WRAIR), laboratory suites at the Medical Research Institute of Infectious Diseases at Fort Detrick, and an NIH-owned GOCO facility were proposed as possible sites.³⁵ A pilot program was proposed, but by 1994 an amendment was introduced to specifically prohibit DoD from further pursuing this initiative.⁵⁰

In 2000, the Institute of Medicine (IOM) of the National Academies convened an expert committee to advise the U.S. Army Medical Research and Materiel Command on production, with a focus on the “naturally occurring disease threats” that are a priority of DHA. The resulting 2002 Expert Committee report recommended that DOD pursue GOCO production facilities.

GOCO initiatives have attracted bipartisan legislative support. Former Republican Governor Jim Gilmore, head of the 2001 Advisory Panel to Assess Domestic Response Capabilities for Terrorism” argued that “The establishment of a government-owned, contractor-operated national facility for the research, development and production of vaccines and therapeutics for specified infectious, especially contagious diseases, is needed.”⁵¹

The *New York Times* reported plans by the Pentagon to “[build] its own vaccine plant to produce eight vaccines for military use – the existing anthrax vaccine and a new one, plus vaccines for smallpox, plague, tularemia, botulinum, ricin and equine encephalitis. It would cost \$1.56 billion to build and run over 25 years, including \$386 million in construction costs, the department estimated.”⁴⁵ Further details of the proposed program are either not in the public domain or I was unable to locate them.

As part of the 2003 National Defense Authorization Act, a bipartisan amendment was introduced by Senator Hutchinson of Texas (R), Senator Mikulski of Maryland (D), Senator Lincoln of Arkansas (D), Senator Sarbanes of Maryland (D), and Senator Roberts of Kansas (R) authorizing the construction of a “government-owned, contractor operated facility” for the “production of vaccines for agents known or anticipated to be used in biological weapons”, for which “The Secretary shall provide for the operation of the facility constructed ... as a government-owned, contractor-operated facility.”⁵² In introducing the

amendment, the sponsor Senator Hutchinson (R-AR) defended the importance of the public sector in provision of some essential medical goods:

*“This problem has been examined many times over the past decade. In fact, it has been studied twice by the Department of Defense. Both times, the conclusion was that our Nation needed a government-owned, contractor-operated vaccine production facility... The private sector, for all of the good that it does, cannot, against some of the boutique biological pathogens and threats that may exist now and in the future against our troops and against our civilian population, and will not in the future see this as a profitable commercial venture. The insurance for the American people, and the insurance for our men and women in uniform, is to have a Government-owned production facility, contractor-operated, to ensure that vaccine will always be available if and when it is needed.”*⁵¹

In a 2004 hearing of the Select Committee on Homeland Security, committee members and expert witnesses discussed the (by that time de-classified) Project Badger findings in the context of revived proposal to establish a GOCO to serve defense medical needs.⁴² Major General Lester Martinez-Lopez (Commanding General, U.S. Army Medical Research and Materiel Command, Fort Detrick, Maryland) described the benefits of government owned facilities as “government control of production, availability, and distribution flexibility for emergency production technologies meets national security priorities for bio-defense vaccines overcomes limited industry interest in bio-defense products.”⁴²

Another expert witness – an experienced researcher and administrator of biological defense programs – acknowledged the political challenge of introducing the GOCO model. Reflecting on the urgent need and failure of the COCO model to deliver reliable access to needed drugs, she strongly encouraged the Select Committee to support the GOCO proposal:

*“Although the pharmaceutical firms seem opposed to the GOCO approach, citing the availability of capacity already existing, this belies that fact that each year industry has difficulty meeting existing market demands. Recent shortages in tetanus, pertussis, and flu vaccines support the perception that there is no excess capacity available for biodefense vaccine work... As time passes, the costs [of building government-owned facilities] will only increase, and the nation will be at the mercy of the fragile, profit-motivated pharmaceutical industry to make the bio-defense vaccines that are needed. In my opinion, Congress should strongly consider appropriating funds for a GOCO facility for bio-defense medical countermeasures.”*⁴²

The hearing also highlighted operational and strategic advantages of GOGO and GOCO models over COCO models, including:⁴²

- RFPs are not required for each product
- Long-term contracts a) provide needed stability in small markets; b) encourage increased capacity by operating contractors for specialized production needs and

regulatory requirements; c) signal sustained government support for medical countermeasures

- Increased efficiencies and flexibility as production needs can be decided by the government on an as-needed basis
- Bidirectional efficiencies and opportunities for innovation through collaborations with government R&D labs

A key theme in the 2023 DOD Biodefense Posture Review was the need for an integrated approach by the Chemical and Biological Defense Program (CBDP) and Defense Health Program (DHP). The Review recommended that DOD “review DHP and DHA efforts to enable far-forward care, speed clinical trials and research within the Military Health System, inform optimal clinical care strategies, and support development of MCM specific to the military population.” The BDP ultimately concluded that the “CBDP and DHP have sufficiently unique missions, partners, and processes that drive a “spirit of competition” and innovation that argue against consolidating authorities and responsibilities into a single program.”

A second key theme in the Biodefense Posture Review was the importance of ensuring supply chain reliability for key medical products. The Review recommended that the Chemical and Biological Defense Program (CBDP) and Defense Health Program (DHP) should partner with the Office of the Assistant Secretary of Defense for Industrial Base Policy “to prioritize on-shoring of production and distribution of key chemicals critical to produce DoD-unique biodefense MCMs.” The Review recommended use of the Defense Production Act (DPA) and Manufacturing Innovation Institutes to expand domestic API production.

2.5 Congress should consider introducing legislation establishing clear options for creating a government-owned facility to manufacture priority health products to meet DOD needs. Such a facility would ensure reliable access to quality drugs for servicemembers, as well as generate significant cost savings.

Maintaining access to quality health products for servicemembers is a critical part of defense strategy. Manufacturing drugs for military use is not a new idea: GOGOs for pharmaceutical production stretch back to at least the Civil War, and analyses by government agencies have recommended GOGOs and GOCOs as a solution to persistent supply challenges for decades.

At present, government creation of manufacturing capacity is often done in a reactive manner, with initiatives created (after a delay) in response to particular crises. Congress should consider introducing legislation establishing clear options for creating a government-

owned facility to manufacture priority health products to meet DOD needs. To avoid the delays and added administrative overhead in this reactive approach, a streamlined and regularized mechanism for identifying relevant needs and feasibility could be created. Such a facility would ensure reliable access to quality drugs for servicemembers, as well as generate significant cost savings.

Appendix A

Table A1. Historical Highlights in the Control of U.S. Military Infectious Diseases by Vaccines^{46,53}

1777	Members of Continental Army inoculated with the variola virus to prevent smallpox
1812	Cowpox immunization replaced variolation for prevention of smallpox in troops
1909	Typhoid vaccine developed
	Chloroform-treated single-dose rabies vaccine for dogs developed through work done in the Philippines
1927	
1940s	Dengue virus types 1 and 2 isolated; first experiments begun with dengue vaccine
	Tetanus toxoid and diphtheria toxoid shown to be highly effective in preventing wound-induced tetanus and diphtheria infections
1940s	Armed Forces Epidemiological Board established; commissions established to deal with influenza, hepatitis, encephalitis, and other diseases that threatened the war effort; vaccine-related activities included conducting research and providing immunization policy advice
1941	
1942	Influenza vaccine developed and used for mass immunization of military forces
	Yellow fever vaccine used in large numbers of military personnel; hepatitis B virus contamination of serum causes a large common-source outbreak of jaundice
1942	
1944	Smallpox vaccine licensed
1944	Troops stationed in Okinawa, Japan, immunized against Japanese encephalitis
	Discovery that adenovirus types 3, 4, and 7 cause most cases of acute respiratory diseases in recruits; adenovirus vaccine research and development initiated
1950s	
1950s	Anthrax vaccine developed
	Outbreaks of meningococcal meningitis on military posts stimulated the study of meningococcal infection and the development of vaccines against meningococcal groups A, C, Y, and W-135
1960s	
1960s	Plague vaccine proven effective in Vietnam
	Malaria vaccine program initiated (protection from bite of radiated mosquitoes shown)
1960s	
	INDs* filed for vaccines against Venezuelan equine encephalitis, tularemia, eastern equine encephalitis, and Rift Valley fever
1965–1969	
1970s	Development and testing of an oral typhoid vaccine
	Prototype vaccines against Russian spring-summer encephalitis and tick-borne encephalitis made at Walter Reed Army Institute of Research (WRAIR)
1970s	
1970s	Live attenuated dengue virus vaccine strains developed; INDs filed
1970	
1970	Anthrax vaccine licensed
	INDs filed for Q fever vaccine and live attenuated Venezuelan equine encephalitis virus vaccine
1972–1975	

1980	Adenovirus vaccines licensed for use in military populations, leading to nearly complete control of epidemic respiratory diseases in recruits
1984–1986	INDs filed for vaccines against western equine encephalitis, Argentine hemorrhagic fever, Venezuelan equine encephalitis, and chikungunya virus
1985	Efficacy of Japanese encephalitis vaccine demonstrated in Thailand; licensure application coordinated by U.S. Army Medical Materiel Development Activity; license granted by Food and Drug Administration
1985–1986	Hepatitis A vaccine developed and tested by WRAIR
1986	WRAIR classification of human immunodeficiency virus infections published
1987	Manufacturing technology for hepatitis A vaccine transferred from WRAIR to a commercial manufacturer; vaccine licensed in 1995
1991	IND filed for Rift Valley fever vaccine
1996	Recombinant circumsporozoite malaria vaccine developed by the U.S. Army and an industrial partner shown to be protective in human volunteers
1997	First successful vaccine against Shigella developed, produced, and tested
1998	First DNA vaccine against malaria administered to humans

Table reproduced from: National Academies of Sciences, Engineering, and Medicine. 2002. *Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military*. Washington, DC: The National Academies Press.^{39,43} The NAM report adapted a table from Hoke CH Jr. 2000. *Military Infectious Diseases Research Program Background*. Presented at the First Meeting of the Institute of Medicine Committee on a Strategy for Minimizing the Impact of Naturally Occurring Infectious Diseases of Military Importance: Vaccine Issues in the U.S. Military, Washington, DC

Acknowledgements:

Given overlapping subject matter, some of the analysis of shortages in Section 1 is borrowed from written testimony I submitted to a U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health hearing on shortages held in September 2023.

I am grateful to Amy Kapczynski and Reshma Ramachandran for foundational work in conceptualizing and helping develop a set of research questions around the role of the public sector in the provision of essential health products. Assembling the dispersed literature on government investments in health product manufacturing is an enormous and yet incomplete task. I thank Sahil Agrawal, Laura Hallas, Trudel Pare, Athena Sofides, and Dolma Tsering for research support this year.

References

1. George Winston Smith. *Medicines for the Union Army: The United States Army Laboratories During the Civil War*. Madison, WS: American Institute of the History of Pharmacy; 1962.
2. Center for Drug Evaluation and Research. Current Drug Shortages [Internet]. U.S. Food and Drug Administration. [cited 2024 Apr 2]; Available from: <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>
3. Building resilient supply chains, revitalizing American manufacturing, and fostering broad based growth: 100 day Reviews under Executive Order 12017 [Internet]. Washington, D.C., USA: The White House; 2021. Available from: <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>
4. Office of the Under Secretary of Defense for Acquisition and Sustainment. Report on the Department of Defense Pharmaceutical Supply Chain Risks [Internet]. Washington, D.C., USA: 2023. Available from: <https://www.warren.senate.gov/imo/media/doc/FY23%20NDAA%20sec%20860%20Risk%20management%20for%20DoD%20Pharmaceuticals1.pdf>
5. Biodefense Posture Review. Washington, D.C., USA: Department of Defense; 2023.
6. Exploring the Growing U.S. Reliance on China's Biotech and Pharmaceutical Products [Internet]. 2019; Available from: <https://www.uscc.gov/sites/default/files/Priest%20US-China%20Commission%20Statement.pdf>
7. United States Committee on Homeland Security & Governmental Affairs. Short supply: the health and national security risks of drug shortages [Internet]. Washington, D.C.: 2023. Available from: <https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report-FINAL-CORRECTED.pdf>
8. Benjamin Ryan. Antibiotic Shortage Could Worsen Syphilis Epidemic [Internet]. The New York Times. 2023; Available from: <https://www.nytimes.com/2023/07/07/health/syphilis-epidemic-antibiotic-shortage-pfizer.html>
9. TRICARE Formulary [Internet]. Health.mil. Available from: <https://health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Pharmacy-Operations/TRICARE-Formulary?type=All>
10. Defense Health Agency. Evaluation of the TRICARE Program: Fiscal Year 2023 Report to Congress. 2023; Available from: <https://health.mil/Reference-Center/Reports/2023/09/07/Annual-Evaluation-of-TRICARE>
11. Socal MP, Ahn K, Greene JA, Anderson GF. Competition And Vulnerabilities In The Global Supply Chain For US Generic Active Pharmaceutical Ingredients: Study examines the competition and vulnerabilities in the global supply chain for US generic active pharmaceutical ingredients. *Health Affairs* 2023;10–1377.

12. Newport Sourcing API Manufacturing Locations, Clarivate Analytics 2020. [Internet]. In: Building resilient supply chains, revitalizing American manufacturing, and fostering broad based growth: 100 day Reviews under Executive Order 12017. Washington, D.C., USA: 2021. Available from: <https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf>
13. Geographic concentration of pharmaceutical manufacturing: USP Medicine Supply Map analysis [Internet]. US Pharmacopeia. 2022; Available from: <https://qualitymatters.usp.org/geographic-concentration-pharmaceutical-manufacturing>
14. USFDA. Drug Shortages: Root Causes and Potential Solutions [Internet]. 2023; Available from: <https://www.fda.gov/media/131130/download?attachment>
15. Government Accountability Office. Drug shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge [Internet]. Washington, D.C., USA: 2016. Available from: <https://www.gao.gov/assets/gao-16-595.pdf>.
16. Hoyt K. Long shot: vaccines for national defense. Cambridge, Mass: Harvard University Press; 2011.
17. Policy Cures Research. Neglected disease research and development: the status quo won't get us there [Internet]. Available from: <https://policy-cures-website-assets.s3.ap-southeast-2.amazonaws.com/wp-content/uploads/2023/02/09104948/2022-G-FINDER-Neglected-Disease-report.pdf>
18. Clark R. The life of Ernst Chain: penicillin and beyond [Internet]. New York, USA: St. Martin's Press; 2011.
19. Neushul P. Science, Government and the Mass Production of Penicillin. *J Hist Med Allied Sci* [Internet] 1993 [cited 2024 Jan 12];48(4):371–95. Available from: <https://academic.oup.com/jhmas/article-lookup/doi/10.1093/jhmas/48.4.371>
20. Executive Order 8807—Establishing the Office of Scientific Research and Development in the Executive Office of the President and Defining Its Functions and Duties.
21. Kendall Hoyt. Memorandum by the secretary of war to the chief of staff, “Research and Development in Biological Warfare” (September 13, 1945), NA: RG 165, E. 488, B. 182. In: Long shot: vaccines for National Defense. Cambridge, MA: Harvard University Press; 2012.
22. Freemon FR. Gangrene and glory: Medical care during the American Civil War [Internet]. University of Illinois Press; 2001.
23. Steiner PE. Disease in the Civil War: natural biological warfare in 1861-1865. CC Thomas; 1968.
24. Glenna R. Schroeder-Lein. The Encyclopedia of Civil War Medicine. Armonk, New York: M.E. Sharpe; 2008.
25. Flannery M. Civil War pharmacy: A history of drugs, drug supply and provision, and therapeutics for the Union and Confederacy [Internet]. CRC Press; 2004.

26. QUININE [Internet]. The New York Times. 1863;Available from: <https://www.nytimes.com/1863/03/26/archives/news-from-washington-where-the-first-draft-is-to-be-made-what-is-to.html>
27. Robert V. Gibbons, Matthew Streitz, Tatyana Babina, Jessica R. Fried. Dengue and US Military Operations from Spanish–American War through Today. *Emerging Infectious Diseases* [Internet] 2012;Available from: https://wwwnc.cdc.gov/eid/article/18/4/11-0134_article
28. Pintado Silva J, Fernandez-Sesma A. Challenges on the development of a dengue vaccine: a comprehensive review of the state of the art. *J Gen Virol* [Internet] 2023 [cited 2024 Apr 14];104(3):001831. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10228381/>
29. Cohn EJ. The University and the Biologic Laboratories of the State of Massachusetts: A Short History. *Harvard Medical Alumni Bulletin* [Internet] 1950;24(3):75–9. Available from: <https://archive.org/details/harvardmedical24harv/page/n3/mode/2up>
30. MassBiologics research into preventive shot for Lyme disease continues to move forward [Internet]. Mass Chan Medical School. Available from: <https://www.umassmed.edu/news/news-archives/2022/05/massbiologics-research-into-preventive-shot-for-lyme-disease-continues-to-move-forward/>
31. Willey S. MassBiologics research into preventive shot for Lyme disease continues to move forward [Internet]. UMass Chan Medical School News. 2022 [cited 2023 Dec 11];Available from: <https://www.umassmed.edu/news/news-archives/2022/05/massbiologics-research-into-preventive-shot-for-lyme-disease-continues-to-move-forward/>
32. nonGMP Monoclonal Antibody / Protein Production [Internet]. Mass Chan Medical School. Available from: <https://www.umassmed.edu/massbiologics/services/developmentservices/nongmpmonoclonalantibodyproduction/>
33. A New Affiliation: the UMass Chan Medical School [Internet]. Mass Chan Medical School. Available from: <https://www.umassmed.edu/massbiologics/history/history/a-new-affiliation-the-university-of-massachusetts-medical-school/>
34. Nicholas Wade. A Vaccine That Experts Say Is Effective [Internet]. The New York Times. 1997;Available from: <https://www.nytimes.com/1997/12/16/us/a-vaccine-that-experts-say-is-effective.html>
35. General Accounting Office. Biological Warfare: Role of Salk Institute in Army's Research Program [Internet]. 1991;Available from: Washington, D.C., USA
36. Government Accountability Office. Technology Assessment: Vaccine Development Capabilities and Challenges for Addressing Infectious Diseases. Washington, D.C., USA: 2021.
37. Weiss MM, Weiss PD, Weiss JB. Anthrax Vaccine and Public Health Policy. *American Journal of Public Health* [Internet] 2007 [cited 2024 Apr 14];97(11):1945. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2040369/>

38. Judith Miller. Company Led by Top Admiral Buys Michigan Vaccine Lab [Internet]. The New York Times. 1998; Available from: <https://www.nytimes.com/1998/07/08/us/company-led-by-top-admiral-buys-michigan-vaccine-lab.html>
39. Steven Lee Myers. U.S. Doubles Payment to Sole Source of Anthrax Vaccine [Internet]. The New York Times. 1999; Available from: <https://www.nytimes.com/1999/08/06/us/us-doubles-payment-to-sole-source-of-anthrax-vaccine.html>
40. General Accounting Office. Contract Management: Observations on DOD's Financial Relationship With the Anthrax Vaccine Manufacturer. Statement of Louis J. Rodrigues, Director, Defense Acquisitions Issues, National Security and International Affairs Division. Washington, D.C., USA: 1999.
41. The Department of Defense Anthrax Vaccine Immunization Program: Unproven Force Protection. Fourth report by the Committee on Government Reform together with dissenting and supplemental views [Internet]. 2000. Available from: <https://www.congress.gov/congressional-report/106th-congress/house-report/556/1?q=%7B%22search%22%3A%22%5C%22Department+of+Defense+Anthrax+Vaccine+Immunization+Program%5C%22%22%7D&s=8&r=4>
42. Towards a national biodefense strategy [Internet]. 2004; Available from: <https://www.congress.gov/event/108th-congress/house-event/LC13942/text?s=1&r=61>
43. Associated Press. A NATION CHALLENGED: THE VACCINE MAKER; Troubled Company Is Allowed To Resume Making Vaccine [Internet]. The New York Times. 2002; Available from: <https://www.nytimes.com/2002/02/01/us/nation-challenged-vaccine-maker-troubled-company-allowed-resume-making-vaccine.html>
44. Testimony of Louis J. Rodrigues, Director, Defense Acquisition Issues, National Security and International Relations Division, GAO, NSVAIR anthrax hearing (III). [Internet]. 2000. Available from: <https://www.congress.gov/congressional-report/106th-congress/house-report/556/1?q=%7B%22search%22%3A%22%5C%22Department+of+Defense+Anthrax+Vaccine+Immunization+Program%5C%22%22%7D&s=8&r=4>
45. Melody Petersen, Andrew Pollack. A NATION CHALLENGED: THE DEFENSES; Big Push to Accelerate Vaccine Effort [Internet]. The New York Times. 2001; Available from: <https://www.nytimes.com/2001/09/28/business/a-nation-challenged-the-defenses-big-push-to-accelerate-vaccine-effort.html>
46. Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military [Internet]. Washington, D.C.: National Academies Press; 2002 [cited 2024 Apr 6]. Available from: <http://www.nap.edu/catalog/10483>
47. Hoke CH, Snyder CE. History of the restoration of adenovirus type 4 and type 7 vaccine, live oral (Adenovirus Vaccine) in the context of the Department of Defense acquisition system. Vaccine [Internet] 2013 [cited 2024 Apr 6];31(12):1623–32. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0264410X12017999>

48. Howell MR, Nang MRN, Gaydos CA, Gaydos CJC. Prevention of Adenoviral Acute Respiratory Disease in Army Recruits: Cost-Effectiveness of a Military Vaccination Policy 11 The opinions presented are those of the authors and do not necessarily reflect the opinions of the Johns Hopkins University, the U.S. Department of Defense, or the U.S. Army. *American Journal of Preventive Medicine* [Internet] 1998 [cited 2024 Apr 14];14(3):168–75. Available from: <https://www.sciencedirect.com/science/article/pii/S0749379797000640>
49. Sun W, Singh AK. Plague vaccine: recent progress and prospects. *npj Vaccines* [Internet] 2019 [cited 2024 Apr 14];4(1):1–9. Available from: <https://www.nature.com/articles/s41541-019-0105-9>
50. Prohibition on use of funds for planning and design of Department of Defense vaccine production facility [Internet]. 1993. Available from: <https://www.congress.gov/103/statute/STATUTE-107/STATUTE-107-Pg1547.pdf>
51. Proceedings and Debates of the 107th Congress, Second Session. *Congressional Record* [Internet] 148(88). Available from: <https://www.congress.gov/107/crec/2002/06/27/CREC-2002-06-27.pdf>
52. Tim Hutchinson. S.Amdt.4069 to S.2514 [Internet]. Available from: <https://www.congress.gov/amendment/107th-congress/senate-amendment/4069/text?s=1&r=77&q=%7B%22search%22%3A%22%26%231606%22%7D>
53. Hoke CH Jr. *Military Infectious Diseases Research Program Background*. 2000.

Senator WARREN. Thank you, Dr. Barber. Mr. Mendez.

STATEMENT OF BRYCE H.P. MENDEZ, SPECIALIST IN DEFENSE HEALTH CARE POLICY, CONGRESSIONAL RESEARCH SERVICE

Mr. MENDEZ. Good afternoon, Chairwoman Warren, Ranking Member Scott, and Members of the Subcommittee. Thank you for inviting the congressional Research Service to testify today.

This afternoon I will summarize my written statement by starting with a brief overview of the medical research and development capabilities of the Department of Defense, or DOD, followed by a summary of why and how the Department aims to use those capabilities to develop drugs. I will conclude by identifying considerations that Congress may face with regard to DOD medical research, development, and manufacturing of these products.

The U.S. military has a long history of contributing to the discovery of novel drugs and other medical countermeasures. Early and well-known contributions took place during and shortly after the Spanish American War when Army medical research efforts supported the discoveries of typhoid, yellow fever, and malaria vaccines. The lessons learned from the Spanish American War, and other conflicts throughout our Nation's history, have laid the groundwork for Congress and DOD to invest in, build, and sustain military medical research and development capabilities. Today, DOD uses these capabilities to protect servicemembers from health threats, respond to medical capability requirements of the joint force, meet the needs of the National Defense Strategy, and to also respond to congressionally directed research topics.

DOD medical research and development enterprise includes a number of entities like the Defense Health Agency, the military departments, Defense Advanced Research Projects Agency, and the Chemical and Biological Defense Program, among others. Congress appropriates research funding to these entities, who are then responsible for resourcing, performing, or sponsoring medical research projects.

Two of these entities, in particular, provide DOD with capabilities to develop drugs using different approaches. One capability is the Pilot Bioproduction Facility at the Walter Reed Army Institute of Research in Maryland. This government-owned facility provides a test ground for Federal agencies, academia, and private companies to pursue early development and small-scale production of drugs so that they can be transitioned into advanced clinical trials.

Another capability is the Advanced Development and Manufacturing Biopharmaceutical Facility in Florida, administered by the Chemical and Biological Defense Program. The contractor-owned, contractor-operated facility, which became operational in 2017, provides DOD with priority access and surge capacity to produce medical countermeasures.

When DOD discovers a potential drug candidate, the Department is generally subject to Food and Drug Administration, or FDA, requirements and procedures for review, approval, and clearance. Since at least 1997, Congress has provided DOD with an ability to request a Presidential waiver of certain FDA requirements, including those for administering investigational new drugs, or off-label

uses of a drug, and informed consent for certain products authorized for emergency use.

In 2017, Congress provided the Secretary of Defense with the ability to make requests to the FDA Commissioner for expedited review, approval, and clearance of certain medical products when there is an existing or potential military emergency. These authorities provide frameworks for DOD and FDA to share information and to collaborate and coordinate on the development of safe and effective medical products that serve the military's needs.

Turning now to the role of Congress, I wanted to highlight two issues that this Subcommittee may face. First, Congress could consider defining or clarifying the role that DOD should have in conducting in-house drug manufacturing. A question that Congress could consider is whether or not DOD should be in the business of manufacturing drugs or other medical products, and if so, for what purpose and to what extent?

Second, Congress could consider assessing DOD's medical research development and manufacturing approach to better understand its effect on industry participation or engagement with the Department. Congress has given DOD certain authorities and tools that it may use to generate interest and incentivize industry to work with the military. These authorities and tools include unique contracting mechanisms, technology transfer opportunities, and a process for expedited FDA reviews and approvals. Congress could evaluate whether DOD has used these authorities and tools as Congress intended and explore how they might attract, influence, or deter companies from doing business with the military.

This concludes my remarks. Thank you for the opportunity to testify, and I look forward to your questions.

[The prepared statement of Mr. Mendez follows:]



Congressional Research Service
Informing the legislative debate since 1914

TESTIMONY

Statement of

Bryce H. P. Mendez
Specialist in Defense Health Care Policy

Before

Committee on Armed Services
Subcommittee on Personnel
U.S. Senate

Hearing on

**“Department of Defense’s efforts to ensure
servicemembers’ access to safe, high-quality
pharmaceuticals”**

April 17, 2024

Congressional Research Service

7-5700

www.crs.gov

<Product Code>

Introduction

Chair Warren, Ranking Member Scott, and distinguished members of the subcommittee, thank you for the opportunity to appear before you today to discuss the Department of Defense’s efforts to ensure servicemembers’ access to safe, high-quality pharmaceuticals. My name is Bryce Mendez, and I am a specialist in defense health care policy at the Congressional Research Service (CRS). CRS provides Congress with policy research and analysis that is authoritative, objective, and nonpartisan in accordance with our authorizing statute (2 U.S.C. §166).

As requested by the committee, my testimony today will provide an overview of Department of Defense (DOD) medical research and development (R&D) capabilities, discuss how and why DOD uses those capabilities to develop drugs and biologics, and how DOD aims to ensure that developed drugs and biologics are safe and effective for human use.¹ I will also discuss several considerations that Congress may face with regard to DOD medical R&D and manufacturing of drugs and biologics.

Background

The U.S. military has a long history of contributing to the discovery of novel drugs, biologics, prophylactics, and other medical countermeasures. Early and well-known contributions took place during and shortly after the Spanish American War when the Army Surgeon General appointed Dr. Walter Reed, a Major in the U.S. Army, to lead investigations into the causes of Typhoid and Yellow fever.² At the time, both infectious diseases, among others, plagued the U.S. military. For example, during the Spanish American War in 1898, more servicemembers died from infectious diseases than combat-related injuries.³ In particular, Typhoid fever infected over 20,000 soldiers and killed 1,590 soldiers across the Army, resulting in degraded fighting capabilities during the war.⁴

Towards the end of the war, President William McKinley appointed retired Army Major General Grenville M. Dodge to lead an investigation (also referred to as the “Dodge Commission”) into the War Department’s management of the conflict, including the root causes of infectious disease outbreaks across the force.⁵ The commission found that, among other findings, preventive health measures could have been implemented to protect servicemembers from infectious diseases of the time, military-supported discoveries in medical science were necessary to fill knowledge and capability gaps and to attract interest

¹ For the purposes of this testimony, CRS utilizes the U.S. Food and Drug Administration (FDA) definition for “drugs,” which refers to substances recognized by an official pharmacopoeia or formulary; intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; intended to affect the structure or any function of the body; or intended for use as a component of a medicine but not a device or a component, part, or accessory of a device. CRS also utilizes the FDA definition for “biologics,” which refer to a “wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.” For more on these definitions, see <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>.

² John R. Pierce, “Walter Reed - A Name for the Ages,” *The Micrograph*, December 22, 2022, at https://medicalmuseum.health.mil/micrograph/index.cfm/posts/2022/walter_reed_a_name_for_the_ages; and Patrick Feng, “Major Walter Reed and the Eradication of Yellow Fever,” *The Army Historical Foundation*, April 10, 2024.

³ Vincent J. Cirillo, “Journal of the History of Medicine and Allied Sciences,” *Fever and Reform: The Typhoid Epidemic in the Spanish-American War*, vol. 55 (October 2000), p. 396.

⁴ Vincent J. Cirillo, *Bullets and Bacilli: The Spanish-American War and Military Medicine* (New Brunswick, NJ: Rutgers University Press, 2003), p. 71.

⁵ U.S. Congress, Senate, *Report of the commission appointed by the President to investigate the conduct of the War Department in the war with Spain*, Volume 1, 56th Cong. (Washington: GPO, 1900), pp. 1-734.

among civilian medical researchers, and that the military could benefit from stockpiling medical supplies during peacetime in order to prepare for future and emergent demands during wartime.⁶

After the war, the Army Medical School continued Dr. Reed's work to explore the causes of Typhoid fever and how to protect soldiers from infection. In 1908, the Army developed and produced their version of a Typhoid vaccine building upon research conducted by the Royal Army Medical College and other European researchers.⁷ Successes observed throughout the Army's clinical trials of its Typhoid fever vaccine resulted in a compulsory vaccination requirement in 1911 as a means to protect servicemembers from the potential health threat.⁸ The Army's historical investment of military personnel, expertise, and resources to understand the causes of infectious diseases helped to inform future development of new drugs, biologics, and medical technologies.

The lessons learned from the Spanish American War and other conflicts throughout American history have laid the groundwork for both Congress and DOD to invest in, build, and sustain medical R&D capabilities. Today, DOD conducts medical R&D as a means to protect servicemembers from current or future health threats, respond to medical capability requirements of the joint force, and meet the research directives of Congress.

DOD Medical Research and Development

Under Title 10, Section 4001, of the *U.S. Code* (U.S.C.), DOD administers a wide range of R&D programs. DOD R&D primarily focuses on "basic research, applied research, advanced research, and development projects" that are

- necessary to the responsibilities of such Secretary's department in the field of research and development; and either
- relate to weapon systems and other military needs; or
- are of potential interest to the DOD.⁹

In general, DOD conducts medical R&D based on the "needs of the National Defense Strategy and the Joint Capabilities Integration and Development System" and in response to Congressionally Directed

⁶ Ibid; Vincent J. Cirillo, *Bullets and Bacilli: The Spanish-American War and Military Medicine* (New Brunswick, NJ: Rutgers University Press, 2003), p. 153; James E. Hewes Jr., "The War Department From Root To Marshall," in *From Root to McNamara: Army Organization and Administration* (Washington, DC: U.S. Army Center of Military History, 1983); and Edward Ranson, "The Investigation of the War Department, 1898-99," *The Historian*, vol. 34, no. 1 (November 1971), pp. 78-99.

⁷ Frederick F. Russell, "Anti-Typhoid Vaccination in the American Army," *Journal of the American Public Health Association*, vol. 1, no. 7 (July 1911), pp. 473-479; Robert M. Hardaway III, "Contributions of Army Medicine to Civilian Medicine," *Military Medicine*, vol. 138, no. 7 (July 1973), pp. 409-412; and Rufus L. Holt and Arthur P. Hitchens, "Typhoid Vaccine: The Technique of Its Preparation at the Army Medical School," *Public Health Reports*, vol. 52, no. 26 (June 25, 1937), pp. 829-844.

⁸ John D. Grabenstein, Phillip R. Pittman, and John T. Greenwood, et al., "Immunization to Protect the US Armed Forces: Heritage, Current Practice, and Prospects," *Epidemiologic Reviews*, vol. 28, no. 1 (August 2006), pp. 3-26; W. D. Tiggert, "The Initial Effort to Immunize American Soldier Volunteers with Typhoid Vaccine," *Military Medicine*, vol. 124, no. 5 (May 1959), pp. 342-349; and Andrew W. Arntstein, Jason M. Opal, and Steven M. Opal, et al., "History of U.S. Military Contributions to the Study of Vaccines," *Military Medicine*, vol. 170, no. Suppl 4 (April 2005), pp. 3-11.

⁹ 10 U.S.C. §4001. For FY2024, Congress appropriated \$148.3 billion for DOD research, development, test, and evaluation activities (see explanatory statement accompanying P.L. 118-47, *Congressional Record*, March 22, 2024, p. H1644. For more on DOD research and development (R&D) programs and historical funding amounts, see CRS Report R47564, *Federal Research and Development (R&D) Funding: FY2024*, coordinated by John F. Sargent Jr.; CRS Report R44711, *Department of Defense Research, Development, Test, and Evaluation (RDT&E): Appropriations Structure*, by John F. Sargent Jr.; CRS In Focus IF10553, *Defense Primer: RDT&E*, by John F. Sargent Jr. Congressional offices may also contact Marcy E. Gallo, CRS analyst in science and technology policy, for more on DOD R&D programs and funding.

Medical Research Programs (CDMRP).¹⁰ DOD has three goals in conducting medical R&D, which are to ensure that the joint force is “(1) better prepared, (2) better protected, and (3) better cared for throughout the operational life cycle.”¹¹ To achieve these goals, DOD organizes its medical R&D efforts under the following focus areas:

- biomedical informatics and health information systems and technology;
- clinical and rehabilitative medicine;
- combat casualty care;
- medical chemical and biological defense;
- medical radiological defense;
- military infectious diseases; and
- military operational medicine.¹²

DOD Medical R&D Enterprise

The DOD medical R&D enterprise is composed of multiple entities. These entities include the Defense Health Agency (DHA), Uniformed Services University of the Health Sciences (USUHS), the military services’ medical departments, Defense Advanced Research Projects Agency, Chemical and Biological Defense Program, and the Defense Threat Reduction Agency. DOD synchronizes these entities through the Armed Services Biomedical Research Evaluation and Management Community of Interest (ASBREM CoI).¹³ The ASBREM CoI serves as the primary coordination body for DOD’s medical research community and to “prevent unnecessary duplication of effort.”¹⁴ While the ASBREM CoI helps advance “communication, coordination, and collaboration” across the DOD medical R&D enterprise, individual entities are responsible for resourcing and performing (or sponsoring) medical R&D projects and activities.¹⁵

¹⁰ Department of Defense (DOD), “Department of Defense Strategic Medical Research Plan,” January 2019, p. 6, at <https://health.mil/Reference-Center/Congressional-Testimonies/2019/04/08/Strategic-Medical-Research-Plan>. For more on the National Defense Strategy, see CRS Report R45349, *The 2018 National Defense Strategy: Fact Sheet*, by Kathleen J. McInnis. For more on the Joint Capabilities Integration and Development System, see pp. 3-4 of CRS Report RL34026, *Defense Acquisitions: How DOD Acquires Weapon Systems and Recent Efforts to Reform the Process*, by Heidi M. Peters. For more on Congressionally Directed Medical Research Programs, see CRS Report R46599, *Congressionally Directed Medical Research Programs: Background and Issues for Congress*, by Bryce H. P. Mendez. Congressional offices may contact Alexandra G. Neenan, CRS analyst in U.S. defense acquisition policy, for more on DOD acquisition policy; and John W. Rollins, CRS specialist in terrorism and national security, for more on the National Defense Strategy.

¹¹ DOD, “Department of Defense Strategic Medical Research Plan,” January 2019, p. 11.

¹² *Ibid.*, p. 6.

¹³ The role of the Armed Services Biomedical Research Evaluation and Management Community of Interest (ASBREM CoI), formerly known as the ASBREM Committee, is to “promote the coordination and synergy of the DoD biomedical R&D efforts to provide medical products and information” required to protect and sustain servicemembers. For more on the ASBREM, see Department of Defense (DOD), *Integrated DoD Biomedical Research and Development Strategy*, Medical Innovation for the Future Force, December 2017, p. iii, https://defenseinnovationmarketplace.dtic.mil/wp-content/uploads/2018/04/ASBREM_Integrated_RD_Strategy_2017.pdf.

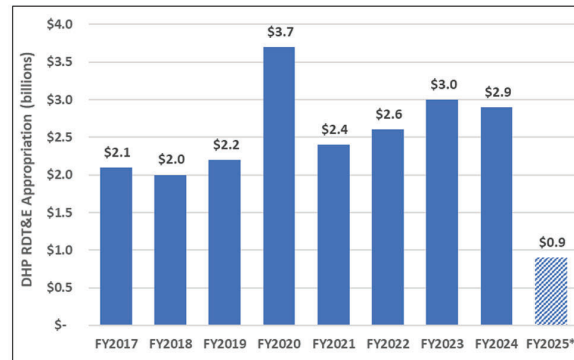
¹⁴ DOD Directive 6025.21E, “Medical Research for Prevention, Mitigation, and Treatment of Blast Injuries,” updated October 15, 2018, p. 1, at <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/602521p.pdf>.

¹⁵ DOD, Department of Defense Strategic Medical Research Plan, January 2019, p. 8.

DOD Medical R&D Funding

DOD has the second-largest departmental expenditures on medical research, after the National Institutes of Health (NIH).¹⁶ Each year, DOD submits its funding request for medical R&D activities and projects as part of the President's annual budget request. Congress evaluates, adjusts, and appropriates discretionary funding for medical R&D activities that DOD may, or may not, have requested. Congress appropriates these funds through an annual DOD appropriations act; the funds are further distributed to the research entities through numerous Research, Development, Test, and Evaluation (RDT&E) budget activities and program elements.¹⁷ Since many DOD entities conduct or fund these activities, there is no consolidated request, appropriations account, budget activity, or program element that incorporates the totality of all medical R&D. One of the DOD accounts that funds medical R&D activities is the Defense Health Program (DHP).¹⁸ The DHP account funds "medical and health care programs," including certain RDT&E programs.¹⁹ DOD often uses DHP RDT&E funding to resource medical research activities throughout the medical R&D enterprise.²⁰ **Figure 1** shows the amount of RDT&E funding appropriated to the DHP account between FY2017 and FY2024, and the amount requested by DOD for FY2025.

Figure 1. RDT&E Appropriations for the Defense Health Program Account
FY2017-FY2025 Request*



Source: CRS In Focus IF12377, *FY2024 Budget Request for the Military Health System*, by Bryce H. P. Mendez; CRS In Focus IF1206, *FY2020 Budget Request for the Military Health System*, by Bryce H. P. Mendez; Explanatory Statement accompanying P.L. 118-47, *Congressional Record*, March 22, 2024, p. H1718; and DOD, "Defense Health Program, Fiscal Year (FY) 2025

¹⁶ Research America, *U.S. Investments in Medical and Health Research and Development, 2016-2020*, January 2022, p. 7, at https://www.researchamerica.org/wp-content/uploads/2022/09/ResearchAmerica-Investment-Report.Final_January-2022-1.pdf.

¹⁷ For more on DOD appropriations for RDT&E, see CRS Report R44711, *Department of Defense Research, Development, Test, and Evaluation (RDT&E): Appropriations Structure*, by John F. Sargent Jr.

¹⁸ For more on the DHP account, see CRS In Focus IF12377, *FY2024 Budget Request for the Military Health System*, by Bryce H. P. Mendez; and Question 2 ("How is the Military Health System Funded?") of CRS Report R45399, *Military Medical Care: Frequently Asked Questions*, by Bryce H. P. Mendez.

¹⁹ 10 U.S.C. §1100.

²⁰ Defense Health Board, *Improving Defense Health Program Medical Research Processes*, August 8, 2017, pp. 9-14, 44-54; at <https://health.mil/Reference-Center/Reports/2017/08/08/Improving-Defense-Health-Program-Medical-Research-Process>.

President's Budget," March 2024, p. 1, at https://comptroller.defense.gov/Portals/45/Documents/defbudget/FY2025/budget_justification/pdfs/09_Defense_Health_Program/00-DHP_Vols_I_and_II_PB25.pdf.

Notes: *Dollar amount represents DOD request for FY2025 DHP RDT&E. Since 1992, Congress has typically appropriated additional dollars to the DHP RDT&E account for the Congressionally Directed Medical Research Programs (CDMRP). The FY2025 request does not reflect an amount for the CDMRP. RDT&E = Research, Development, Test, and Evaluation.

DOD Capabilities to Develop Drugs and Biologics

DOD has existing capabilities to develop and manufacture (on a limited scale) drugs and biologics to protect servicemembers from current or future health threats. These capabilities use different manufacturing approaches, including strategic partnerships with public and private entities, to meet certain medical R&D objectives and other military requirements for *force health protection*.²¹ These partnerships can take many forms, including a contractual agreement, grant award, cooperative research and development agreement (CRADA), or Other Transaction Authority.²² In addition, DOD typically negotiates terms for medical technology transfer, allowing a partner entity to retain certain intellectual property rights for further development or commercial use purposes.²³

Army Pilot Bioproduction Facility

The Walter Reed Army Institute of Research (WRAIR) administers a "pharmaceutical manufacturing facility" in Silver Spring, MD, known as the Pilot Bioproduction Facility (PBF). In 1953, the Army Medical Department established the PBF as a government-owned, government-operated manufacturing capability.²⁴ The function of the PBF is to assist in the early development and small-scale production of drugs and biologics to defend against "military-relevant infectious disease threats."²⁵ According to WRAIR, the PBF is compliant with U.S. Food and Drug Administration (FDA) regulations on current Good Manufacturing Practice (cGMP),²⁶ certified for biosafety level-2 (BSL-2) research,²⁷ and has developed drugs and biologics to address Hepatitis A, Japanese encephalitis, Malaria, Zika, COVID-19, and others.²⁸ The PBF capability allows WRAIR to provide a test ground to produce and transition newly

²¹ DOD defines *force health protection* (FHP) as measures taken to "promote, protect, improve, conserve, and restore the mental and physical well being of Service members across the range of military activities and operations." For more on FHP, see DOD Directive 6200.04, *Force Health Protection (FHP)*, updated April 23, 2007, at <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/620004p.pdf>.

²² Army Medical Research and Development Command, "Medical Technology Transfer," May 17, 2019, at https://technologytransfer.health.mil/index.cfm?pageID=about_tech_transfer; CRS Report R45521, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress*, by Heidi M. Peters; and DOD, "Other Transactions Guide," July 2023, at https://www.acq.osd.mil/asda/dpc/cp/policy/docs/guidebook/TAB%20A1%20-%20DoD%20OT%20Guide%20JUL%202023_final.pdf.

²³ Army Medical Research and Development Command, "Medical Technology Transfer," May 17, 2019; WRAIR briefing and discussions with CRS, October 2023; DOD Instruction 5535.08, *DoD Domestic Technology Transfer Program*, September 22, 2022, at <https://www.esd.whs.mil/portals/54/documents/dd/issuances/dodi/553508p.pdf>; and Defense Health Agency Procedural Instruction 3201.05, *Technology Transfer (T2) Program*, June 20, 2019, at <https://www.health.mil/Reference-Center/DHA-Publications/2019/06/20/DHA-PI-320105>.

²⁴ Walter Reed Army Institute of Research (WRAIR), "Pilot Bioproduction Facility," accessed April 5, 2024, at <https://wrair.health.mil/Collaborate/Pilot-Bioproduction-Facility/>.

²⁵ *Ibid.*

²⁶ For more on current Good Manufacturing Practice (cGMP) regulations, see <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>; and CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*, by Amanda K. Sarata and Hassan Z. Sheikh.

²⁷ For more on laboratory biosafety levels, see <https://www.phe.gov/s3/BioriskManagement/biocontainment/Pages/BSL-Requirements.aspx>.

²⁸ Kenneth H. Eckels, "Product Development for the Warfighter," presentation to the Association of the U.S. Army, Washington, (continued...)

developed drugs and biologics into “advanced clinical trials and licensure.”²⁹ WRAIR partners with public and private biomedical research entities to explore and develop drugs and biologics that address current and future health threats.³⁰

DOD Advanced Development and Manufacturing Biopharmaceutical Facility

The Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), an office under the Chemical and Biological Defense Program, administers the DOD Advanced Development and Manufacturing (ADM) Biopharmaceutical Facility located in Alachua, FL.³¹ The ADM facility is a contractor-owned, contractor-operated facility that provides DOD with an “enduring capability and infrastructure” to meet military medical requirements and the “capability for agile and flexible advanced development and manufacturing” of medical countermeasures.³² In December 2010, then-Assistant to the President for Homeland Security, John O. Brennan, transmitted a memorandum calling for the Secretary of Defense to “establish agile and flexible advanced development and manufacturing capabilities to support the development, licensure, and production of medical countermeasures.”³³ In response to this directive, on March 21, 2013, Army Contracting Command awarded a \$135.8 million contract to then-Nanotherapeutics Inc. to build and operate the ADM facility, which provides DOD with “priority access” to the contractor’s manufacturing capabilities in order to “produce medical countermeasures more quickly and more effectively than other drug makers.”³⁴ According to JPEO-CBRND, the ADM facility is compliant with cGMP regulations, certified for biosafety level-3 (BSL-3) research, and has developed biologics to address COVID-19, Botulism neurotoxin, and other health threats.³⁵

DC, July 25, 2017, at <https://www.ansa.org/sites/default/files/amy-medical-eckels.pdf>; and WRAIR, “Pilot Bioproduction Facility (PBF),” fact sheet, November 2022, at https://wrair.health.mil/Portals/87/Documents/PBF%20Handout%202022_Updated_21NOV22_final.pdf.

²⁹ *Ibid.*; and WRAIR briefing and discussions with CRS, October 2023.

³⁰ *Ibid.*

³¹ Kelly Burkhalter and Chris Southworth, “Enduring Capability: JPEO-CBRND evolves public/private partnership with National Resilience,” *JPEO-CBRND News*, December 5, 2023, at <https://www.jpeocbrnd.osd.mil/Media/News/Article/3607443/enduring-capability-jpeo-cbrnd-evolves-public-private-partnership-with-national/#:~:text=Located%20in%20Alachua%2C%20Florida%2C%20the,agents%20and%20emerging%20infectious%20diseases>.

³² SAM.gov, “A—Medical Countermeasure Manufacturing Advanced Development Manufacturing (ADM) Capability,” Presolicitation Notice ID W911QY11R0023, August 9, 2011, at <https://sam.gov/opp/6d98c844d9d76510d7cf6bfdefc33e/view>.

³³ U.S. Government Accountability Office (GAO), *Biological Defense: Additional information that Congress may find useful as it considered DOD’s advanced development and manufacturing capability*, GAO-17-701, July 2017, p. 7, at <https://www.gao.gov/assets/gao-17-701.pdf>; and White House, Memorandum for the Secretary of Defense, “Medical Countermeasures against Biological and Other Public Health Threats,” December 29, 2010.

³⁴ DOD, “Contracts for March 21, 2013,” accessed April 8, 2024, at <https://web.archive.org/web/20130408205027/http://www.defense.gov/contracts/contract.aspx?contractid=5002>; Kelly Burkhalter, “Enduring Capability: JPEO-CBRND evolves public/private partnership with National Resilience,” *JPEO-CBRND News*, December 4, 2023, at <https://www.dvidshub.net/news/459375/enduring-capability-jpeo-cbrnd-evolves-public-private-partnership-with-national-resilience>; and Anthony Clark, “U.S. Department of Defense Expands Medical Countermeasure Capabilities,” *JPEO-CBRND News*, December 20, 2016, at <https://www.jpeocbrnd.osd.mil/Media/News/Article/2597346/us-department-of-defense-expands-medical-countermeasure-capabilities/>. In 2017, Nanotherapeutics, Inc. was renamed to Ology Bioservices, Inc. In 2021, National Resilience, Inc. acquired Ology Bioservices.

³⁵ Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND), “Medical Countermeasures Advanced Development and Manufacturing (ADM),” accessed April 8, 2024, at https://www.jpeocbrnd.osd.mil/Portals/90/fact-sheet_adm.pdf; JPEO-CBRND, “JPEO-CBRND Capabilities Catalog,” 2023, at https://www.jpeocbrnd.osd.mil/Portals/90/Documents/JPEO-CBRND_Capabilities%20Catalog_20%20April%202023_Final.pdf; and Hannah Feldman, Chris Earhart, and Traci Pals, “Toxic at Best,” *JPEO-CBRND News*, January 22, 2019, at <https://www.jpeocbrnd.osd.mil/Media/News/Article/2593990/toxic-at-best/>.

Ensuring Safe and Effective Drugs and Biologics

Prior to the enactment of the Federal Food, Drug, and Cosmetic Act (FFDCA; 52 Stat. 1040) in 1938, the military administered its own procedures to ensure drugs and biologics used on servicemembers were safe and effective.³⁶ In 1964, DOD and FDA entered into a Memorandum of Understanding (MOU) to ensure requirements enacted in the FFDCA, the Drug Amendments Act of 1962 (P.L. 87-781), and related regulations were “fully met without jeopardizing or impeding the requirements of national security or the requirements of Federal laws and regulations related to such use of drugs.”³⁷ Under a 1974 MOU, DOD agreed to adhere to the FDA regulatory requirements governing the “investigational use of new drugs and medical devices in human beings,” informed consent, and Institutional Review Board procedures.³⁸ Today, DOD generally adheres to FDA requirements and procedures designed to ensure developed drugs and biologics are deemed safe and effective for human use.³⁹

Congress has enacted several laws to provide DOD with a process to request a presidential waiver of certain FDA requirements, including requirements for administering investigational new drugs or off-label uses of a drug,⁴⁰ and informed consent for certain “products authorized for emergency use.”⁴¹ In addition, Congress has authorized DOD to request an expedited FDA review, approval, and clearance process for certain medical products when there is an existing or “significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of such application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk.”⁴²

In January 2018, DOD and FDA outlined their initial work plan to enhance collaboration and coordination to “see safe and effective products more efficiently reach those protecting our Nation.”⁴³ As of March 2024, DOD and FDA have 10 MOUs in effect that provide frameworks on how both federal entities are to interact in the development of safe and effective medical products that serve the military’s needs, facilitate information sharing, and to clarify interagency cooperation on issues relating to safety and effectiveness of drugs, biologics, and other medical products.⁴⁴

³⁶ Guy R. Hasegawa, “Pharmacy in the American Civil War,” *Pharmacy in History*, vol. 42, no. 3/4 (2000), pp. 67-86.

³⁷ Jeremiah J. Kelly, “Enhanced Engagement: The Evolving Relationship between FDA and DoD Regulatory Authorities,” *Food and Drug Law Journal*, vol. 78, no. 2 (October 2023), p. 159, at <https://www.fdl.org/2023/10/enhanced-engagement-the-evolving-relationship-between-fda-and-dod-regulatory-authorities-open-access/>.

³⁸ FDA, “Memorandum of Understanding between the Food and Drug Administration and the Department of Defense Concerning Investigational Use of Drugs, Antibiotics, Biologics, and Medical Devices by the Department of Defense,” MOU 224-75-3003, accessed April 8, 2024, at <https://www.fda.gov/about-fda/domestic-mous/mou-224-75-3003>. The regulatory requirements include those specified in Parts 50, 56, 312, and 812 of Title 21, *Code of Federal Regulations*. DOD and FDA last updated the MOU in 1987, which is still in effect.

³⁹ For more on how FDA approves new drugs and biologics, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Hassan Z. Sheikh.

⁴⁰ 10 U.S.C. §1107. DOD Instruction 6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs*, implements this statutory authority.

⁴¹ 10 U.S.C. §1107a. DOD Instruction 6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs*, implements this statutory authority.

⁴² P.L. 115-92.

⁴³ FDA, “Initial Work Plan for Products Relevant to the Department of Defense (DoD), January 2018, at <https://www.fda.gov/media/110237/download>.

⁴⁴ FDA, “Domestic MOUs,” March 21, 2024, at <https://www.fda.gov/about-fda/fda-memoranda-understanding/domestic-mous>.

Considerations for Congress

Defining the Role of DOD Manufacturing Capabilities

The role of DOD's government-owned (sometimes referred to as *organic*) manufacturing capabilities is limited to the early research and development phases of novel drugs and biologics intended to protect servicemembers from certain health threats. Since the 1950s, the Army Pilot Bioproduction Facility (PBF) has supported this function by conducting limited, in-house manufacturing of newly developed drugs and biologics for the clinical trials process.⁴⁵ WRAIR asserts that the PBF "fills a crucial need in a very important part of the vaccine production pipeline" since the "the availability of independent facilities willing to manufacture a full range of Phase 1 production under one roof is extremely limited."⁴⁶ Army scientists have also suggested that facilities like the PBF "remove some of the risk perceived by commercial partners looking for products emerging from early research and development phases," while acknowledging that DOD "does not have a suitable mechanism for manufacturing and fill/finish capability" in late-stage product development and scaling.⁴⁷

Congress could consider further defining or clarifying any role DOD has or might have in conducting in-house manufacturing of drugs and biologics. Congress could direct DOD to expand, contract, or sustain its drug and biologics manufacturing capabilities or capacity based on Congress's assessment of needs to mitigate broader supply chain resiliency challenges, to meet military requirements for medical countermeasures, or to avoid unintended effects on the commercial market. Another question that Congress could consider is whether or not DOD's capabilities to manufacture drugs and biologics should extend to non-military purposes (e.g., supporting the availability of medical countermeasures for public health emergencies or to address existing drug shortages). In calendar year 2022, the FDA was notified of 1,293 potential drug and biological product shortage situations.⁴⁸ An FDA-led interagency task force found three major root causes of drug shortages:

- lack of incentives to produce less profitable drugs;
- the market does not recognize and reward manufactures for mature quality management systems; and
- logistical and regulatory challenges make it difficult for the market to recover after a disruption.⁴⁹

Expanded DOD manufacturing capabilities or capacity could address some of these root causes since the military is not a profit-driven entity and DOD adheres to quality management standards (e.g., cGMP regulations) and quality control measures throughout the medical R&D and manufacturing continuum. If Congress were to assess that DOD's manufacturing capabilities should be used to mitigate national drug

⁴⁵ For more on clinical trials, see CRS Legal Sidebar LSB10483, *Testing, Testing, (Phase) 1-2-3: Legal Considerations for Clinical Trials of Potential COVID-19 Vaccines*, by Erin H. Ward.

⁴⁶ Samir Deshpande, "WRAIR Re-launches Vaccine Manufacturing Facility," *Defense Visual Information Distribution Service*, May 6, 2021, at <https://www.dvidshub.net/news/395778/wrair-re-launches-vaccine-manufacturing-facility>. "Phase 1 production" refers to small-batch manufacturing of drugs or biologics used to evaluate its safety in a small group of test subjects and to identify side effects (i.e., Phase 1 clinical trial).

⁴⁷ Jeffrey M. Osgood, Jeffrey W. Froude, and Sherri P. Daye, et al., "Cross-Cutting Lessons Learned During the COVID-19 Pandemic—the Walter Reed Army Institute of Research Experience," *Military Medicine*, vol. 188, no. 1-2 (January-February 2023), pp. 158-165. "Fill/finish capability" refers to a portion of the manufacturing process that includes filling, labeling, packaging, and quality inspection of drugs or biologics prior to distribution.

⁴⁸ FDA, "Report to Congress, Drug Shortages CY2022," June 7, 2023, p. 9, at <https://www.fda.gov/media/169302/download?attachment>.

⁴⁹ FDA, "Drug Shortages: Root Causes and Potential Solutions," updated February 21, 2020, p. 6, at <https://www.fda.gov/media/131130/download?attachment>.

shortage issues, additional authorities or investments may be necessary. In 2019, the Defense Health Agency Deputy Assistant Director for Healthcare Operations testified to the U.S.-China Economic and Security Review Commission that DOD is “neither authorized, by law, nor funded to produce commercial pharmaceuticals.”⁵⁰ Congress could consider whether or not to provide an explicit authority, appropriations, or parameters for DOD to expand its manufacturing capabilities for non-military purposes. Congress also could assess whether DOD’s manufacturing capabilities should be utilized only for military-specific requirements and to prevent a duplication of effort with existing whole-of-government actions that “enable investment in domestic manufacturing.”⁵¹

Addressing Commercial Interest and Perceptions of Risk

Since at least 1990, DOD has identified concerns with its ability to “acquire and maintain the capability to research, develop and manufacture medical countermeasures.”⁵² A 2009 study found that biopharmaceutical companies had few incentives to work with DOD on the development of medical countermeasures, citing “low profit margins, the risk of liability for adverse reactions to the products, marginal federal funding . . . and inconsistent priorities” as obstacles to public-private cooperation in this area.⁵³ Some biopharmaceutical companies have expressed that certain incentives could be used by the federal government to encourage companies to partner with DOD and other U.S. government agencies, including

- direct incentives that provide a “steady revenue commensurate with shareholder expectations” through guaranteed payments for developed and manufactured products, or
- indirect incentives that offer provisions to financially benefit a company’s commercial efforts, including excess capability to produce commercial products in a government-owned, contractor-operated manufacturing model, intellectual property rights, and expedited FDA reviews and approvals.⁵⁴

Congress could assess the effectiveness of DOD’s medical R&D and manufacturing approach on the propensity of the commercial biopharmaceutical industry to work with the military. Congress has given

⁵⁰ Testimony of Defense Health Agency Deputy Assistant Director for Healthcare Operations, in U.S. Congress, U.S.-China Economic and Security Review Commission, “Exploring the Growing U.S. Reliance on China’s Biotech and Pharmaceutical Products,” hearings, 116th Cong., 1st sess., July 31, 2019, at <https://www.uscc.gov/sites/default/files/Priest%20US-China%20Commission%20Statement.pdf>.

⁵¹ Department of Health and Human Services, “Biden-Harris Administration Announces Actions to Bolster Medical Supply Chain,” press release, November 27, 2023, at <https://www.hhs.gov/about/news/2023/11/27/biden-harris-administration-announces-actions-bolster-medical-supply-chain.html>; and Executive Office of the President, National Science and Technology Council, “National Strategy for Advanced Manufacturing,” October 2022, at <https://www.whitehouse.gov/wp-content/uploads/2022/10/National-Strategy-for-Advanced-Manufacturing-10072022.pdf>.

⁵² Secretary of Defense Memorandum to the Assistant Secretary of Defense for Health Affairs, “Expansion of Industrial Base for Biological Vaccine Production,” October 3, 1990, at https://gulflink.health.mil/va/va_refs/n46en061/970107_sep96_decls48_0001.htm; DOD Memorandum for the Record, “Fourth Tri-Service Task Force (Project Badger) Meeting,” October 26, 1990, at https://gulflink.health.mil/va/va_refs/n46en067/102596_sep96_decls4_0002.htm; and GAO, *Biological Defense: Additional information that Congress may find useful as it considered DOD’s advanced development and manufacturing capability*, GAO-17-701, July 2017, p. 1.

⁵³ Thomas Fuerst, Kim Wallace, and Phillip Gomez, et al., *Ensuring Biologics Advanced Development and Manufacturing for the United States Government: A Summary of Key Findings and Conclusions*, University of Pittsburgh Medical Center, October 6, 2009, pp. 1-2, at <https://apps.dtic.mil/sti/tr/pdf/ADA506569.pdf>.

⁵⁴ Ibid., pp. 79-80; Bobby Clark and Jeff Callis, “Public Good vs. Private Gain: The Role of Public-Private Partnerships in Drug Innovation and Pricing,” *The Commonwealth Fund*, June 8, 2022, at <https://www.commonwealthfund.org/blog/2022/public-good-vs-private-gain-role-public-private-partnerships-drug-innovation-and-pricing>; and PhRMA, *The Power and Promise of a Collaborative Biopharmaceutical Ecosystem*, March 2021, pp. 22-23, at https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/D-F/PhRMA_EcosystemMarch-Report_FINAL.pdf.

DOD certain authorities and tools that it may use to generate interest among potential industry partners, reduce regulatory barriers, and mitigate some associated risks. These include traditional and non-traditional contracting approaches under the Defense Acquisition System,⁵⁵ technology transfer

⁵⁵ Traditional federal contracting mechanisms include those subject to the Federal Acquisition Regulation (FAR) and Defense Federal Acquisition Regulation Supplement (DFARS), while non-traditional federal contracting mechanisms include Other Transaction Authorities, procurement for experimental purposes, and R&D agreements. For more on DOD contracting mechanisms, see CRS Report RL34026, *Defense Acquisitions: How DOD Acquires Weapon Systems and Recent Efforts to Reform the Process*, by Heidi M. Peters; and CRS Report R45521, *Department of Defense Use of Other Transaction Authority: Background, Analysis, and Issues for Congress*, by Heidi M. Peters. Congressional offices may contact Alexandra G. Neenan, CRS analyst in U.S. defense acquisition policy, for more on DOD acquisition policy.

opportunities, and a process for expedited FDA reviews and approvals. Congress could evaluate whether DOD has used these authorities and tools as Congress intended, including whether or not it has been utilized to alleviate industry concerns or to address commercial interest in doing business with the military for advanced development and manufacturing of drugs and biologics.

Conclusion

Thank you for the opportunity to testify. I look forward to responding to any questions that you may have. If additional research and analysis related to these issues would be helpful, CRS is prepared to assist.

CRS TESTIMONY
Prepared for Congress

Senator WARREN. Thank you, Mr. Mendez. Colonel Suarez.

**STATEMENT OF COLONEL VICTOR A. SUAREZ, USA (RET.),
FOUNDER AND PRINCIPAL GROWTH PARTNER, BLU ZONE
BIOSCIENCE & SUPPLY CHAIN SOLUTIONS, LLC**

Colonel SUAREZ. Good afternoon, Chairwoman Warren, Ranking Member Scott, and distinguished Members of this Committee. Thank you for the opportunity to speak with you today.

My name is Vic Suarez, and I have recently retired from the U.S. Army after 27½ years of Active Service, as a medical service and acquisition corps officer, specializing in the advanced development of biologics, managing the medical supply chain, and meeting

America's finest sons and daughters as a commander four times, twice in the combat zone.

During the past 10 years I have been heavily involved in advanced development of biodefense medical countermeasures, served as the Chief of Staff at the Walter Reed Army Institute of Research, and was selected by General Gus Perna to serve at Operation Warp Speed, from 2020 to 2021 as the Lead Vaccine Program Manager. I am speaking today primarily in my role as a Founder of Blu Zone Bioscience, a life science consulting firm.

When I left Active Duty 6 months ago, my principal goal was to affiliate with organizations that were mission-aligned with my responsibilities in the DOD, including enhancing national security and protecting human health, and to that end supporting domestic companies that could support those two missions. To this end, I partnered with two organizations, the Council on Strategic Risks and the Securing America's Medicines and Supply coalition. Both organizations are focused on ensuring access to essential medicines for patients and the warfighter.

On November 27, 2023, the Department of Defense, in response to the fiscal year 2023 National Defense Authorization Act, Section 860, provided the Senate and House Armed Services Committee an interim risk report on the Department's reliance on overseas-derived pharmaceuticals. A significant finding was that 54 percent of the national drug codes sourced from the DOD had active pharmaceutical ingredients, or APIs, and excipients non-API, that came from non-Trade Agreement Act compliant countries, including China.

This recent finding presents a clear and present danger to national security. It should compel us to explore better legislative and trade policies that strengthen our Federal acquisitions, economic, and health security to reduce our reliance on overseas essential medicines, their key starting materials, and API. We must manufacture more of these materials domestically to ensure high-quality manufacturing processes and products, including a reliable and resilient material medical supply chain supporting this essential industry.

A major contributing factor to this national security and health security risk is a little-known but controversial court case titled *Acetris Health, LLC v. United States*. In this case, the United States 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 considered to be manufactured or substantially transformed in the U.S. and sold to the Federal Government, even if its API and all of its components, to include excipients, were manufactured in TAA-banned countries.

Today, a Chinese firm could make all the API and precursor materials for a medicine, ship it to a United States subsidiary that does packaging and final labeling, and still be able to label it as American made. This would be considered an American-made drug and principally illustrates this loophole.

In my testimony today I wish to highlight a dysfunctional market where generic drug companies compete in a race to the bottom in generic drug pricing and manufacturing, a principal driver of drug shortages, which just 2 weeks ago, as you mentioned earlier, Sen-

ator, was reported by the American Society of Health System Pharmacists, that our Nation is at an all-time high, since 2001, of 323 known drug shortages.

Overwhelming downward pressure in generic drug costs with no consideration for supply reliability or quality leads domestic manufacturers to operate at approximately 50 percent utilization capacity. Many of these domestic companies are closing plants and essential medicine production lines, or being acquired by foreign entities, which will only downgrade our Nation's ability to independently provide health care for its citizens during a global pandemic or during a national security event.

Finally, I want to applaud the Department of Defense efforts to assess these strategic risks through both the assessment of the origin supply chain at the Defense Logistics Agency as well as the Uniformed Services University Pharmaceutical Assessment of Quality Pilot Study, or PhaQS, as both these efforts will provide more transparency and potentially enable millions of our service men and women, their families, and other TRICARE retiree, like me, confidence that when they go to a military treatment facility in the U.S. or serve in combat that they will always have access to the highest quality medicines, at the most affordable prices, something that is possible if we are 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 I 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.

I look forward to your questions.

[The prepared statement of Colonel Suarez follows:]

STATEMENT OF
COL(RET) VICTOR A. SUAREZ
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
APRIL 17, 2024

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.

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,

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

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:

¹¹Administration for Strategic Preparedness and Response, Essential Medicines and Manufacturing Resilience Assessment (2022) (https://www.armi.usa.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.

Mr. Suarez has submitted supportive articles found in Appendix A.

Senator WARREN. Thank you, Colonel Suarez. I appreciate it.

I am going to start the questions here. Most of the time DOD will continue to purchase drugs from the commercial drug market, but there are some instances when it makes sense for DOD to produce the medication itself, for example, when DOD is the only customer. An example is the adenovirus vaccine. While adenovirus typically causes mild cold or flu-like symptoms, it is a major cause of serious respiratory illness among servicemembers, particularly during basic training. That is why WRAIR developed an adenovirus vaccine which it then licensed to private industry.

But because there is not a broad market for the adenovirus vaccine, it has sometimes been difficult to find a manufacturer that was willing to produce it. In fact, for over a decade, DOD was unable to vaccinate new recruits for adenovirus because the manufacturer decided to stop producing the vaccine, and there was no other manufacturer who was interested in doing this.

Mr. Mendez, you have studied the defense health care system closely. First, let's start with, how did this disruption affect the health of servicemembers?

Mr. MENDEZ. Thank you for the question, Senator, and that is correct. DOD exhausted their last supply of the adenovirus vaccine in about 1998, 1999. At that time, DOD estimated that the absence of that supply of vaccine would lead to about over 10,000 preventable infections from the adenovirus, over 4,200 medical visits of recruits in the recruit training pipeline, who are at risk for

adenovirus, and over 850 hospitalizations, within a year, to an extent DOD did observe that in the absence of the vaccine.

Senator WARREN. Okay. So in other words people got sick, they had to go to the doctor. There were deaths associated with this adenovirus. All of that potentially affects warfighter readiness. You have got all these young people who are together, and the disease is moving among them, right? The virus is moving among them.

Dr. Barber, you are an expert on pharmaceutical manufacturing. What did it take to finally get a new manufacturer to produce the adenovirus vaccine for DOD?

Dr. BARBER. After stocks were depleted in 1999, DOD does what it usually does. It put out a tender, and the previous manufacturer that had pulled out of the market, Wyeth, they agreed to do a tech transfer, but only if DOD would reimburse them for it, which is quite the demand given, as we heard today, DOD developed that vaccine and had done tech transfer to them free of charge in the first place.

Only one manufacturer even considered bidding at the time, Greer, but they withdrew because they asked DOD for \$10 million up front, and DOD could not agree to it at the time.

All in all, it is estimated that it took about \$100 million and 10 years for new vaccines to become available again.

Senator WARREN. You know, this is just stunning. DOD, as you say, does the research, develops the vaccine, gives it away to try to be able to get a manufacturer going, and they end up paying a private manufacturer, I think you said \$100 million. Is that about right?

Dr. BARBER. In the end, yes.

Senator WARREN. In the end, in order to build a facility to manufacture this vaccine that we need, on top of the money they paid to purchase the vaccine from the manufacturer, all because DOD is at the mercy of private actors who just are not interested in marketing these products for a relatively small market.

Mr. Mendez, is the adenovirus vaccine the only example of a product that the private market has been unwilling to manufacture for DOD/

Mr. MENDEZ. No. The adenovirus is not a unique case. DOD has many challenges in finding a lot of medical countermeasures, over many decades. Current challenges that they experience and are working through include products to address anthrax, botulism, cholera, hemorrhagic fevers, tularemia, and other health threats.

Senator WARREN. All right. You know, this is a real problem, when the market just does not meet what it is that DOD needs, and this is going to continue. We are going to continue to have medications that DOD requires in order to keep servicemembers healthy, and that simply are not profitable for private industry to come in and produce.

Dr. Barber, what would be the advantages if DOD decided to manufacture these drugs itself?

Dr. BARBER. A public manufacturer is likely, depending on the drug, to be enormously cost saving. To bring back the adenovirus example, the current contract with Teva is worth about \$38 million per year. That is actually a lot of money to pay for a single vaccine.

As a point of comparison, it is about 80 percent annually of how much California has budgeted to build an entire insulin factory.

A report by the Army estimated adenovirus factory startup cost at \$100 million, with annual costs to \$10 million per year. So that works out to DOD breaking even from building and running a manufacturing facility in just 3 years.

Besides costs, by manufacturing their own drugs, DOD could ensure reliable supply and support wider strategic aims and restoring domestic production capacity.

Senator WARREN. Okay. So you pencil this out and discover at least for some of these drugs it would be cheaper for DOD to manufacture it themselves, and it would have the added benefit of you know what your supply chain is, there would not be any secrets in the supply chain, and we would have a reliable source for these drugs.

This is why I am introducing a new bill, the Keep DOD's Drug Supply Secure Act, to direct DOD to manufacture the drugs, devices, vaccines, and other medical products when there is a risk of shortage or quality concerns. This bill gives us an opportunity to resolve drug shortages, to secure the pharmaceutical supply chain, and to ensure safe and effective drugs for our servicemembers. Thank you.

Senator Scott.

Senator SCOTT. Thank you, Chair. Colonel Suarez, So you heard the testimony before, and Mr. Beebe said there are about 10,000 drugs that they buy. Does that sound about right?

Colonel SUAREZ. When we are talking about national drug codes, we are talking in the thousands. So between 5,000 to 10,000 that they can source from within the industry for pharmaceuticals.

Senator SCOTT. All right. So today, is there just even one of those that they could just say, "Today I'm not going to buy anything else from China?" Do you know of any one of them that they could do that?

Colonel SUAREZ. No, but I think the fundamental issue that they could probably do that is with help from the Congress to address the loophole I mentioned in my opening statement. The Department tried to do this—and I am talking the VA—back in 2019, and they were challenged in court when they wanted to execute an executive order to buy American products. They were challenged by this company, Acetris Health, to say, well, we make this product overseas, and then we do the final packaging and labeling in the United States, and we are going to call it United States. Well, that is not how precedent was defined for a Made in America drug. That was always defined by where the API was made.

Senator SCOTT. So you think we have to have a law that says that Made in America means something different than what that court case said?

Colonel SUAREZ. Yes. I think this is an opportunity—

Senator SCOTT. Can you get that to us?

Colonel SUAREZ. Yes.

Senator SCOTT. I will work on that. Okay. So let's say we get that fixed. Is there anything else that would prevent us from somebody in Mr. Beebe's position from just saying, "Today we are not buying any more"? What else would there be? Any other limitation?

Colonel SUAREZ. I think some of the challenges that could be there is especially in those areas where we are solely reliant on a supply chain that is only made in China, for example. So right now if you look at the API Innovation Center, they have really done some studies where they have looked at the supply chain. They call out 60 vital medicines in the United States. They estimate of the 60 vital medicines in the United States, about 20 percent of them are solely sourced with APIs from China, and then for key starting materials, it is about 45 percent of those vital medicines are solely sourced—that means there is no other supplier.

Senator SCOTT. Just go back, on solving the problem. Is the only limitation is if we get a law passed that says that Made in America means X, that it is all produced here, we do not use any of their ingredients, blah-blah-blah, and no packaging, nothing, so is that going to give the Department of Defense the ability to fix it today?

Colonel SUAREZ. I think when that loophole is closed I think it gives a clear pathway to do what you are suggesting.

Senator SCOTT. Okay. That is the only limitation.

Colonel SUAREZ. I do not think that is the only limitation.

Senator SCOTT. What else would it be?

Colonel SUAREZ. I think an understanding that having quality differentiation in the marketplace other than cost is another big hurdle for us to try to grapple with, and this is dealing with the status quo—

Senator SCOTT. Oh, are you saying that they decide based on price and nothing else?

Colonel SUAREZ. What I am suggesting is that the marketplace for generic small-molecule pharmaceuticals is primarily based on a cost basis, and no real measure of quality in that decision matrix.

Senator SCOTT. So I am a business guy. In business, I would not buy just based on price.

Colonel SUAREZ. Correct.

Senator SCOTT. Do you think we do that?

Colonel SUAREZ. Unfortunately, that is where the market is going for that commodity.

Senator SCOTT. Why?

Colonel SUAREZ. Because what has happened over the last couple of decades—and this really happened around late 2021, when we voted for China to be a Most Favored Nation, and they all of a sudden grew their economy and we started to transition our manufacturing overseas—what they found was they used their most competitive advantages, and that is access to cheap labor and their inability to really focus on environmental concerns in manufacturing.

So they could lower the price of goods very low, to the point where they could target specific industries, like the pharmaceutical industry, and even specific drugs, and actually push some of our companies either out of business or from stopping making critical medicines.

Senator SCOTT. So is there anything else we need to do to stop it?

Colonel SUAREZ. I think part of it also is you could leverage Defense Production Act to incentivize and pass legislation for funding to actually bolster our domestic supply chains and manufacturing in the United States. You created incentives for the marketplace to

say, hey, there is an initial incentive, just like the CHIPS and Science Act, to manufacture in the United States.

Senator SCOTT. So why do they not do it now. We have got the Defense Production Act right now. Why don't they just do it?

What I do not get is everybody—I think we have all come to the conclusion China is bad. They want to destroy our way of life. Why are we buying their crap?

Colonel SUAREZ. Part of it is because in the past 20-plus years they have done a very masterful job of integrating into our biotech and biopharma and many pharmaceutical manufacturing industries. They started with early innovative companies, when they are small biotechs and they are desperate because they are cash strapped. So they basically hire them as contract research organizations. They develop those drugs and products throughout the life of that drug application. So as that company matures and it gets licensure, their entire supply chain might be dependent on materials from China.

Senator SCOTT. So do we need to prevent China from being able to invest in our pharmaceutical industry?

Colonel SUAREZ. What I would suggest to the Congress is that they place limits on those known companies that have either stolen intellectual property or have a bad intent to take American technology—

Senator SCOTT. Do we need legislation, or can they do that on their own right now?

Colonel SUAREZ. Well, so companies can make those decisions—

Senator SCOTT. No. Can the Department of Defense prevent a Chinese company from investing?

Colonel SUAREZ. I do not know if the Department could do that directly without getting challenged in court.

Senator SCOTT. I do not get this. I mean, we do not buy stealth bombers from China, so why do we buy drugs from China?

Colonel SUAREZ. So what I would offer is that when you look at things like the Berry Amendment, those were originally designed, like in 1941, and they focused on important things like textiles and food and all those to support defense purchasing of those critical commodities.

What I would suggest is either you amend that to include pharmaceuticals and medicines, or you address the loophole that I mentioned, and once you can do that—and this is not an original idea from me. The API Innovation Center pointed this out about 18 months ago. So what I would say is once we fix that through legislation, a lot of the other things that you are suggesting can more easily occur without challenges in court.

Senator SCOTT. Okay. So if we want to solve this, name the list. We have got to change that court case, and that is one.

Colonel SUAREZ. Yes, so that is one. The second one is I would encourage the DOD to continue monitoring this quality assessment pilot so that we can better understand that health care systems actually can buy low-cost drugs that are of high quality, because some initial data shows that that is very possible, and then the third thing—

Senator SCOTT. We do it in the private sector every day, so it is all possible.

Colonel SUAREZ. Yes. Yes, sir.

Senator SCOTT. We would not have to have a study. I mean, that is pretty basic stuff.

Colonel SUAREZ. The study actually generates the data that is irrefutable that you could use to justify the decisions. So yes, sir.

Senator SCOTT. We do it every day, because we like our products to work. Every manufacturing company buys based on quality, because it likes their end product to work.

Colonel SUAREZ. Yes, in normal markets you are absolutely correct, sir. That is how normal markets work. Unfortunately, in the pharmaceutical industry that has not been the standard.

Senator SCOTT. Because we did not do any testing.

Colonel SUAREZ. No. It is not that we did not do any testing. It is that the regulatory agency had a very difficult time, as we transitioned our manufacturing over to Asia, mostly India and China, we lost an ability to actually regulate and inspect those manufacturing plants.

Senator SCOTT. Yes, but we can inspect it afterwards.

Colonel SUAREZ. Right. But the problem is we have such a big backlog right now, and now when they are checking these facilities they are finding egregious problems. That is why some of those plants are shutting down as they remediate those problems, and thus that increases more drug shortages, and that is part of what we are seeing right now.

Senator SCOTT. Okay. So we have got the court case, assess, what else?

Colonel SUAREZ. Then I think really provide incentives to industry to domestically manufacture more essential medicines here, not only the finished product, the API, and the key starting materials.

Senator SCOTT. Well, I think it will happen, except for what Dr. Barber is talking about. I mean, some things are going to be so small you cannot do it. But there is enough money, if it is big enough, right.

Colonel SUAREZ. Correct.

Senator SCOTT. If we say we are going to have a domestic product, we can do it. I do not disagree with what you are saying. There are going to be some markets that are not going to be big enough, and this is going to be cheaper. There are two options. One, pay somebody to do it, like what you said, or do it ourselves.

Colonel SUAREZ. May I add one other thing, too? There are some really good initiatives that are happening in the United States right now, for example, in Senator Kaine's State, for example, with Civica RX, a public benefit corporation, working with Phlow and AMPAC, where they are actually going after these most essential medicines. That is a model that actually could be expanded across the country to address those critical, essential, low-cost generic medicines.

So I think we are starting to see more and more examples like what we see in the commonwealth of Virginia that could actually help correct the market over time, so that we can actually address these critical risks.

Senator SCOTT. Thank you.

Senator WARREN. Good. Thank you. Dr. Barber?

Dr. BARBER. It was just to say that in terms of market share, DOD's fund really is quite, quite low. I mean, \$7 billion is not very much in multinational corporation terms, in terms of global markets. So it really is a drop in the bucket, and the market power just is not there for most products.

Senator SCOTT. I mean, I agree. That makes sense. But you would think if everybody worked together, like if all of our allies were part of this, which we should be able to do, there are still going to be things that make sense, that you cannot get. Somebody is not going to have an incentive because there is not enough profit margin. But if we could get everybody to buy together, we could, in theory.

Dr. BARBER. A major limitation is the data still is not there in terms of where provenance is, and thank you for bringing up the Acetris case. It is incredibly important, and I would encourage the Committee to reach out to the DLA for legal counsel in terms of kind of what their powers are.

I have been doing API research for a long time in terms of capacity building and distribution, and I am heartened that in the last 3 years people have started to take it really seriously in terms of initiatives to not supply. But they are still very ad hoc. There is no systematic mapping. FDA is not doing it. EMA is not doing it. The WHO is not doing it. We have to show data with everyone, with our allies, with all countries. So it has to be an international effort to map how many factors are making a given drug, where are they, what is the capacity. We need to do this systematically. We cannot rely on ad hoc measures.

Senator WARREN. You know, I very much appreciate that. What I think we are hearing over and over is we need to bring pharmaceutical manufacturing back to the United States, and that it is a critical national defense issue. It is also critically important for the health of our people.

I hear this breaks into two parts. One is commercial manufacturing, which as you rightly point out, we do not have the right incentives in place. We do not even have the right information in place to require meaningful domestic manufacturing and meaningful insight into the supply chain, to know that we are safe in the drugs that we are getting and into the APIs that we are getting. That is one part of the problem.

Then the other part of the problem is the manufacturing challenges for what are much more modestly scaled projects that we are going to have to move to military manufacturing. Otherwise, we are just not going to get this stuff, or we will pay prices that are so outrageous that we would have been a lot better off—it would have been cheaper to have built it internally.

So I think those are the two challenges we face, and I know that we both want to work on here.

I want to thank all of our witnesses for their testimony today. I also want to thank Jon Clark, Gary Leeling, Noah Sisk, and Katie Magnus, for their work in helping put today's hearing together.

We have a letter from the National Association of Manufacturers. They have asked that it be included in the record. Any objection?

Without objection on that.
[The information referred to follows:]



Charles Crain
Vice President,
Domestic Policy

April 30, 2024

The Honorable Elizabeth Warren
Chair
Subcommittee on Personnel
Committee on Armed Services
U.S. Senate
Washington, DC 20510

The Honorable Rick Scott
Ranking Member
Subcommittee on Personnel
Committee on Armed Services
U.S. Senate
Washington, DC 20510

Dear Chair Warren and Ranking Member Scott,

The National Association of Manufacturers appreciates the Subcommittee holding today's hearing on servicemembers' access to safe, high-quality pharmaceuticals.

The NAM is the largest manufacturing association in the United States, representing manufacturers in every industrial sector and in all 50 states. Biopharmaceutical manufacturers accounted for \$355 billion in value-added output to the U.S. economy in 2021 and directly employed 291,000 workers in the United States, with each of these jobs supporting an additional 4.1 jobs. The average employee in the industry earns roughly 3.5 times the U.S. workforce average income, and roughly 25% of all jobs in pharmaceutical and medicine manufacturing are STEM-related.¹

Beyond the sector's economic impact, biopharmaceutical companies are innovative manufacturers that discover and bring to market incredible new medicines to treat and cure challenging conditions. In 2023, the Food and Drug Administration approved a record-breaking 71 new medicines that will improve the lives of patients, including U.S. servicemembers.² The investment necessary to bring these treatments to patients is immense: the average cost of developing a new drug was \$2.3 billion as of 2022.³

These high development costs are reflective of the complex nature of groundbreaking R&D. Only 12% of investigational drugs that enter a Phase I clinical trial ultimately receive FDA approval⁴—to say nothing of the hundreds of discoveries that never make it into clinical trials. Further, breakthrough scientific discoveries take immense time, with early-stage research, clinical trials, FDA approval and manufacturing accounting for 10-15 years in most cases.⁵

¹ National Association of Manufacturers. "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing" (October 2023). Available at https://documents.nam.org/COMM/NAM-Creating%20Cures.%20Saving%20Lives_FINAL3.pdf.

² Senior, Melanie. "Fresh from the biotech pipeline: record-breaking FDA approvals." *Nature Biotechnology* (February 2024). Available at <https://doi.org/10.1038/s41587-024-02166-7>.

³ Deloitte. "Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022" (January 2023). Available at <https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf>.

⁴ DiMasi, Joseph A., Grabowski, Henry G., and Hansen, Ronald W. "Innovation in the pharmaceutical industry: New estimates of R&D costs." *J Health Econ.* 2016; 47:20-33.

⁵ Pew Charitable Trusts. "From Lab Bench to Bedside: A Backgrounder on Drug Development" (March 2014). Available at <https://www.pewtrusts.org/en/research-and-analysis/articles/2014/03/12/from-lab-bench-to-bedside-a-backgrounder-on-drug-development>.

Biopharmaceutical companies are committed to these extraordinary efforts, which in recent years have revolutionized treatments for COVID, cancer, HIV/AIDS, sickle cell disease, diabetes, obesity and more. Across the industry, biopharmaceutical manufacturers spent \$139 billion on R&D in just 2022 alone.⁶

The NAM respectfully encourages members of the Subcommittee to be mindful that the costs of manufacturing a branded medicine include potentially decades of research and billions of dollars of investment—well before a single pill or injection is produced for public consumption. Additionally, a biopharmaceutical company likely will have undertaken years of research and millions or billions of dollars of investment into any number of *other* projects that may or may not prove scientifically viable.

Further, it is important to note that a treatment's list price is often significantly different from the price a patient pays at the pharmacy counter given biopharmaceutical manufacturers' efforts to reduce out-of-pocket costs via rebates and other programs that help patients afford needed treatments. The list price of a drug also includes external costs and pressures from other areas of the health care system that biopharmaceutical companies do not control. For example, the prices that Americans pay are heavily influenced by middlemen like pharmacy benefit managers. PBMs often dictate which medicines are covered by which health insurance plans, all while pocketing manufacturer rebates rather than passing them on to patients. Their compensation structure, under which higher list prices lead to higher PBM profits, means that patients pay more: in 2020, more than half of every dollar spent on brand medicines went to stakeholders other than the medicine's manufacturer.⁷

Congress must therefore exercise caution in considering policies that seek to address health care costs. Critically, policies like price controls, compulsory licensing and weaker intellectual property protections would hurt patients by reducing access to life-saving treatments.

Unfortunately, however, biopharmaceutical companies have already been subjected to these harmful policies in recent years, each of which will limit innovation and slow efforts to develop life-saving medicines. First and foremost is the Medicare Drug Price Negotiation Program, which subjects life-changing biopharmaceutical innovations to government price controls. At the same time, the Biden Administration has proposed unlawfully expanding the government's ability to "march in" on private sector patents, undermining the IP rights that are foundational to the biopharmaceutical business model. And the Federal Trade Commission has promulgated a new rule that will disincentivize, delay and potentially destroy innovative companies' ability to access capital via mergers and acquisitions.

These policies can harm product development at all stages of the biopharmaceutical life cycle. In particular, policies that undermine innovation will limit the early-stage capital available to finance novel research. Biopharma investors—both venture capitalists and larger biopharma companies that partner with or acquire smaller businesses—understand the uncertain and difficult nature of scientific advancement. They often fund a broad portfolio of projects, knowing that many will never make it to FDA approval. These investors need to know that the projects that do become life-changing treatments will be able to succeed in a fair marketplace and benefit from robust IP protections. Absent these policy guarantees, early-stage capital for the

⁶ DiMasi et al., *supra* note 4.

⁷ Brownlee, A., and Watson, J. "The Pharmaceutical Supply Chain, 2013-2020." Berkley Research Group (January 2022). Available at <https://www.thinkbrg.com/insights/publications/pharmaceutical-supply-chain-2013-2020/>.

industry will be under threat—as will potential treatments and cures for devastating diseases, and the innovation ecosystem that supports thousands of well-paying jobs across the country.

All Americans, including servicemembers, deserve access to high-quality, affordable health care. Biopharmaceutical manufacturers invest heavily in groundbreaking research in order to discover and commercialize medicines to save and improve these patients' lives. The NAM respectfully encourages Congress to avoid adopting policies that will stymie this life-saving innovation. Limiting drug development would significantly harm Americans from all walks of life, including servicemembers and their families.

Sincerely,

A handwritten signature in black ink that reads "Charles F. Crain". The signature is written in a cursive, flowing style.

Charles Crain
Vice President, Domestic Policy

Senator WARREN. With that, do we have a period of time for questions? Nope. Alright. We have got 7 days for questions for anybody who wants them. You will have 30 days to reply to those if there are answers that are needed.

With that, this hearing is adjourned. Thank you all.

[Whereupon, at 4:10 p.m., the Committee adjourned.]

[Questions for the record with answers supplied follow:]

QUESTIONS SUBMITTED BY SENATOR MAZIE K. HIRONO

PRODUCTION LOCATION OF DRUGS

1. Senator HIRONO. Dr. Martínez-López, Dr. Smith, Dr. Dertzbaugh, and Mr. Beebe, in the Report on the DOD Pharmaceutical Supply Chain Risks from November 2023, I am concerned that DLA could not identify 22 percent of the sources of ingredients for 211 drugs on the Essential Medicines List. DOD recommended that manufacturers of pharmaceuticals sold in the U.S. be required to provide the Food and Drug Administration with definitive information on the production location of finished drugs and the source of key ingredients because this information gap is a substantial vulnerability to the supply chain. For the Panel, do you have an update on what has been done to make this change?

Dr. MARTÍNEZ-LÓPEZ, Dr. SMITH and Dr. DERTZBAUGH. Thank you for this important question. The Defense Logistics Agency is in the best position to provide the answer to this question consistent with their functions and responsibilities.

Mr. BEEBE. To DLA's knowledge, no changes have been made that would require manufacturers of pharmaceuticals sold in the U.S. to provide definitive information on the production location of finished drugs and the source of key ingredients. DLA continues to work with the FDA and other Federal stakeholders through participation in various working groups focused on addressing the broad national challenges posed by the prominence of foreign sources for APIs and pharmaceuticals.

NATIONAL PREPAREDNESS

2. Senator HIRONO. Dr. Martínez-López, Dr. Smith, Dr. Dertzbaugh, and Mr. Beebe, how does the Department plan to work with the rest of the interagency to address our national preparedness to ensure access to high quality pharmaceuticals, even during times of national emergency like a war or global pandemic?

Dr. MARTÍNEZ-LÓPEZ, Dr. SMITH and Dr. DERTZBAUGH. The Department is working within the interagency in alignment with Executive Order (EO) 14017, "America's Supply Chains" and EO 13953, "Addressing the Threat to Domestic Supply Chain from Reliance on Critical Minerals From Foreign Adversaries and Supporting the Domestic Mining and Processing Industries" to address an all of government approach and solution to pharmaceutical supply chain vulnerabilities. The Department is committed to a supply chain risk management framework that promotes coordination and communication within the Department as well as with the interagency. As part of this effort, and to address DOD pharmaceutical supply chain management requirements more effectively, the Department developed the Pharmaceutical Provenance Solution (PPS) which provides a means and method to identify active pharmaceutical ingredients (API) with associated risks and dependencies. This program requires continuous monitoring and information updates to sustain as a relevant source of risk and dependencies. PPS enables the Department to consider specific pharmaceutical sourcing risk considerations as part of the supply chain risk analysis, e.g., to avoid pharmaceutical sources considered very high or high risk.

Mr. BEEBE. In December 2023, DOD chartered the Pharmacy Supply Chain Risk Management Working Group ("Pharm SCRM WG" or "WG") as a standing work group under the Defense Medical Logistics Proponent Committee (DMLPC). The WG has established three sub-working groups, each of which is responsible for one of the deliverables identified within Section 860(b) of the fiscal year 2023 NDAA.

The WG has three Co-Chairs consisting of a Defense Health Agency (DHA) Medical Logistics Pharmacist, a DHA Pharmacy Operations Division (POD) Pharmacist, and a Defense Logistics Agency (DLA) Pharmacist. The WG Voting Members include pharmacist representatives from the Army, Navy, Air Force, Marines, DHA Medical Logistics, DHA POD, and DLA. The WG has advisors who participate in the working group but are non-voting members. These advisors are representatives from the Food and Drug Administration (FDA), the Administration for Strategic Preparedness and Response (under the Department of Health and Human Services),

the DHA Medical Logistics Chief Medical Officer, Military Service Logistics Subject Matter Experts, Defense Advanced Research Projects Agency, the Department of Homeland Security, the Office of the Joint Chiefs of Staff, the Office of Naval Research, Office of the Assistant Secretary of Defense (Health Affairs), and the DHA Medical Logistics Supply Chain Management Office.

The Pharm SCRM WG's deliverables are to develop and publish implementing guidance for risk management for the DOD's supply chain for pharmaceuticals. Additionally, the WG will:

- Assess risks to the Department's pharmaceutical supply chain.
- Identify the pharmaceuticals most critical to beneficiary care at military treatment facilities.
- Develop and recommend establishment of DOD-level policies for allocating scarce pharmaceutical resources of the DOD in case of a supply chain disruption.

3. Senator HIRONO. Dr. Martínez-López, Dr. Smith, Dr. Dertzbaugh, and Mr. Beebe, how does the Department use its purchasing power to address drug shortages?

Dr. MARTÍNEZ-LÓPEZ, Dr. SMITH and Dr. DERTZBAUGH. Thank you for this important question. The Defense Logistics Agency is in the best position to provide the answer to this question consistent with their functions and responsibilities.

Mr. BEEBE. DOD's pharmaceutical purchasing power does not impact or address drug shortages in the commercial market. The DOD pharmaceutical supply chain is fully dependent on the U.S. commercial pharmaceutical sector which is facing an ongoing nation-wide drug shortage crisis. As a result, DOD experiences the same drug shortages and risks as the rest of the Nation. In addition, the DOD pharmaceutical supply chain represents less than 2 percent of the U.S. commercial purchases and a much smaller percentage of the global commercial market. As such, DOD does not have enough pharmaceutical purchasing power to leverage significant change on either the U.S. or global commercial pharmaceutical market.

U.S. chronic drug shortages are a national security risk that requires a whole of government response. The Department of Health and Human Services is the Federal agency responsible for decisions on priorities and allocation under the Defense Production Act for pharmaceuticals and is the ultimate Federal arbiter of resource allocation. Pharmaceutical purchasing power, which in the case of DOD is less than 2 percent of U.S. purchases, is not relevant to resource allocation authorities.

The Department relies on the actions of its logistics and medical professionals to mitigate the impacts of shortages. In the past when DOD has experienced shortages, DOD has taken the following actions to resolve/mitigate:

- Explored the shortage circumstances and engaged the commercial partners (pharmaceutical manufacturers, Prime Vendors, etc.) to determine the root cause of the shortage and developed a joint strategy with the commercial partners and DLA customers to mitigate or resolve the shortage.
- Identified clinically appropriate pharmaceutical alternatives, if they exist, and communicated this information to Military Treatment Facilities and other DOD medical organizations.
- Leveraged pharmaceutical experts to develop formulary alternatives, limit fill quantities, etc.

4. Senator HIRONO. Dr. Martínez-López, Dr. Smith, Dr. Dertzbaugh, and Mr. Beebe, how is the Department working with its Pharmacy Benefits Manager (PBM) to support a more diverse supply chain?

Dr. MARTÍNEZ-LÓPEZ, Dr. SMITH and Dr. DERTZBAUGH. In accordance with TRICARE Pharmacy contract requirements, if there is a supply disruption and the National Prime Vendor (NPV) cannot support, Express Scripts (ES) can access their commercial supply, if they can support, without negatively impacting their commercial book of business. However, that is typically only for a very short period while they try to work with the NPV to find an alternate source. Once the supply for a drug is re-established, the government will replenish ES for the commercial supply used during the disruption.

Mr. BEEBE. DLA does not engage with Pharmacy Benefits Managers.

PROTECTING DOD HEALTHCARE FROM CYBERATTACKS

5. Senator HIRONO. Dr. Martínez-López, Dr. Smith, Dr. Dertzbaugh, and Mr. Beebe, Change Healthcare, one of the largest drug prescription processors in the U.S., including for the Department of Defense, was the victim of a cyberattack in

February of this year that disrupted service. Is the Defense Health Agency working with U.S. CYBERCOM and our interagency partners to help protect critical commercial companies that support DOD's health mission like Change Healthcare from cyber intrusions?

Dr. MARTÍNEZ-LÓPEZ, Dr. SMITH and Dr. DERTZBAUGH. The DHA, in conjunction with Joint Force Headquarters—DOD Information Network (DODIN), a component of U.S. Cyber Command, protects and defends its own networks and systems. As a member of the Defense Industrial Base (DIB), Change Healthcare and its parent company Optum participate with other DIB partners in collaboration with the DOD's Cyber Crime Center (DC3) which provides cyber security support to the DIB and works across industry to address risks and threats to all of DOD's commercial partners.

The DHA is a member of the Department of Health and Human Services (HHS) sponsored Health Threat Operations Center (HTOC), with which it receives and shares cyber threat intelligence information affecting Federal healthcare delivery partners. Collaboration among HHS' Federal healthcare delivery partners including the Department of Veterans Affairs (VA) and the DHA through HHS' HTOC enables advancement of Federal cyber threat predictive analytics, information sharing and engagement.

Cyber security incidents in the commercial sector are a law enforcement matter, with the FBI typically leading the investigation. With respect to the cyberattack in February 2024, the DHA remained in close contact with Optum security officials during the investigation and through restoration of services, and used all available threat intelligence information, with the approval of law enforcement, to fortify DHA's defenses against the same or similar attacks and threat actors.

Mr. BEEBE. While DLA cannot respond for DHA, DLA recognizes the importance of implementing cybersecurity safeguards across all Department of Defense contracts, including those within the defense pharmaceutical supply chain. DLA contracts appropriately include cybersecurity clauses as prescribed by the Federal Acquisition Regulation (FAR) and Defense Federal Acquisition Regulation Supplement (DFARS).

6. Senator HIRONO. Dr. Martínez-López, Dr. Smith, Dr. Dertzbaugh, and Mr. Beebe, does the DOD have a mitigation plan in the event a future catastrophic cyberattack cripples the pharmaceutical supply chain for an extended period of time?

Dr. MARTÍNEZ-LÓPEZ, Dr. SMITH and Dr. DERTZBAUGH. Thank you for this important question. The Defense Logistics Agency is in the best position to provide the answer to this question consistent with their functions and responsibilities.

Mr. BEEBE. DLA maintains close operating relationships between the DHA and the pharmaceutical industrial base. For a crippling cyber-attack on the commercial supply chain, DLA would work with the industrial base to process manual orders, may conduct distribution support actions, and work with DHA to both prioritize and allocate supplies, as well as potentially redistribute supplies within the DOD Medical Network.

QUESTIONS SUBMITTED BY SENATOR DAN SULLIVAN

PHARMACEUTICAL SUPPLY CHAIN

7. Senator SULLIVAN. Dr. Martínez-López and Mr. Beebe, AstraZeneca, announced last month their plans to manufacture drugs for the U.S. and China independently as the potential for conflict would disrupt getting drugs to market. Other pharmaceutical manufacturers are following suit. Do you assess that the independent supply chains that many in the pharmaceutical industry are already doing mitigate risk of Chinese or other high-risk sources for both pharmaceuticals and their raw components from being used for servicemembers?

Dr. MARTÍNEZ-LÓPEZ. Thank you for this important question. The Defense Logistics Agency is in the best position to provide the answer to this question consistent with their functions and responsibilities.

Mr. BEEBE. DLA supports efforts to increase the number of manufacturers of APIs and other pharmaceutical components from domestic or Trade Agreements Act countries to the extent that those products are available for servicemembers. DLA would require additional information to assess the potential and mitigation effectiveness of removing high-risk sources from the supply chain.

8. Senator SULLIVAN. Dr. Martínez-López and Mr. Beebe, servicemembers will still require pharmaceuticals while deployed or forward stationed. Logistics and supply chains in a contested environment are likely to be disrupted during large scale conflict, particularly in the Indo-Pacific. What options are you exploring to ensure continuity of access for servicemembers far from the United States during time of conflict?

Dr. MARTÍNEZ-LÓPEZ. To facilitate continuity of access to pharmaceuticals for servicemembers, the DHA manages the Joint Deployment Formulary (JDF). The JDF consists of 917 medication line items needed for contingency operations. The JDF is not just a list of medications but also a logistical readiness tool that aligns procurable National Stock Numbers (NSNs) to each of the 917 medication line items. These procurable NSNs are monitored daily to maximize readiness and ensure any supply chain disruptions are adjudicated as quickly as possible. The JDF team works with each of the Services to maximize use of JDF medications in their assemblages to help ensure supply chain resilience. Additionally, the Services/Theater Lead Agent(s) for Medical Materiel (TLAMMs) need to be better postured and positioned to ensure access to (catalogued) and availability of (stocked) these critical medications when they are needed most. That may also entail developing and/or increasing pre-positioned stocks of select pharmaceuticals that would be most critical during the early stages (i.e., the first 60 days) of large-scale combat operations), especially if we face a near-peer competitor and must deal with a contested logistics environment.

Mr. BEEBE. In general, DLA supports its OCONUS customers using the same processes and networks it uses for its CONUS customers. We use premium air transportation to move medical materiel from the U.S. to our OCONUS customers worldwide. We are currently working with our USTRANSCOM counterparts to open new transportation lanes to support customers in the CENTCOM, AFRICOM, and INDOPACOM.

PROLONGING STORAGE OF MATERIALS AND PHARMACEUTICALS

9. Senator SULLIVAN. Dr. Barber and Mr. Mendez, in the transition to lower-risk and domestic supply chains, what in your opinion can DOD and the FDA do to ensure continuity of available drugs?

Dr. BARBER. The two most effective reforms that the FDA and DOD could undertake to ensure sustainable and reliable drug supply are 1) increasing transparency across the public and private sector supply chains and 2) increasing public sector manufacturing capacity.

Transparency: In the last 2 years, legislation has been proposed that would require companies to disclose their API sources and some information about production volumes (see for example the Drug Shortage Prevention Act of 2023 (H.R. 3008); the Drug Shortages Prevention and Quality Improvement Act (S. 2586); the Senate Finance Committee Addressing Drug Shortages discussion draft; and the Energy and Commerce Stop Drug Shortages Act discussion draft). None of these bills have passed. However, DOD and FDA have other tools that can improve transparency. DOD can use its purchasing power to compel disclosure of this information and FDA could issue administrative guidance to these ends. The following information should be requested and made publicly available so actors across the supply chain can accurately forecast demand and the effects of markets shocks: approximate production volumes of API and finished product by company and facility, source of API, and anticipated demand increases.

Transparency through company reporting alone is inadequate, however. Despite their importance to global drug supply, there is no systematically collected data, monitoring, or international coordination to map global API production. As a result, the central questions for supply chain resilience for medicines—how many API manufacturers are there globally, and what capacity exists or could be mobilized in an emergency?—cannot be answered with currently collected data. Existing analyses only account for API for products marketed in the USA, rather than a more comprehensive scope of global API productionsites. Global data are important because the loss of a manufacturer (for example, due to a natural disaster or factory fire) that does not supply the United States will nevertheless affect US supply and markets, as global demand competes for a reduced supply. Another limitation of existing data is that there is little accounting for the common situation where two facilities are documented as unique API suppliers, despite buying either finished or nearly finished API from a single facility (in effect, allowing a drug to appear to have more stable multiple producers when it in fact is monosource). Fundamental limitations in existing data highlight the importance of FDA and DOD conducting proactive

risk assessments and supply mappings rather than relying on existing administrative data.

Public sector manufacturing capacity: As I outlined in my written testimony, both government-owned, government operated (GOGO) and government-owned, contractor operated GOCO models have been successful in ensuring reliable access to drugs on a cost-effective basis. Public capacity is especially vital for drugs with limited commercial markets. A range of government reviews in recent decades have recommended GOGO and GOCO models to address military drug production needs.

- The DOD commissioned a special task force (“Project Badger”) in the 1990’s to assess whether or not commercial markets could serve defense needs.^{1*} After making inquiries to all commercial manufacturers as to their interest and ability to manufacture needed vaccines, the task force concluded that “the best option appeared to be a facility that was government owned (and funded).”^{1*} The proposed model was a GOCO model, where the government would own and construct a facility as a “national asset”, but a contractor would staff production.^{1*} In the mid-1990’s, a GOCO vaccine facility was included within a DOD budget request but “was subsequently withdrawn in favor of an approach that relies upon private industry to meet the vaccine needs of the DOD.”^{1*}

**Please see References on page 103.*

- Separately, a GAO report recommended in 1991 that “the Army could improve and expand its in-house vaccine production facilities to meet its needs.”^{2*} Walter Reed Army Institute of Research (WRAIR), laboratory suites at the Medical Research Institute of Infectious Diseases at Fort Detrick, and an NIH-owned GOCO facility were proposed as possible sites.^{2*} A pilot program was proposed, but by 1994 an amendment was introduced to specifically prohibit DOD from further pursuing this initiative.^{3*}

**Please see References on page 103.*

- In 2000, the Institute of Medicine (IOM) of the National Academies convened an expert committee to advise the U.S. Army Medical Research and Materiel Command on production, with a focus on the “naturally occurring disease threats” that are a priority of DHA.^{4*} The resulting 2002 Expert Committee report recommended that DOD pursue GOCO production facilities.

**Please see References on page 103.*

- GOCO initiatives have attracted bipartisan legislative support. Former Republican Governor Jim Gilmore, head of the 2001 Advisory Panel to Assess Domestic Response Capabilities for Terrorism argued that “The establishment of a government-owned, contractor-operated national facility for the research, development and production of vaccines and therapeutics for specified infectious, especially contagious diseases, is needed.”^{5*}

**Please see References on page 103.*

- The New York Times reported plans by the Pentagon to “[build] its own vaccine plant to produce eight vaccines for military use—the existing anthrax vaccine and a new one, plus vaccines for smallpox, plague, tularemia, botulinum, ricin and equine encephalitis. It would cost \$1.56 billion to build and run over 25 years, including \$386 million in construction costs, the Department estimated.”^{6*} Further details of the proposed program are either not in the public domain or I was unable to locate them.

**Please see References on page 103.*

- As part of the 2003 National Defense Authorization Act, a bipartisan amendment was introduced by Senator Hutchinson of Texas (R), Senator Mikulski of Maryland (D), Senator Lincoln of Arkansas (D), Senator Sarbanes of Maryland (D), and Senator Roberts of Kansas (R) authorizing the construction of a “Government-owned, contractor operated facility” for the “production of vaccines for agents known or anticipated to be used in biological weapons”, for which “The Secretary shall provide for the operation of the facility constructed . . . as a Government-owned, contractor-operated facility.”^{7*} In introducing the amendment, the sponsor Senator Hutchinson (R-AR) defended the importance of the public sector in provision of some essential medical goods:

**Please see References on page 103.*

“This problem has been examined many times over the past decade. In fact, it has been studied twice by the Department of Defense. Both times, the conclusion was that our Nation needed a Government-owned, contractor-operated vaccine production facility . . . The private sector, for all of the good that it does, cannot, against some of the boutique biological pathogens and threats that may exist now and in the future against our troops and against our civilian population, and will not in the future see

this as a profitable commercial venture. The insurance for the American people, and the insurance for our men and women in uniform, is to have a Government-owned production facility, contractor-operated, to ensure that vaccine will always be available if and when it is needed.”^{5*}

** Please see References on page 103.*

- In a 2004 hearing of the Select Committee on Homeland Security, committee members and expert witnesses discussed the (by that time de-classified) Project Badger findings in the context of revived proposal to establish a GOCO to serve defense medical needs.¹ Major General Lester Martinez-Lopez (Commanding General, U.S. Army Medical Research and Materiel Command, Fort Detrick, Maryland) described the benefits of Government owned facilities as “government control of production, availability, and distribution flexibility for emergency production technologies meets national security priorities for bio-defense vaccines overcomes limited industry interest in bio-defense products.”^{1*} Another expert witness—an experienced researcher and administrator of biological defense programs—acknowledged the political challenge of introducing the GOCO model. Reflecting on the urgent need and failure of the contractor-owned, contractor operated (COCO) model to deliver reliable access to needed drugs, she strongly encouraged the Select Committee to support the GOCO proposal:

** Please see References on page 103.*

“Although the pharmaceutical firms seem opposed to the GOCO approach, citing the availability of capacity already existing, this belies that fact that each year industry has difficulty meeting existing market demands. Recent shortages in tetanus, pertussis, and flu vaccines support the perception that there is no excess capacity available for biodefense vaccine work ... As time passes, the costs [of building government-owned facilities] will only increase, and the Nation will be at the mercy of the fragile, profit-motivated pharmaceutical industry to make the bio-defense vaccines that are needed. In my opinion, Congress should strongly consider appropriating funds for a GOCO facility for bio-defense medical countermeasures.”^{1*}

** Please see References on page 103.*

The hearing also highlighted operational and strategic advantages of GOGO and GOCO models over COCO models, including:^{1*}

** Please see References on page 103.*

- RFPs are not required for each product.
- Long-term contracts a) provide needed stability in small markets; b) encourage increased capacity by operating contractors for specialized production needs and regulatory requirements; c) signal sustained government support for medical countermeasures.
- Increased efficiencies and flexibility as production needs can be decided by the government on an as-needed basis.
- Bidirectional efficiencies and opportunities for innovation through collaborations with government R&D labs.
- A key theme in the 2023 DOD Biodefense Posture Review was the need for an integrated approach by the Chemical and Biological Defense Program (CBDP) and Defense Health Program (DHP).^{8*} The Review recommended that DOD “review DHP and DHA efforts to enable far-forward care, speed clinical trials and research within the Military Health System, inform optimal clinical care strategies, and support development of MCM specific to the military population.” The BPR ultimately concluded that the “CBDP and DHP have sufficiently unique missions, partners, and processes that drive a “spirit of competition” and innovation that argue against consolidating authorities and responsibilities into a single program.”

** Please see References on page 103.*

- A second key theme in the Biodefense Posture Review was the importance of ensuring supply chain reliability for key medical products.^{8*} The Review recommended that the Chemical and Biological Defense Program (CBDP) and Defense Health Program (DHP) should partner with the Office of the Assistant Secretary of Defense for Industrial Base Policy “to prioritize on-shoring of production and distribution of key chemicals critical to produce DOD-unique biodefense MCMs.” The Review recommended use of the Defense Production Act (DPA) and Manufacturing Innovation Institutes to expand domestic API production.

** Please see References on page 103.*

I agree with these recommendations, and urge this Committee to consider ways to adequately resource and direct DOD to invest in public capacity for priority products.

Mr. MENDEZ. CRS can provide options as a basis for discussion, but does not provide policy recommendations, opinions, or endorse specific options. The following selected options, offered in no priority, may address potential effects of a transition to “lower-risk and domestic supply chains” on the availability of certain drugs¹ to meet DOD supply requirements. These options may produce effects that could impact existing programs, costs, resources, beneficiary care, military readiness, defense industrial base, drug manufacturing industry, or other stakeholders.

- DOD could reinvigorate efforts to standardize drug supply requirements as a means to improve medical interoperability across the joint force and reduce the demand for an expansive drug inventory or formulary.²
- DOD could expand existing capabilities and capacity to conduct research, initial development, safety and effectiveness testing, advanced development, or manufacturing of drugs.
- DOD could stimulate commercial interest by addressing perceptions of risk and barriers to entry in drug research, development, and manufacturing for the military.³
- DOD could evaluate the cost and benefits of scaling-up its existing drug product lines and/or building capacity for new product lines at the DOD advanced development and manufacturing biopharmaceutical facility.⁴
- DOD, in coordination with other Federal agencies, could explore the use of global health engagement activities⁵ to develop or expand the drug manufacturing capacity of partner nations or countries designated as compliant under the Trade Agreements Act.⁶
- DOD could continue or enhance its partnership with the Department of Health and Human Services to provide inputs to, ensure military equities are represented in, and generally support whole-of-government solutions to address nationwide drug shortages and to enhance supply chain resilience for medical products.
- DOD could continue executive order-directed⁷ or congressionally directed efforts to identify risks, develop mitigation strategies, and support whole-of-govern-

¹For the purposes of this memorandum, CRS utilizes the U.S. Food and Drug Administration (FDA) definition for “drugs,” which refers to substances recognized by an official pharmacopoeia or formulary; intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; intended to affect the structure or any function of the body; or intended for use as a component of a medicine but not a device or a component, part, or accessory of a device. CRS also utilizes the FDA definition for “biologics,” which refer to a “wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.” For more on these definitions, see <https://www.fda.gov/drugs/drug-approvals-and-data-bases/drugsfda-glossary-terms>.

²Standardization efforts include those pursued by the Defense Medical Materiel Standardization Program, available at <https://www.health.mil/Military-Health-Topics/Health-Readiness/Medical-Logistics/Defense-Medical-Materiel-Standardization-Program>; and other activities aligned under the 2015 Joint Concept for Health Services, available at https://www.jcs.mil/Portals/36/Documents/Doctrine/concepts/joint_concept_health_services.pdf.

³For an overview of perceptions of risk, see CRS Testimony TE10099, Department of Defense’s efforts to ensure servicemembers’ access to safe, high-quality pharmaceuticals, by Bryce H. P. Mendez.

⁴For more on the DOD advanced development and manufacturing biopharmaceutical facility, see Kelly Burkhalter and Chris Southworth, “Enduring Capability: JPEO-CBRND evolves public/private partnership with National Resilience,” DOD News, December 5, 2023, at [https://www.youtube.com/watch?v=24714DROHfE](https://www.jpeocbrnd.osd.mil/Media/News/Article/3607443/enduring-capability-jpeo-cbrnd-evolves-publicprivate-partnership-with-national/#:~:text=Locatedpercent20inpercent20Alachua;and Joint Program Executive Office for Chemical, Biological, Radiological, Nuclear Defense, “DOD ADM: Advanced Development and Manufacturing Facility,” YouTube video, January 6, 2021, at <a href=).

⁵For more on global health engagement, see CRS Report R47326, Global Health Engagement in the Department of Defense, by Bryce H. P. Mendez.

⁶For more on the Trade Agreements Act, see CRS Report R46748, The Buy American Act and Other Federal Procurement Domestic Content Restrictions, by David H. Carpenter and Brandon J. Murrill. For a list of Trade Agreements Act-designated countries, see <https://www.gsa.gov/buy-through-us/purchasing-programs/multiple-award-schedule/help-with-mas-contracts-to-sell-to-government/roadmap-to-get-a-mas-contract/readiness-assessment-for-mas-offerors/look-up-trade-agreements-act-designated-countries>.

⁷For example, see Executive Order 14017, “America’s Supply Chains,” 86 Federal Register 38, March 1, 2021; Executive Order 13953, “Addressing the Threat to the Domestic Supply Chain From Reliance on Critical Minerals from Foreign Adversaries and Support the Domestic Mining

ment initiatives to address the security and resilience of the U.S. drug supply chain.⁸ These efforts include ongoing coordination with the U.S. Food and Drug Administration (FDA) for medical product development and assessment,⁹ implementation of DOD risk management guidance for the drug supply chain,¹⁰ development of plans to mitigate drug shortages and reducing dependence of active pharmaceutical ingredients from foreign sources.¹¹

10. Senator SULLIVAN. Dr. Barber and Mr. Mendez, does DOD need to anticipate disruption while transitioning supply chains by stockpiling now?

Dr. BARBER. The question of stockpiles is nuanced and context-specific. Maintaining ‘buffer stocks’ is common practice in supply chain management and should be increased in correlation with the degree of risk for a given product (i.e., monosource or other high-risk products and components should have more months of stockpiled product than products with more stable and low-risk supply chains). However, there can be negative repercussions to health systems if stockpiling is not conducted responsibly. Responsible stockpiling requires: a) providing ample notice to relevant stakeholders, b) encouraging manufacturers to increase production to meet expanded demand in advance, and c) responsibly and transparently sharing stock.

Federal contracts should require that manufacturers develop regular production risk evaluation and management plans and keep buffer stocks corresponding to expected risk. Stockpile volumes should correspond to the anticipated time needed to remedy production shocks. These vary by product, but as a rough rule of thumb, small-molecule drug production takes between 6 months and a year to bring new suppliers online, and biologics and complex injectable drugs take two to 3 years. Thus, for a small-molecule drug with only one supplier, in the short term the government should ensure 1 year of stockpiled supply, and in the long term should work to diversify suppliers, including by establishing public production.

Mr. MENDEZ. DOD maintains several stockpiles to support wartime requirements and to mitigate potential supply chain challenges in times of national emergency.¹² These stockpiles include the National Defense Stockpile, war reserve materiel stocks, Army prepositioned stocks, and the Defense Health Agency pandemic stockpile program. DOD components (i.e., military departments and DOD agencies) generally develop stockpile requirements (e.g., types of materials or products, quantities, prepositioning, and distribution) based on combatant commander requirements for campaign and contingency plans.¹³ Each DOD component managing a stockpile is also responsible for accounting, storing, maintaining, and distributing stocks to support military operations.¹⁴ For example, the Department of the Army

and Processing Industries,” 85 Federal Register 193, October 5, 2020; and Executive Order 13944, “Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are made in the United States,” 85 Federal Register 158, August 6, 2020.

⁸For more on whole-of-government initiatives to address U.S. drug supply chain resilience, see Department of Health and Human Services (HHS), Public Health Supply Chain and Industrial Base, One-year Report in Response to Executive Order 14017, February 2022, <https://aspr.hhs.gov/MCM/IBx/2022Report/Documents/Public-Health-Supply-Chain-and-Industrial-Base-percent20-One-Year-Report-Feb2022.pdf>; HHS, “Public Health Emergency Medical Countermeasure Enterprise Strategy and Implementation Plan,” 2022, at <https://aspr.hhs.gov/PHEMCE/2022-SIP/Documents/PHEMCE-SIP-2022-508.pdf>; and Cybersecurity and Infrastructure Security Agency, “Healthcare and Public Health Sector Government Coordinating Council Charter,” updated March 10, 2016, at <https://www.cisa.gov/sites/default/files/publications/hph-gcc-charter-2016-508.pdf>.

⁹P.L. 115–92.

¹⁰P.L. 117–263 § 860.

¹¹P.L. 118–31 § 716.

¹²For more on DOD stockpiles, see CRS Report R47833, Emergency Access to Strategic and Critical Materials: The National Defense Stockpile, by Cameron M. Keys; CRS In Focus IF11574, National Stockpiles: Background and Issues for Congress, by G. James Herrera and Frank Gottron; and CRS In Focus IF11699, Defense Primer: Department of Defense Pre-Positioned Materiel, by Cameron M. Keys.

¹³Ibid; and DOD Instruction 3110.06, War Reserve Materiel (WRM), January 7, 2019, at <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/311006p.pdf>. For more on campaign and contingency planning, see Joint Publication 5–0, Joint Planning, updated December 1, 2020 at https://irp.fas.org/doddir/dod/jp5_0.pdf.

¹⁴CRS analysis of DOD Instruction 3110.06, War Reserve Materiel (WRM), January 7, 2019; and DHA Administrative Instruction 7040.03, Defense Health Program Stockpile Materials, October 3, 2023, at <https://www.health.mil/Reference-Center/DHA-Publications/2023/10/03/AI-7040-03>; and Joint Service Regulation 4145.04, Department of Defense (DOD) Stock Readiness Program, updated March 13, 2023, at <https://www.marines.mil/Portals/1/Publications/MCOpercent204450.15Bpercent20wpercent20CH-1.pdf>.

manages the Army prepositioned stocks, which include medical products (e.g., drugs) to support instances where a temporary surge in medical supplies is required to provide immediate support for military operations.¹⁵

Since DOD components manage these stockpiles based on combatant commander requirements, medical products in these stocks do not account for supply requirements generally needed to support day-to-day health care operations in military treatment facilities (MTFs). In a 2021 report, the DOD Inspector General (DODIG) stated that DOD “continues to evaluate the pre-positioned capabilities and stocks to maximize its effectiveness in an increasingly constrained resource environment.”¹⁶ The DODIG also asserted that “to mitigate the risks of disruptions to the pharmaceutical supply chain due to the DOD’s reliance on foreign suppliers, the DOD should identify the quantity of critical finished drug products needed for routine MTF operations and develop policy for allocating scarce pharmaceutical resources in case of a supply disruption.”¹⁷

Within the context of broader U.S. national drug supply shortages over the past decade, some experts have advocated for health systems and medical product suppliers to create “stockpiles set aside for times of emergency” and “buffer inventories” to mitigate acute changes to the drug supply chain.¹⁸ Other experts have cautioned that drug stockpiling could have unintended consequences like increased costs and “excessive hoarding” behaviors that exacerbate current shortages.¹⁹

In December 2023, Congress directed DOD to establish a military pharmaceutical and medical device vulnerability working group, which is tasked to, among other items, develop a plan for “stockpiling essential medications to ensure availability of a 180-day supply during an armed conflict or other supply chain disruption.”²⁰

11. Senator SULLIVAN. Dr. Barber and Mr. Mendez, does DOD need to anticipate disruption by exploring potentially prolonging the storage life of already available drugs?

Dr. BARBER. This is a critical and relatively low-cost, high-benefit intervention by DOD. DOD and FDA already jointly administer the Federal Shelf Life Extension Program (SLEP), but this is restricted only to federally maintained stockpiles. A 2006 review of SLEP testing reported that products had an average extension of 66 months, and 88 percent of 3,005 tested lots had expiration dates extended by at least 1 year.^{9*}

*Please see References on page 103.

DOD and FDA should conduct shelf-life studies for a wider range of products. Better understanding of longer-term effectiveness of products across the wider supply chain benefits both the health system at large and DOD’s specific needs. Studies should also evaluate storage conditions. As one example, recent heat stability testing of insulin found that while pharmacopoeias recommend that unopened insulin vials be refrigerated and insulin be stored at ambient temperatures of up to 25 to 30 degrees Celsius during a 4-week period of treatment, insulin was heat stable in temperatures 25 to 37 degrees Celsius.^{10*} Rising temperatures and more frequent extreme weather events add further urgency to heat stability research.

*Please see References on page 103.

Mr. MENDEZ. The Defense Health Agency (DHA) manages the drug products included in the DOD shelf-life extension program (SLEP).²¹ The program establishes procedures to consider and extend the shelf life of certain stockpiled products that are near or at the date of expiration. For certain medical products (e.g., FDA-regu-

¹⁵ Crystal Maynard, “Army Medical Prepositioned Stockpiles: Ready for Action,” U.S. Army Medical Research and Development Command, May 22, 2023, at https://mrhc.health.mil/index.cfm/media/articles/2016/army_medical_prepositioned_stockpiles_ready_for_action.

¹⁶ DOD, Evaluation of the Department of Defense’s Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain, September 20, 2021, p. 27, at <https://media.defense.gov/2021/Sep/22/2002859154/-1/-1/1/DODIG-2021-126-RRDACTRD.PDF>.

¹⁷ Ibid.

¹⁸ Marta E. Wosinska, Drug Shortages: A Guide to Policy Solutions, The Brookings Institution, March 2024, at https://www.brookings.edu/wp-content/uploads/2024/03/20240318CHP_Wosinska_DrugShortagesFULL.pdf.

¹⁹ FDA, Drug Shortages: Root Causes and Potential Solutions, updated February 21, 2020, at <https://www.fda.gov/media/131130/download/attachment>; and American Society of Health-System Pharmacists, Drug Distribution and Control: Procurement-Guidelines, ASHP Guidelines on Managing Drug Product Shortages, 2024, pp. 100–108, at <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/managing-drug-product-shortages.pdf>.

²⁰ P.L. 118–31 § 716.

²¹ DOD Manual 4140.27 (Volume 1), DOD Shelf-Life Management Program: Program Administration, updated December 11, 2019, p. 17, at <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/414027-vol1.PDF>. DOD also manages the SLEP for other Federal stockpiles (e.g., Strategic National Stockpile) in collaboration with the administering Federal agency.

lated pharmaceutical drugs), DOD may request product testing and shelf-life extension from the FDA in order to maintain stockage requirements or continue use of the product beyond the labeled expiration date.²² Current DOD policy stipulates that a product may be considered for shelf-life extension if the following criteria are met:

- the shelf-life extension is directed by a military service or agency,
- the product is part of a pre-positioned and/or contingency stock,
- the total inventory value per lot is at least \$10,000, and
- the product was not requested and denied for shelf-life extension within the last 12 months.²³

DOD components may also submit a request for an exemption to the criteria based on other reasons (e.g., national security, market availability, or service-specific priorities).²⁴

DOD's original intent for SLEP was to "limit expenditures and defer drug replacement costs" for stockpiled products.²⁵ CRS is not aware of whether or not DOD has or is considering use of SLEP as a potential mitigation strategy to curb drug supply chain disruptions, or to address other potential concerns with DOD's supply and demand for drugs. Congress could consider whether or not the use of shelf-life extensions for drugs can viably mitigate short-or long-term "disruption" to the supply chain. Congress could also consider whether or not DOD and the FDA have the appropriate capacity and capability to accommodate a potential increase in shelf-life extension requests for drug products.

EMERGING & NOVEL THREATS

12. Senator SULLIVAN. Dr. Dertzbaugh, how can DOD best leverage Walter Reed's Army Institute of Research to make vaccines to new or novel infectious diseases that servicemembers might be more susceptible to than the greater population?

Dr. DERTZBAUGH The DOD can best leverage its organic vaccine manufacturing capacity to make small batches of experimental vaccine candidates to use in early stage preclinical and clinical testing of their safety and immunogenicity under the standards defined by the FDA. These vaccine candidates should address DOD-validated infectious disease threats that servicemembers may encounter when deployed overseas, and for which there are no current medical countermeasures available from other sources.

13. Senator SULLIVAN. Dr. Dertzbaugh and Dr. Smith, there are foreseeable threats, particularly biological and chemical threats, which might only be used to target servicemembers. Since servicemembers are a relatively small group compared to the greater population, civilian pharmaceutical suppliers and manufactures are less likely to work on those problem sets. Does DOD have the organic capacity to address the likely biological and chemical threats that servicemembers might face that aren't being addressed by industry?

Dr. DERTZBAUGH The DOD has the organic research capacity to develop medical countermeasures to address infectious disease threats that servicemembers may encounter, and for which pharmaceutical companies may not view as commercially viable to pursue. However, the DOD does not have the organic expertise or capacity to perform large-scale manufacturing of these countermeasures to protect servicemembers. The DOD would be dependent on a commercial entity, such as a Contract Development & Manufacturing Organization (CDMO) for scale-up, manufacturing, and fill/finish of the final product under FDA Good Manufacturing Processes (GMP).

²² For more on SLEP, see Ibid.; DHA Procedural Manual 6430.05, Shelf-Life Extension Program, updated March 10, 2023, at <https://www.health.mil/Reference-Center/DHA-Publications/2023/03/10/DHA-PM-6430-05>; FDA, "Expiration Dating Extension," accessed June 18, 2024, at [https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#:~:text=Shelf%20Life%20Program,-Stockpiling%20drugs%20C%20vaccines&text=SLEP%20is%20the%20Federal%20C%20fee,stability%20testing%20conducted%20by%20FDA;and%20FDA%20briefing%20slides,Shelf-Life%20Extension%20Program%20\(SLEP\),December%2015,%202010,at%20https://web.archive.org/web/20170722095243/https://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/UCM253309.pdf](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#:~:text=Shelf%20Life%20Program,-Stockpiling%20drugs%20C%20vaccines&text=SLEP%20is%20the%20Federal%20C%20fee,stability%20testing%20conducted%20by%20FDA;and%20FDA%20briefing%20slides,Shelf-Life%20Extension%20Program%20(SLEP),December%2015,%202010,at%20https://web.archive.org/web/20170722095243/https://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/UCM253309.pdf).

²³ DHA Procedural Manual 6430.05, Shelf-Life Extension Program, updated March 10, 2023, p. 13.

²⁴ Ibid.

²⁵ Ibid., p. 11.

Dr. SMITH. The DOD has the organic research capacity to develop medical countermeasures to address infectious disease threats that servicemembers may encounter, and for which pharmaceutical companies may not view as commercially viable to pursue. However, the DOD does not have the organic expertise or capacity to perform large-scale manufacturing of these countermeasures to protect servicemembers. The DOD would be dependent on a commercial entity, such as a Contract Development & Manufacturing Organization (CDMO) for scale-up, manufacturing, and fill/finish of the final product under FDA Good Manufacturing Processes (GMP).

14. Senator SULLIVAN. Mr. Suarez, having worked in both the Army and industry, you are well-suited to answer if you think DOD has partnered appropriately with industry to advance pharmaceuticals designed to protect servicemembers in austere environments?

Mr. SUAREZ. Thank you for this question. I think the DOD has struggled to appropriately partner with industry to advance pharmaceuticals designed to protect servicemembers due to its lack of visibility in the upstream supply chain, the “Acetris Loophole” enabling non-TAA generic medicines to dominate the market and a lack of federally driven legislation that incentivize more domestic, high quality and reliable drug suppliers to sell to the DOD and Federal customers. During my service in the U.S. Army, I had the opportunity to help lead, plan, and manage the end-to-end global defense supply chain for pharmaceuticals, other medical supplies, and devices. As I testified, the medical supply chain offers unique challenges, many of which are addressed in the procurement of other key materials. During my time on Active Duty, I observed three distinct challenges unique to the medical supply chain: (1) lack of upstream supply chain visibility; (2) perverse disincentives related to the ‘Acetris’ loophole; and (3) a lack of ‘pull’ incentives to sufficiently allow for a domestic manufacturing preference in DOD and other Federal procurement activities.

By addressing these challenges, I believe that the DOD will be better positioned to lead and advance the resiliency of the medical supply chain and ensure availability of medicines to our servicemembers; and can set the example for the rest of the Federal Government and industry to follow.

1. *Upstream Supply Chain Visibility*

Sec. 860(a) of the Fiscal Year 2023 National Defense Authorization Act (NDAA) required the Under Secretary of Defense for Acquisition and Sustainment (USD(A&D)) to issue a report on the DOD’s Pharmaceutical Supply Chain Risks. As a part of that report, the DOD analyzed 1,744 (drug families), equating to approximately 12,917 national drug codes (specific drugs), or about 10 percent of the total U.S. marketplace. The DOD found that for the GSNs (generic sequence numbers) analyzed, at least 22 percent had an unknown source of active pharmaceutical ingredient (API). More troublesome, 54 percent of the total DOD pharmaceutical supply chain is considered “*high or very high risk*” with dependency on non-Trade Agreement Act (TAA) compliant suppliers, sourcing from China or other nations often dependent upon China for raw materials and precursor chemicals.

The lack of upstream supply chain visibility and the inability of regulatory agencies to effectively oversee production have contributed to ongoing drug shortages. A case study example is a generic antimicrobial product that addresses warfighter wound injury. While such antimicrobials may be characterized as multi-source drugs (MSDs), it is very possible that, with the trends toward manufacturing consolidation, all manufacturers will utilize API from the same upstream facility. In the event of a drug shortage—whether prompted by a natural disaster, economic crisis, manufacturing delays due to quality deficiencies, or geopolitical conflict—all downstream suppliers would subsequently lose access to the drug, leading to major adverse healthcare impacts domestically and globally.

To this end, I have been supportive of a procurement requirement within the DOD that would require contracting officers to procure from manufacturers that meet the following criteria: (1) source the finished drug product (FDP) from a U.S.-based manufacturer and (2) source API for the drug from a domestic source or a TAA-compliant nation, and preference suppliers who can validate that key starting and precursor materials for API are primarily coming from domestic or TAA compliant sources. To mitigate exacerbating shortages or other capability gaps, I also support the utilization of waiver authority to ensure continued access to these drugs. Such a program would simultaneously reduce supply chain risks while providing critical visibility as to the drug’s country of origin.

2. *‘Acetris’ Loophole*

In February 2020, the U.S. Court of Appeals for the Federal Circuit in *Acetris Health LLC v United States* overturned a long-standing precedent regarding a drug’s origin, holding that a drug could be “*manufactured*” in the U.S. even if its

API and all its components were derived from non-TAA compliant countries. This loophole exacerbates national security and known drug quality risks.

The DOD health system and the Veteran Health Administration (VHA) should be required to adhere to the intent of the Berry Amendment, which could be done by overturning what has been colloquially known as the “Acetris Loophole” and clearly defined in Federal law that a drug’s country of origin should be defined by where the API is physically synthesized and manufactured.

The Berry Amendment was enacted in 1941 to promote purchasing certain U.S. goods (primarily food and textiles) for national security and domestic trade. I recommend that Congress update this language to include the purchase of essential medicines explicitly to include the purchase of essential drugs and medical supplies. The idea to drive necessary change in an otherwise broken market using U.S. Federal procurement is supported by a 2022 Department of Health and Human Services (HHS) report entitled “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.”*

3. Properly Incentivizing Domestic Manufacturing

Procurement policy is just one policy lever that the U.S. Government and the DOD should employ to create a resilient global supply chain with U.S.-domiciled facilities. To this end, I am encouraged by exploring partnerships between the Department of Defense (DOD) and the Administration for Strategic Preparedness and Response (ASPR) to promote industrial base expansion efforts for manufacturing generic and essential medicines. To this end, I have supported a ‘CHIPS-style’ program for the U.S. pharmaceutical supply chain. Such a program would lean on DOD expertise to make targeted investments in U.S. manufacturers to increase line capacity and utilization for essential drugs. Those in shortage employ the use of advanced and continuous manufacturing technologies, employ the use of advanced and continuous manufacturing technologies, and work with the Centers for Medicare and Medicaid Services (CMS) to provide proper payment reform to incentivize hospital and retail uptake of high-quality generic drugs manufactured.

In conclusion, I believe a combination of policy and legislative reforms will better position the DOD to partner with industry to address drug shortages, meet warfighter needs, and mitigate ongoing national security risks to the Department its servicemembers and beneficiaries.

COVID-19 LESSONS LEARNED

15. Senator SULLIVAN. Dr. Barber, has U.S. industry at-large implemented lessons learned from the COVID-19 pandemic related to vaccine production?

Dr. BARBER. Thank you for this query. This is a challenging question to answer given the broad scope of issues at play. Broadly, my assessment is that while there were some important developments—for example, Operation Warp Speed was a testament to the power of the public sector to lead accelerated vaccine development and rollout timelines—broadly the wider industry at large has returned to business as usual. The private sector has not significantly increased spending into pandemic preparedness. To prepare for the next pandemic, long-term, predictable investment is needed to develop vaccines and therapeutics for priority pathogens with pandemic potential. Collaborations with the private sector must include strong conditionalities that lock in fair prices and give the Federal Government the power to scale up and transfer technology as needed.

16. Senator SULLIVAN. Dr. Barber, has U.S. industry at-large implemented lessons learned from the COVID-19 pandemic related to vaccine distribution?

Dr. BARBER. Questions of production and distribution are closely linked. Difficult distributional and prioritization questions were exacerbated by artificial scarcity in supply that could have been addressed through public leadership to exercise existing legal powers to facilitate technology transfer and collaboration with global partners.

17. Senator SULLIVAN. Dr. Barber, has U.S. industry at-large implemented lessons learned from the COVID-19 pandemic related to vaccine storage?

Dr. BARBER. I was not involved in vaccine storage during the COVID-19 pandemic, and defer to other experts with more first-hand experience to answer this question. Briefly, I would encourage this Committee and Congress more broadly to support programs that integrate product use considerations into product design and

support wider public infrastructure for the manufacture, storage, and distribution of critical health products.

QUESTIONS SUBMITTED BY SENATOR TED BUDD

PHARMACEUTICAL SUPPLY CHAIN

18. Senator BUDD. Mr. Beebe, the Department of Defense has identified that 54 percent of its pharmaceutical supply chain is considered either high or very high risk, with dependency on non-Trade Agreements Act compliant suppliers. Can you describe ongoing efforts to address our dependency on foreign and sometimes adversarial nations for our pharmaceutical supplies? What does success look like for decreasing reliance on foreign supply chains?

Mr. BEEBE. DLA continues to use the Pharmaceutical Provenance Solution (PPS) tool to illuminate the supply chain for pharmaceuticals DOD considers key to its mission. DLA has expanded its analysis to include the drugs in the DLA Warstopper Program, the DOD Joint Deployment Formulary, and the top 1,000 drugs, by volume, purchased by DOD customers. This progress has expanded analytics to cover all drugs included in DOD's go-to-war contingency programs and those necessary to support DOD's nine million beneficiaries. DLA continues to conduct these analyses, which are ongoing; however, initial results mirror the findings in the NDAA Section 860 report, which is that the sourcing for more than half of this pharmaceutical group is identified as high or very high-risk locations (in accordance with the definitions used in the report, which included from unknown sources). In view of these findings, the Supply Chain Risk Integration Framework (SCRIF), previously known as the SCRM Working Group, has taken the following actions to ensure coordination and communications across the enterprise to identify, assess, and mitigate or resolve the risks associated with the sourcing of its mission essential pharmaceuticals.

DLA uses a four-step process to reduce its pharmaceutical supply chain risk. First, DLA is advising all stakeholders of the risk and garnering their support in mitigating the risks. Second, the DLA Customer Pharmaceutical Operations Center is identifying viable alternatives to products from high-risk sources and providing them to DLA customers. Third, DLA is working with the interagency to increase on-shore or near-shore FDA-approved, TAA-compliant sources for finished drugs and APIs. DLA's long-term target is to eliminate dependence on high-risk sources. However, progress will come slowly. DLA depends on the U.S. commercial sector for the pharmaceuticals it acquires and reversing 20 years of drug and API globalization will take time, investment, and a national commitment to change.

A major risk to DLA's ability to mitigate foreign dependency is not being able to identify the sources for APIs. Having access to the right level of data is the first step in being able to identify and mitigate risk.

19. Senator BUDD. Mr. Beebe, do you see opportunities to shift some of our supply chains to domestic sources or to diversify the supply chain, perhaps to Allied and Partner countries?

Mr. BEEBE. In any supply chain, diversity and redundancy of reliable sources is beneficial to those who rely upon that supply chain for products. To that end, DLA supports efforts to increase the number of domestic and TAA manufacturers and producers for pharmaceuticals. However, DOD is fully dependent on the global commercial supply chain, where manufacturing is driven largely by low labor and production costs. Without a business incentive to increase domestic and/or near-shore manufacturing, a change to the current geographic structure of the market is unlikely.

20. Senator BUDD. Mr. Beebe, how is the DOD coordinating or sharing information with the Department of Health and Human Services related to pharmaceutical supply chains?

Mr. BEEBE. DOD and the Department of Health and Human Services (FDA and ASPR) are both members of the Pharmacy SCRM Working Group. DLA has also engaged the FDA to increase and enhance data sharing capabilities.

ACADEMIC RESEARCH INSTITUTIONS

21. Senator BUDD. Dr. Martínez-López, how is the DOD leveraging academic research and science out of our universities to address current health threats?

Dr. MARTÍNEZ-LÓPEZ. The Department continues to utilize academic research and science to address various health threats facing our servicemembers through health-related research, development, testing, and evaluation activities. The DHA research

program partners with universities to focus on advancing the state of medical science in those areas of most pressing need and relevance to today's emerging threats and future threat scenarios. Health threat areas include traumatic brain injury (TBI), psychological health (including Post Traumatic Stress Disorder (PTSD)), combat casualty care, military operational medicine, military infectious diseases, radiation health effects, and clinical and rehabilitative medicine. The Military Health System utilizes collaborative partnership agreements such as Educational Partnership Agreements, Cooperative Research and Development Agreements, and Military Training Agreements to enter into strategic health research, education, and training collaborations with universities.

FDA-DOD COLLABORATION

22. Senator BUDD. Mr. Mendez, the Fiscal Year 2018 NDAA contained a provision that authorized the Secretary of Defense to work with the Food and Drug Administration on additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war. How has DOD-FDA collaboration been so far?

Mr. MENDEZ. On December 12, 2017, Congress enacted Section 716 of the National Defense Authorization Act for fiscal year 2018 (Fiscal Year 2018 NDAA; P.L. 115–91), which amended 10 U.S.C. § 1107a, to allow the Secretary of Defense to authorize emergency use of a non-Food and Drug Administration (FDA) approved medical product outside of the United States to “reduce the number of deaths or the severity of harm” to servicemembers and others deployed in support of the Armed Forces caused by a risk or agent of war.²⁶ The enacted provision allowed the Secretary of Defense to utilize this authority only when the emergency use of the medical product does not meet Federal Food, Drug, and Cosmetic Act requirements for involving an “actual or threatened attack with a biological, chemical, radiological, or nuclear agent or agents.”²⁷ In the report accompanying the Fiscal Year 2018 NDAA, the conferees stated that the traditional pathways to the Food and Drug Administration’s approval and licensure of critical medical products for combat casualty care are too slow to allow for rapid insertion and use of these products on the battlefield. The conferees believe this provision could lead to even higher survival rates from severe combat wounds and injuries suffered by servicemembers. The conferees expect the Department of Defense to consult with the Commissioner of the Food and Drug Administration when evaluating medical products for combat casualty care and to use this new authority strictly for approval of medical products for battlefield wounds and injuries.²⁸

After enacting P.L. 115–91, on that same day, Congress also enacted P.L. 115–92 to repeal Section 716 of the Fiscal Year 2018 NDAA and to amend the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. § 360bbb–3) to provide for a process in which the Secretary of Defense may request that the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, take actions to “expedite the development and review” of an application or notification for emergency use of a medical product “if there is a military emergency, or significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of such application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk.”²⁹ The law (P.L. 115–92) also established requirements for DOD, FDA, and other Federal entities to meet periodically in order to “facilitate enhanced collaboration and communication.”³⁰

After Congress enacted P.L. 115–92, DOD and FDA published an “Initial Work Plan for Products Relevant to the Department of Defense” in January 2018.³¹ The plan’s aim is to “create a robust and enduring pathway that will efficiently address the needs of the DOD and meet the [FDA’s] obligations” to servicemembers.³² DOD

²⁶ P.L. 115–91 § 716.

²⁷ *Ibid.*; and 21 U.S.C. § 360bbb–3 (prior to December 12, 2017).

²⁸ H.Rept. 115–404, p. 851.

²⁹ P.L. 115–92.

³⁰ *Ibid.*

³¹ FDA, “Initial Work Plan for Products Relevant to the Department of Defense (DOD),” January 2018, at <https://www.fda.gov/media/110237/download>.

³² *Ibid.*, p. 1.

and FDA also signed a memorandum of understanding (MOU) in 2018 to formalize collaboration and communication between the two entities.³³

With regard to the status of DOD and FDA collaboration, CRS is unable to assess the collaboration in the absence of objective performance metrics. It remains to be seen how well DOD and FDA work together and whether or not they have adhered to the collaboration requirements directed by Congress in P.L. 115–92.³⁴ What can be observed is that after the enactment of P.L. 115–92, both entities have announced a number of DOD medical products that may have received FDA approval utilizing the processes established in the initial work plan, the 2018 MOU, and other existing interagency agreements.³⁵ These products include laboratory-based and field deployable traumatic brain injury (TBI) blood tests; medical countermeasures for nerve agents and chemical weapons; vaccines to protect against tick-borne encephalitis and Ebola; and freeze-dried plasma.³⁶

23. Senator BUDD. Mr. Mendez, given the FDA already has oversight over the pharmaceutical industry and the DOD and the FDA are able to work in collaboration with each other as pharmaceutical supply chains relate to national security, is there an imminent need for the DOD to manufacture drugs?

Mr. MENDEZ. CRS cannot make a determination as to whether or not DOD or other Federal agencies have a “need” to perform or not perform certain actions. CRS can inform the congressional debate about whether there may be a need for DOD to manufacture drugs, the timeliness of addressing a need (if it exists), and potential effects of certain actions or inaction.

In several instances described below, DOD and Congress have considered this question of whether or not a need exists for DOD to manufacture drugs and explored options to address drug supply challenges.

- In 1990, the Secretary of Defense directed the Assistant Secretary of Defense for Health Affairs to create a task force to investigate the industrial base capability for producing medical countermeasures against anthrax and botulinum toxin and to develop short-and long-term options and recommendations for increasing vaccine production.³⁷
- In 1993, Congress prohibited DOD from using fiscal year 1994 appropriated funds for “architectural and engineering services or for construction design in connect with the Department of Defense vaccine production facility.”³⁸
- In 1994, DOD considered a proposal to create a vaccine production facility “that can produce vaccines to counter the use of biological warfare.”³⁹
- In 1994, the House Armed Services Committee questioned the Secretary of Defense and other DOD witnesses about DOD plans to establish a vaccine production facility during authorization and oversight hearings on an Fiscal Year 1995 NDAA.⁴⁰

³³ FDA, “Memorandum of Understanding Concerning Coordination With The Food and Drug Administration Regarding Department of Defense Medical Product Development and Assessment” (MOU 225–19–001), November 2, 2018, at <https://www.fda.gov/about-fda/domestic-mous/mou-225-19-001>.

³⁴ Ibid.

³⁵ Other interagency agreements include MOUs between FDA and Army Medical Research and Materiel Command (MOU 225–20–010), and FDA and the Uniformed Services University of the Health Sciences (MOU 225–22–016), available at <https://www.fda.gov/about-fda/fda-memoranda-understanding/domestic-mous>.

³⁶ For more on these products, see FDA, “FDA/DOD Collaborations,” updated March 29, 2023, at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/fdadod-collaborations>.

³⁷ Assistant Secretary of Defense for Health Affairs Memorandum, “Expansion of Industrial Base for Biological Vaccine Production,” October 5, 1990, at https://gulflink.health.mil/va/va_refs/n46en061/970107_sep96_decls48_0001.htm. For more on these efforts, see Anna Johnson-Winegar, Department of Defense Biological Defense Program Needs for Strategic Biotechnology Development, DOD, Presentation to the BIO-Defense and Homeland Security Procurement Conference and Expo, April 30, 2002, at https://web.archive.org/web/20030624231021/http://www.acq.osd.mil/cp/winegar30_apr02_bio.pdf.

³⁸ Section 2852 of the National Defense Authorization Act for Fiscal Year 1994 (P.L. 103–160).

³⁹ DODIG, “Expanded Uses of the Major Range and Test Facility Bases,” Audit Report 95–061, December 30, 1994, p. 6, at <https://media.defense.gov/1994/Dec/30/2001714848/-1/-1/1/95-061.pdf>.

⁴⁰ U.S. Congress, House Armed Services Committee, Authorization and Oversight, hearing on National Defense Authorization Act for Fiscal Year 1995 and Oversight of Previously Authorized Programs, 103d Cong., 2d sess., 1994, HASC No. 103–32, pp. 266–268.

- In 2000, Congress directed DOD to provide a report on the “implications of reliance on the commercial sector to meet the requirements of the Department of Defense for biological warfare defense vaccines.”⁴¹
- In 2000, the Deputy Secretary of Defense tasked an independent panel of experts to provide recommendations on how DOD should “best develop and oversee a vaccine acquisition production program.”⁴²
- In 2015, Congress limited the availability of appropriated funds that DOD may obligate for a medical countermeasures advanced development and manufacturing (ADM) facility and required a report to Congress describing the ADM facility.⁴³

Congress could assess whether or not a need exists for DOD to manufacture drugs to mitigate broader supply chain resiliency challenges. Congress may also consider requirements, if any, of such an initiative to avoid unintended effects on the commercial market, to meet military requirements for medical countermeasures, to support the availability of medical countermeasures for public health emergencies, or to address existing drug shortages in the United States.

⁴¹Section 218 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 (P.L. 106–398).

⁴²DOD, DOD Acquisition of Vaccine Production, Report to the Deputy Secretary of Defense by the Independent Panel of Experts, November 29, 2000, at <https://apps.dtic.mil/sti/tr/pdf/ADA422848.pdf>.

⁴³Section 221 of the National Defense Authorization Act for Fiscal Year 2016 (P.L. 114–92). The law also required a Comptroller General review of DOD’s report to Congress. For more, see U.S. Government Accountability Office, Biological Defense: Additional Information that Congress May Find Useful as It Considers DOD’s Advanced Development and Manufacturing Capability, July 2017, at <https://www.gao.gov/products/gao-17-701>.

APPENDIX A

**References of
Dr. Melissa Barber**

1. Toward a national biodefense strategy [Internet]. 2004; Available from: <https://www.Congress.gov/event/108th-congress/house-event/LC13942/text?s=1&r=61>
2. General Accounting Office. Biological Warfare: Role of Salk Institute in Army's Research Program [Internet]. 1991; Available from: Washington, DC, USA
3. Prohibition on use of funds for planning and design of Department of Defense vaccine production facility [Internet]. 1993. Available from: <https://www.Congress.gov/103/statute/STATUTE-107/STATUTE-107-Pg1547.pdf>
4. Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military [Internet]. Washington, DC.: National Academies Press; 2002 [cited 2024 Apr 6]. Available from: <http://www.nap.edu/catalog/10483>
5. Proceedings and Debates of the 107th Congress, Second Session. Congressional Record [Internet] 148(88). Available from: <https://www.Congress.gov/107/crec/2002/06/27/CREC-2002-06-27.pdf>
6. Melody Petersen, Andrew Pollack. A NATION CHALLENGED: THE DEFENSES; Big Push to Accelerate Vaccine Effort [Internet]. The New York Times. 2001; Available from: <https://www.nytimes.com/2001/09/28/business/a-nation-challenged-the-defenses-big-push-to-accelerate-vaccine-effort.html>
7. Tim Hutchinson. S.Amdt.4069 to S. 2514 [Internet]. Available from: <https://www.Congress.gov/amendment/107th-congress/senate-amendment/4069/text?s=1&r=77&q=%7B%22search%22%3A%22%26%231606%22%7D>
8. Biodefense Posture Review. Washington, DC, USA: Department of Defense; 2023.
9. Lyon RC, Taylor JS, Porter DA, Prasanna HR, Hussain AS. Stability profiles of drug products extended beyond labeled expiration dates. *Journal of Pharmaceutical Sciences* [Internet] 2006 [cited 2025 Jan 24];95(7):1549–60. Available from: <https://linkinghub.elsevier.com/retrieve/pii/S0022354916320457>
10. Kaufmann B, Boulle P, Berthou F, et al. Heat-stability study of various insulin types in tropical temperature conditions: new insights toward improving diabetes care. *PLoS One* [Internet] 2021 [cited 2025 Jan 24];16(2):e0245372. Available from: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0245372>

Supportive articles submitted by Mr. Victor A. Suarez to follow:

White House Plan To Curb Drug Shortages Doesn't Address Generics' Quality

Arthur L. Kellermann
Contributor

Apr 24, 2024, 08:03am EDT

<https://www.forbes.com/sites/arthurkellermann/2024/04/24/will-the-white-houses-plan-to-curb-drug-shortages-work/?sh=7f7410eb4458>



XIANGYANG, CHINA - DECEMBER 30: An employee works on the production line of ibuprofen, a fever ... [+]

VCG VIA GETTY IMAGES

Drug shortages are at an [all-time high](#). Earlier this month, the White House rolled out a [plan](#) intended to sharply reduce future shortages of essential medicines, such as antibiotics and cancer drugs.

The Administration wants to “address the market failure that currently exists, which is that there is no entity that's accountable to [maintain the] supply chain,” said Neera Tanden, President Joe Biden’s domestic policy adviser, in

an [interview](#) with Bloomberg News. “Today, when we have a drug shortage, various entities within the healthcare system point to each other.”

While I applaud the Administration’s determination, I am concerned that its plan ignores the main cause of drug shortages: [the variable quality](#) of America’s generic drug supply, much of which is imported from overseas.

What The White House Plan Would Do

The [White House plan](#) calls for creating and accrediting two new nongovernmental organizations—one to rate drug manufacturers on how well they maintain resilient supply chains and the other to score hospitals based on how well they avoid future drug shortages. A lot of money is involved—between \$3.26 billion and \$5.11 billion over the next 10 years.

A key component of the plan is the creation of a “Manufacturing Resiliency Assessment Program” that will monitor drug shortages and evaluate drugmakers’ efforts to prevent them, such as by sourcing key starting materials from several suppliers instead of just one. The plan also calls for boosting domestic manufacture of essential drugs.

plan also proposes incentives and penalties to induce hospitals to adopt more resilient sourcing of essential drugs. To assess how well they respond, the White House proposes a “Hospital Resilient Supply Program” that will score each hospital’s purchasing practices. Those who buy from drugmakers that are highly rated by the Manufacturing Resiliency Assessment Program will score better than those that do not. So will hospitals that buy drugs in quantity rather than relying on “just-in-time” delivery. Hospitals that execute long-term contracts to ensure stable supply will also receive higher scores—and the incentives that come with them.



A pharmacist checks stock levels of medication in pharmacy stock room
(Photo by Universal Images ... [+]

UNIVERSAL IMAGES GROUP VIA GETTY IMAGES

What The Plan Won't Do

The plan does not encourage, much less require, U.S. wholesalers and pharmacy benefits managers (the powerful middlemen in the drug supply chain) to source the generic drugs they buy from manufacturers that consistently produce high-quality products. This is surprising, since [quality concerns](#) cause more drug shortages than all other factors combined. In her interview with Bloomberg, Tanden explained that the Administration did not want to undermine the FDA's role as the "arbiter of the quality of drugs."

Unfortunately, there's a big disconnect between the frequency of quality problems that trigger FDA recalls and the agency's stand on generic drug quality. Although the FDA does little product testing—opting instead to review company-supplied paperwork and occasionally inspect plants—the FDA's Office of Generic Drugs' [website](#) asserts that "All approved generic drugs have the same high quality, strength, purity, and stability as brand-name drugs."

When contacted for comment, the agency offered a more nuanced view, but basically stood by the assertion that this applies to *all* approved generic drugs.



WHITE OAK, MD - JULY 20: Food And Drug Administration headquarters in White Oak, Maryland, July 20, ... [+]

GETTY IMAGES

Based on this assurance, America's drug wholesalers and pharmacy benefits managers scour the globe to find manufacturers willing to sell at the lowest possible price. Because U.S. companies can't make products as cheaply as competitors in countries with low labor costs and lax regulatory oversight, most closed their doors or switched to repackaging drugs sourced overseas.

Today, China, India, and a few other nations dominate global production of generic drugs and ingredients. This makes America increasingly vulnerable to supply disruptions or embargoes. U.S. Department of Defense recently [determined](#) that more than half of its pharmaceutical supply chain is at "high" or "very high" risk.

A Consumer-Focused Alternative

Other consumer-facing agencies take a different approach to product quality. For example, the National Highway Traffic Safety Administration is responsible for assuring that all automobiles sold in the U.S. meet or exceed federal standards for quality and safety. To verify that they do, NHTSA crash-tests various makes and models of cars and [posts](#) the results on its website.

The [Insurance Institute of Highway Safety](#) also crash-tests cars and independently posts its findings. *Consumer Reports* and other groups rate cars based on their performance and features and share their findings with consumers. None of this work infringes on NHTSA's regulatory authority.

Dr. Ricardo Martinez, who led NHTSA from 1994 to 1999, explained the agency's philosophy to me this way: "From the perspective of enhancing safety, the more the consumer knows about the safety performance of vehicles, the greater the market competition for safety. And NHTSA just doesn't allow vehicle manufacturers to certify their compliance with federal regulations, it has the authority to pull any vehicle produced and test it for compliance. NHTSA also monitors the fleet of existing cars for potential defects that could trigger a recall and require a remedy."

Perhaps the White House should consider a similar approach to strengthen its drug shortage strategy.



Stop-motion photograph of a side-impact crash test. Crash-testing vehicles this way provides ... [+]

PHOTO COURTESY OF THE INSURANCE INSTITUTE FOR HIGHWAY SAFETY, WWW.IIHS.ORG

When Quality Is Known, Markets Respond

According to a 2023 [survey](#) by the American Society of Hospital Pharmacists, the vast majority of its members would be willing to pay more for drugs sourced from high-quality suppliers. Besides, testing for quality isn't costly. It's possible, if not likely, that some high-quality manufacturers are only little more expensive than those selling lower-quality drugs. But without independent testing, pharmacies, doctors and patients are flying blind.

In the coming months, findings from the U.S. military's pilot drug testing program may start rolling out. When they do, the FDA's insistence that "all generic drugs have the same high quality" may become untenable.

Large healthcare systems need not wait for the FDA to rethink its approach. If they informed drug wholesalers and pharmacy benefit managers that they will only buy drugs that have been independently tested by a qualified third party laboratory to confirm quality and safety, the market would swiftly correct itself.

If the test results were then shared with the FDA the same way “Official Medicines Control Laboratories” in Europe [share their test results](#) with the EU’s FDA counterpart, the agency could send its inspectors to the most worrisome overseas and U.S. plants.

Commenting on the White House plan, President Biden's national economic adviser Lael Brainard said, “We need new solutions, including increased domestic production, rewarding resilience, and transparency among middlemen.”

Pressing drug middlemen for greater transparency about product quality is a good place to start. When quality matters as well as price, U.S. generic drug manufacturers will be able to compete and win. America’s patients will be the biggest winners of all.



BRIEFER

No. 57 | March 5, 2024

THE NATIONAL SECURITY RATIONALE FOR STOCKPILING KEY PHARMACEUTICAL INGREDIENTS

Reducing America's Overreliance on
Imports for Essential Medicines

Vic Suarez

Edited by John Moulton, Christine Parthemore, and Francesco Femia

INTRODUCTION

The COVID-19 global pandemic has underscored the critical need for resilient and secure supply chains, particularly in the pharmaceutical industry. As the United States grapples with near-all-time high drug shortages¹ and the vulnerability of its supply chain, it has become a national security imperative to address the overreliance on imports for active pharmaceutical

ingredients (API) to the United States. Today, China is the sole source for about 20% of the API of our most vital medicines.² 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 KSM, a vital subcategory of API, are solely sourced from China, according to the API

¹ American Society of Health System Pharmacists, "Drug Shortages Statistics," accessed February 5, 2024.

² USP and Center for Analytics and Business Insight, Olin Business School at Washington Louis University, unpublished data image, October 13, 2023.

Innovation Center.³ To be sure, this level of import dependence on any single nation poses a serious risk to the nation's general preparedness and resilience, and could become devastating in a crisis.

Highlighting the issues the United States faces: drug shortages in the nation's healthcare system consistently affected approximately 300 medicines throughout 2023.⁴ Moreover, during most of 2023, many operational military units could not get allocation for primary ketamine injection, commonly used for sedation and analgesia during deployment operations.⁵ Upon further investigation, the primary reason these shortages happen is when market forces drive too much concentration or consolidation in the global marketplace; this often leads to lack of focus and investment in current good manufacturing practices and the exclusive focus on drug cost without much regard to supply chain resiliency and product quality.

This brief is based on a retrospective and prospective assessment of this strategic risk, along with numerous inputs from industry, academic, and government experts and reports. It also identifies and recommends several specific and feasible actions that can be implemented immediately to address the risk. Additionally, this document calls on policymakers, business leaders, and national security professionals to recognize that the domestic medical supply chain's reliance on China is equally as threatening as our reliance on China for critical minerals and rare metals for the production of semiconductors, electronics, renewable energy hardware, supercomputers, and our most advanced weapon systems.

³ Ibid.

⁴ Erin Fox, "National Drug Shortages Active Shortages by Quarter – 10 Year Trend," [University of Utah Drug Information Service](#).

⁵ Victor A. Suarez, author's first-hand experience with customer and stakeholder inquiries, June 2023.

⁶ The U.S. House of Representatives, [House Select Committee Report on the CCP](#), December 12, 2023.

WHY SHOULD THE UNITED STATES STOCKPILE KEY PHARMACEUTICAL INGREDIENTS?

- Critical commodity which could undermine the nation's healthcare system and national defense mobilization and sustainment capabilities during geopolitical tensions.
- Depending on the nation's pacing military threat and largest economic competitor for these materials is a significant security threat.
- Key Starting Materials (KSM) and Active Pharmaceutical Ingredients (API) stockpiles in the US would provide strategic flexibility and agility and can be stored for many more years than finished pharmaceutical products. They also can cover a broad spectrum of finished products further up the supply chain.
- The US government has a long history of stockpiling materials deemed essential for national security.
- Pharmaceutical ingredient stockpiles can provide a solid foundation to stabilize the economy, advance the continuity of high-quality patient care and long-term health outcomes, and provide essential predictability to patients, government and first responder actors, and the pharmaceutical and healthcare industries.

Notably, this issue is already garnering policy-maker attention. The risks of pharmaceutical supply chain dependence were underscored in the US House Select Committee on China Report dated 12 Dec 2023, titled "*Reset, Prevent, Build: A Strategy to Win America's Economic Competition with the Chinese Communist Party*."⁶ Congress also showed its attention to addressing import-dependence risks when it passed the 2022 CHIPS and Science Act,

which made a \$53B investment for manufacturing, research, and development, and workforce growth to revitalize the domestic semiconductor industry and reduce domestic reliance on overseas manufacturers. Within a year, this act incentivized the industry to pledge over \$166B in investments to bolster domestic semiconductor manufacturing, highlighting the significance that initial priming and commitment from the government can have in boosting private markets to infuse additional capital.⁷

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 at a time when systems are already strained by epidemics or pandemics, conflict, or other conditions. This brief will describe the fragile state of domestic United States generic pharmaceutical manufacturing, address why the pharmaceutical supply chain is a major national security issue, and propose immediate, mid-term, and long-term solutions to eliminate these critical strategic risks.

CURRENT STATE OF DOMESTIC PHARMACEUTICAL MANUFACTURING

A study released in late 2022 by the API Innovation Center looked into the United States generic pharmaceutical manufacturing plant capacity and 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 off-shore buying activities, generally in countries with access to cheap labor which often struggle to produce consistently high-quality medicines, as meticulously documented by Rosemary Gibson and Janardan Prasad Singh in their seminal book *China Rx*.⁹

Most group-purchasing, pharmacy benefit management, and rebate schemes with exclusively contracted member hospitals have further complicated the pharmaceutical market and its underlying economics. Despite being well-intentioned, antitrust practices in what is essentially an oligopoly have pushed the cost of many generic medicines so low and hence

7 The White House, “FACT SHEET: CHIPS and Science Act Will Lower Costs, Create Jobs, Strengthen Supply Chains, and Counter China,” August 9, 2022.

8 Anthony Sardella, “U.S. Generic Pharmaceutical Manufacturing Available Capacity Research Survey,” Washington UniversityOlin School of Business Center for Analytics and Business Insights, September 30, 2022.

9 Rosemary Gibson and Janardan Prasad Singh, *China Rx: Exposing the Risks of America's Dependence on China for Medicine* (Lanham: Prometheus Books, 2018).

off-shore that domestic manufacturers cannot financially justify producing these medicines, let alone invest in advanced manufacturing technologies to improve and sustain production quality.¹⁰

Moreover, this incentive to drive the lowest possible costs for generics has led to massive displacement of drug manufacturing to India and China 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. In both these countries, there are large backlogs in Food and Drug Administration (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 and sourcing of KSM and API, and underinvestment in quality manufacturing technologies, processes, facilities, and staffing. These combined factors place the strategic risk of reliably sustaining pharmaceuticals in America squarely upstream in the supply chain. This multicomponent 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.¹¹

As a result of this unsavory mixture of flawed market forces and perverse incentives making quality more challenging to achieve, the U.S. healthcare

system is currently dealing with a near all-time high drug shortage, consistently affecting approximately 300 medicines throughout 2023.¹² These shortages not only adversely impact patient care but present life-threatening risks to many cancer and chronic disease-afflicted patients. These shortages also adversely affect our tactical military operations, foreshadowing a strategic national security vulnerability during a crisis or war.

NATIONAL SECURITY IMPLICATIONS AND GENERAL RECOMMENDATIONS

One of the most critical national security lessons from U.S. experiences in major wars is the importance of having domestically vital manufacturing industries and vertically integrated supply chains before mobilizing at scale. In Arthur Herman's 2012 New York Times best-selling book, *Freedom's Forge: How American Business Produced Victory in World War II*,¹³ Herman describes how critical America's steel, chemical, and automotive manufacturing plants were - producing thousands of tanks, airplanes, ships, and explosives - in eventually defeating the Nazis and imperial Japan. Similarly, during World War II, the U.S. pharmaceutical industry also dramatically expanded in response to the need for critical medicines such as penicillin, sulfa drugs, and other life-saving medical supplies.¹⁴

¹⁰ Numerous interviews with industry and government experts, October 2023 through January 2024.

¹¹ US Government Accountability Office, "DRUG SAFETY: FDA Should Take Additional Steps to Improve Its Foreign Inspection Program," January 2022.

¹² Erin Fox, "National Drug Shortages Active Shortages by Quarter - 10 Year Trend," University of Utah Drug Information Service.

¹³ Arthur Herman, *Freedom's Forge: How American Business Produced Victory in World War II* (New York: Random House, 2013).

¹⁴ 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.

The United States can and should take action now so that any potential disruption of KSM and API from a sole source supplier—for example, in case China ceases exports due to tensions over Taiwan—would not result in the collapse of our health system. A minimal goal should be preventing a significant catastrophic disruption worse than the 2020-2023 COVID-19 pandemic.

Stockpiling is one approach the United States has commonly taken to mitigate such risks. In 1977, the Strategic Petroleum Reserve (SPR) received its first crude oil deliveries and was created to reduce supply disruptions and avoid the devastating effect of oil embargo during geopolitical tensions.¹⁵ In 2020, in response to the COVID-19 pandemic, the US government funded the construction of a pharmaceutical equivalent to the SPR, called the Strategic Active Pharmaceutical Ingredient Reserve (SAPIR). However, instead of financing it to maintain nearly two years' worth of supply and incentivizing private industry to incorporate it into a means to wean off reliance on overseas supply, it currently sits at approximately 1% of its capacity.¹⁶

The United States should begin filling the near-empty SAPIR stockpile warehouse with essential API and KSM this year. This action would be no less necessary than the United States addressing the need for petroleum reserves starting in 1910 after the US Navy began converting its ships from coal to oil as fuel.¹⁷ Establishing strategic reserves for critical API and KSM would enable the US government to remove the potential significant leverage that China could exercise over the United States if it so chose—and help

create paths to reducing the risk that such an import dependence might create with other nations in the future. A consistent national security plan would complement actions the US government has already taken to address other vulnerable areas, like cybersecurity, as it would ensure that, despite an embargo of key API and KSM, the United States could rapidly release essential materials and ingredients to domestic drug manufacturers and ensure production continuity and quality ingredients of finished products. Furthermore, stockpiling API makes sense as typically KSM and API have a three to four times longer shelf-life than finished drug products.

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 strong preparedness, this would help meet the need that the Department of Defense's demand for these items in case of war would surge significantly more (on a per person basis) than any demand from the civilian healthcare system. This proposed national KSM and API "safety stock" capability 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 attacks.

During most of 2023, many operational military units could not get allocation for primary ketamine injection, commonly used for sedation and analgesia during deployment operations.¹⁸ Upon further investigation, the primary reason these shortages happen is when too much concentration or consolidation

¹⁵ Office of Cybersecurity, Energy Security, and Emergency Response, "History of SPR Releases," accessed February 7, 2024.

¹⁶ Interviews with key experts to remain anonymous.

¹⁷ Naval Petroleum and Oil Shale Reserves, "Ninety Years Ensuring the National Security," accessed February 7, 2024.

¹⁸ Victor A. Suarez, author's first-hand experience with customer and stakeholder inquiries, June 2023.

occurs in the global marketplace. This, in turn, leads to an oligopoly when often only one, two, or three global manufacturers remain for a critical drug. This typically occurs when domestic manufacturers begin closing plants or cease making select medicines when foreign competitors in places like China and India offer rock-bottom prices, sometimes with government subsidies and often because of much cheaper labor, fewer environmental restrictions, and underinvestment in quality manufacturing processes, equipment, and facilities.

And, if there is a quality issue or a shortage in API or key material due to manufacturing quality delays when one-third or half of the world's supply is unavailable, a major drug shortage ensues, thus eroding patient care and military readiness. Typical status quo actions to address this include implementing minor, incremental improvements (such as requiring manufacturers, distributors, and hospitals to create buffer stockpiles of finished products, or for generic-drug manufacturers in other nations to invest in higher-quality manufacturing technologies) and desperate efforts to import non-FDA-approved medicines. However, to effectively address such a potential shortfall, we ought to explore, debate, and finally take action on feasible solutions which may better address the root causes of this strategic vulnerability in the generic pharmaceutical industry.

Finally, on November 27, 2023, the Department of Defense (DOD) sent its interim Pharmaceutical Supply Chain Risk Assessment to the House and Senate Armed Services Committees, as mandated in the FY23 National Defense Authorization Act (NDAA), Section 860. 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) and were derived from China, India, or of unknown origin. 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 which 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 considered to be "manufactured" in the U.S. even if its API and all of its components were derived from TAA-banned countries, such as China and India.¹⁹ This loophole exacerbates national security and known drug quality risks. As such, this case should be brought before the Supreme Court or remedied with a more precise interpretation by Congress of what it means to have a pharmaceutical substantially made in the United States.

SPECIFIC IMMEDIATE, MID-TERM AND LONG-TERM SOLUTIONS AND RECOMMENDATIONS

As we migrate from understanding the background of our drug supply chain vulnerabilities and the national security implications of overrelying on foreign derived KSM and API, this brief proposes the following specific immediate, mid-term, and long-term solutions and recommendations.

¹⁹ API Innovation Center, Addressing the Acetris "Loophole," Aug 2023

IMMEDIATE SOLUTIONS AND RECOMMENDATIONS (YEARS 1–2)

1. The U.S. government should commit to sustaining the Department of Health and Human Services (HHS) Administration of Strategic Preparedness & Response (ASPR) by purchasing at least an 18-month supply of essential KSM and API and stockpiling them in the already-built SAPIR facility under a dynamic life-cycle managed stability and stock rotation program (industrial conversion). An 18-month supply is estimated to cost in the tens of millions of dollars—a tiny fraction of the security return on investment. It is calculated by some leading industry experts to be able to be completed in less than one year.²⁰
2. ASPR, in partnership with the newly created HHS Supply Chain Resilience and Shortage Coordinator,²¹ should coordinate and prioritize purchases for specific items with the DOD and the FDA. ASPR should also take the lead on collecting the diverse and sometimes diverging inputs from various non-governmental and industrial organizations already monitoring this vulnerability in deciding which purchases to prioritize.²²
3. Operationalize and sustain staffing of the SAPIR facility and at least quarterly test its ability to release key materials to address temporary shortfalls in domestic supply and measure progress against domestic pharmaceutical manufacturing capacity utilization rates as surveyed and measured by leading industrial manufacturing trade organizations.
4. Government and private healthcare systems should work together to ensure all purchased KSM and API for the SAPIR meet or exceed US Pharmacopeia (USP) and FDA quality standards by implementing independent third-party testing and supplier audits for the chemical quality attributes of these materials. The FDA should embrace more independent quality testing of medicines and coordinate efforts with the European Medicines Agency (EMA) and the European Union's Official Control Medicines Laboratories for allied and international partner harmonization of quality product standards to expand the scope and reach for detecting poor quality, adulterated, and fraudulent medicines. They should also ensure that all advanced purchase agreements for materials include requirements for quality audits and testing for authenticity, purity, contaminants, and carcinogens within USP/FDA standards where applicable.
5. The Department of Commerce's Economic Development Administration (EDA) should revitalize the Federal Loan Guarantees for Innovation Technologies in Manufacturing (ITM) program for the domestic generic pharmaceutical industry. ITM could provide:

²⁰ Author interviews with industry experts at the C-Suite level.

²¹ Biden-Harris Administration Announces Actions to Bolster Medical Supply Chain | HHS.gov, accessed 12 February 2024.

²² These NGOs include the American Society of Health-System Pharmacists (ASHP), the API Innovation Center (APIIC), the Association for Accessible Medicines (AAM), the End Drug Shortage Alliance (EDSA), the American Hospital Association (AHA), Physicians Against Drug Shortages (PADS), the Duke-Margolis ReVAMP Drug Supply Chain Consortium, Pharmaceutical Research, and Manufacturers of America (PhRMA), and the United States Pharmacopeia (USP).

- Grants or loans to established U.S.-based pharmaceutical companies that possess FDA-approved medicines that are currently manufactured in Trade Agreement Act (TAA) non-compliant countries such as China or India to technically transfer current Good Manufacturing Practice (cGMP) processes and sources of supply of these medicines to US manufacturing plants.
 - Priority for loans for any medication (generic small molecule or biologics) on the FDA essential medicines list, with the highest priority being medicines, API, and KSM which are currently solely sourced from China or any other single country.
6. The U.S. government should create and fund HHS/ASPR to host a unique grant program for domestic generic drug manufacturers for FDA-approved medicines that are exclusively made in China or any other single nation but are considered essential for life-threatening (oncology medicines), chronic (cardiac/metabolic/autoimmune), neurological, and infectious diseases (beta-lactams), which could be technically transferred to a US manufacturing plant. Approval considerations should include whether the recipient companies are willing to cost share, whether the medicine is sole-source manufactured in TAA non-compliant nations, the severity of the disease treated by the medications, whether there are alternative medicines available, and if the medicine is essential for national defense (DOD essential medicine list) or is stockpiled in the US Strategic National Stockpile.
7. The API Innovation Center recommends²³ that Congress closes the *Acetris* 'loophole' by revising the U.S.-made end product definition and clarifying that the definition of "manufacture" requires meeting the "substantial transformation" standard to encourage the industry to work toward manufacturing API and other critical components of pharmaceuticals in the U.S.

The US House Select Committee on China Report issued in December 2023²⁴ also recommends that Congress consider the following near-term actions:

- Require 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.
- 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.
- Direct a Buy American program for federal entities that purchase pharmaceuticals and medical devices.

²³ Active Pharmaceutical Ingredient Innovation Center, accessed 7 February 2024

²⁴ House Select Committee on the Strategic Competition Between the United States and the Chinese Communist Party, accessed 12 Feb 2024

MID-TERM SOLUTIONS AND RECOMMENDATIONS (YEARS 1-5)

8. Once the SAPIR stockpile program has been initiated, the U.S. government should direct ASPR's Industrial Base Management & Supply Chain (IBMSC) Program Office to pivot to a parallel project to identify and incentivize capable domestic manufacturers to produce KSM and API for every sole source material currently produced in China with a target to replace the initial purchased stock within five years using a dynamic domestic industrial materials conversion and life cycle management program.
9. HHS/ASPR should ensure the initially acquired products sold or delivered to the SAPIR facility are contracted in competitive, long-term advanced purchase agreements. Preference should be given to domestic manufacturers specifically focused on API and KSM manufacturing for sales to the SAPIR simultaneously and until the United States has 18 months' worth of stock based on net imports of foreign-sourced API and KSM. Incrementally shift from an acquisition-focused program from overseas sources to domestically produced sources over a period of two to five years or until a dynamic domestic product conversion program can be achieved.
10. The SAPIR operator should map and match the API and KSM to domestic drug product manufacturers and specific drugs that are in perpetual short supply to create an enduring marketplace of domestic long-term buyers and sellers in a transparent market-driven economy free from oligopolistic and predatory practices as done by some of the major Group Purchase Organizations and Pharmacy Benefit Managers.
11. Once the sole source API and KSM have been addressed as described in recommendations 1-4, transition to domestic or near-shore manufacturing for those API and KSM for which there may be only 2 or 3 suppliers globally or are aligned to drugs that have high HHI (Herfindahl-Hirschman Index, a standard index measurement of market concentration).²⁵
12. The U.S. government should find ways to incentivize the domestic manufacturing of medicines and their precursor chemicals (including KSM, API, and raw materials) and reward health systems and insurers for domestically sourcing these items. This may necessitate closing the Acetris loophole.²⁶
13. All federal agencies that have health systems (DOD, Department of Veterans Affairs, HHS) or have a significant role in reimbursements for pharmaceuticals (Centers for Medicare & Medicaid Services) should be required to adhere to the intent of the Berry Amendment via executive order which was enacted in 1941 to promote the purchase of certain US goods for national security and domestic trade purposes.²⁷

²⁵ US Department of Justice, Herfindahl-Hirschman Index, Antitrust Division, accessed January 19, 2024.

²⁶ See recommendations in the American Made Pharmaceuticals (AMP) Act. 118th Congress (2023-2024), "S.3311 – American Made Pharmaceuticals Act of 2023," introduced November 15, 2023.

²⁷ International Trade Administration, "Berry Amendment", March 1, 2024.

LONG-TERM SOLUTIONS AND RECOMMENDATIONS (YEARS 6-10)

14. Within ten years, ensure the SAPIR facility can stockpile all API and KSM for the essential medicines in the United States, as compiled by the US FDA,²⁸ and adjust stock levels and rotations based on the monitoring of HHI for each essential drug and their likelihood to face a shortage as predicted by tools such as USP's Medicine Supply Map.²⁹
15. ASPR's Office of Industrial Base Management and Supply Chain (IBMSC) should measure and evaluate program success by developing well-designed metrics such as domestic manufacturing plant utilization capacity, drug shortages, regulatory quality findings, and HHI assessments for each essential drug. These metrics should be tested annually in state, regional, and national tabletop exercises based on real-world emergency mobilization scenarios for national defense and pandemic response.

END STATE

The U.S. has a domestic generic pharmaceutical manufacturing industry utilized at over 75% capacity within five years and can produce high-quality and reliable medicines that do not depend on China for the sole source of KSM and API within two years by operationalizing and stocking the SAPIR facility. The end state should also include a domestic manufacturing base that can maintain drug shortages below 100 drugs within five years and 50 drugs within ten years

that is highly transparent and operates like other non predatory free-market commodity sectors.

At this sustained end state, the industry would not be beholden to oligopolistic organizations that erode the reliability and quality of supply, preventing manufacturers from investing in advanced and continuous manufacturing technologies or introducing innovative and disruptive technologies in the spirit of continuous product and process improvement. Finally, China would no longer be able to leverage an embargo of essential and sole-sourced pharmaceutical KSM and API during periods of tension in the United States-China relationship, and the domestic pharmaceutical industry would competitively and fairly operate within a healthy, transparent, high-quality, and ever-improving marketplace.

CONCLUSION

Correcting America's overreliance on China for essential medicines and their upstream API and KSM is not only a matter of economic stability and critical national security purposes but also important because patients ultimately require these life-saving medicines. The recommended immediate, mid-term, and long-term solutions can begin to be implemented now. As recommended in this brief, these proposed actions should be discussed, debated, modified, and implemented by policymakers, elected officials, government agencies, and private industry to ensure the pharmaceutical supply chain's resilience, quality, and security. By diversifying suppliers, domestically producing critical materials, and fostering collaboration with like-minded allies and partners committed to quality

²⁸ US Food and Drug Administration, "Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs," May 23, 2022.

²⁹ US Pharmacopeia, "U.S. Pharmacopeia Medicine Supply Map Releases Global API Manufacturing Findings," March 16, 2022.

and reliable medicines, the United States can mitigate the risks associated with its current overreliance on China (or any other single nation) within the first year of taking action.

The good news is that this is a fixable strategic problem. Yet it will take bold leadership to disrupt the status quo and dynamic efforts in an election year to achieve bipartisan, whole-of-government, and cross-industrial support to make this happen. It is time to rise above the powerful inertia of admiring the problem and begin to take action in 2024 to reverse the trajectory of this strategic vulnerability and rebuild the domestic pharmaceutical industry throughout the entire supply chain. This can be another example of how the United States can lead in achieving a common goal with its allies, its partners, and its patients.

ABOUT THE AUTHOR

Colonel **Victor A. Suarez** (USA Ret.) is a visiting Senior Fellow at the Council on Strategic Risks (CSR). Before his affiliation with CSR, he served in the US Army as an advanced biotechnology product developer, senior healthcare supply chain leader, and combat-experienced commander.

The Pentagon Wants to Root Out Shoddy Drugs. The FDA Is In Its Way.

The U.S. drug-safety regulator has resisted independent testing that's widely used in Europe.

Bloomberg

By Anna Edney and Riley Griffin

December 4, 2023 at 7 PM EST

One morning in October, U.S. Army Colonel Victor Suarez finished his usual morning workout—a 32-mile bike ride—and then sat down in his home office in Frederick, Maryland. When he opened his email, his stomach dropped.

Suarez spent his career getting medicines to military hospitals and combat troops, including those in Iraq and Afghanistan. He had recently sought out an independent lab to assess the quality of those drugs, in large part because he doubted the US Food and Drug Administration's ability to police a supply chain now dominated by low-cost manufacturers in India and China. His inbox offered a glimpse of the first batch of test results.

They revealed that some generic versions of one important drug, given to soldiers who've lost limbs in combat, might not work. They could even cause kidney failure and seizures. The idea that already-wounded personnel might be facing an even more difficult recovery—all to save a dollar or two a pill—gutted Suarez. “Oh my God, what are we doing here?” he recalled thinking.

Still more infuriating was that doctors had long warned the FDA that some versions of the drug performed poorly. Known by the chemical name tacrolimus, it's typically prescribed to organ-transplant patients. The lab Suarez engaged had started testing samples in early September. One of the generics assessed as problematic is manufactured in India by Intas Pharmaceuticals Ltd. It was only a couple of weeks later that the FDA announced, after more than a decade of study, that the Intas version wasn't equivalent to the brand-name drug it sought to mimic. The outside lab had taken a month to flag similar problems.

As Suarez well knew, this isn't just a problem for the military. Tacrolimus is just one example of the painful compromises at the heart of an American health-care system in love with—and increasingly suffering from—cheap generic drugs.

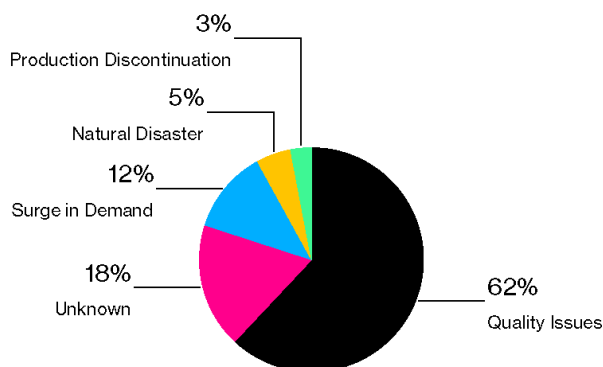
They've saved taxpayers and consumers hundreds of billions of dollars a year. But recalls related to drug manufacturing quality *doubled* in the U.S. from 2018 to 2022. With almost 80 percent of FDA-registered generic production facilities located overseas, years can pass between inspections. Profit margins on generics are so *thin* that there are often only one or two suppliers of vital medications. As a result, quality issues are fueling shocking shortfalls in supply, which a U.S. Senate committee will examine on Tuesday. Shortages in the U.S. reached *near-record* highs this year and left cancer patients, among others, waiting for life-saving treatments. Generics are supposed to be affordable and safe. Instead, they're cheap—but sometimes dangerous.

In February, U.S. health authorities linked eye drops made in India to a rare bacterial strain that led to four deaths, blinded others and caused dozens of infections. Sold over the counter at major U.S. drugstores, the drops came from a factory that had never been inspected by the FDA. Indian-made *cough syrups* laced with toxic industrial solvents have turned up over the past year and a half in 10 countries. They've been linked to the deaths of at least 140 children. The discovery of a probable carcinogen in blood pressure pills made in India and China five years ago is still driving recalls, with the same chemical appearing more recently in diabetes treatments.

The US reliance on India's manufacturers is only growing as it turns away from China, a geopolitical rival. But in the effort to woo a strategic partner and ensure needed supplies, the FDA has been slow to address mounting evidence of flawed drugs. The regulator shut down a program of unannounced inspections in India almost a decade ago. When FDA inspectors do make it inside factories there, they've documented disturbing conditions, from barefoot workers in areas supposed to be sterile to widespread corner-cutting on tests.

What Causes Drug Shortages in the US?

The FDA examined 163 drugs in its database that first went into shortage from 2013 to 2017. It found that quality issues were the biggest cause by far:



Source: US Food and Drug Administration

Amid the scrutiny, Intas is becoming a familiar name. Maker of the tacrolimus that jumped out in the tests Suarez saw, it's also an essential supplier of generics used to treat cancer. The company suspended production of them after FDA inspectors found that workers at one plant in India stashed shredded test results in garbage bags to hide evidence of shoddy manufacturing practices. (Intas said in a statement that it is "in the process of remediating the findings" and that it is "committed to providing safe and effective medicines.") The subsequent shortages impacted care for one in 10 patients this year, the American Cancer Society says.

Concern about the Nation's drug supply has reached the point that big hospitals, the Defense Department and Congress are raising questions about the FDA's ability to monitor it. The Pentagon in August chose an independent lab with which the FDA has publicly feuded, Valisure LLC, to test some of the generics available to millions of military personnel and their families, 2 years after Kaiser Permanente, a health system serving 12.7 million in the US, started a similar program with the lab.

The efforts have run headlong into a major roadblock: the FDA itself. One might assume the US drug regulator, which dates to the 19th century Division of Chemistry, leads the mission of testing drugs. In fact, the FDA resists the idea of grading drugs by quality and rarely conducts tests of its own. Agency officials sought to block the Pentagon's nascent study, cast doubt on Valisure's methods and, according to multiple government officials, soured a Biden administration effort this year to introduce third-party testing more widely.

FDA spokesperson Jeremy Kahn said the agency "is continuously working to ensure that all drugs meet the highest quality standards with the health and well-being of Americans top of mind." Agency officials have said many of the problems are a hangover from a decline in inspections during the pandemic and that a system based on spot checks and occasional reprimands is working.

The drawbacks of that approach were apparent in May, when an inspection of a second Intas facility in Ahmedabad, India, turned up more quality issues, including workers who made up favorable test results and ignored evidence of contamination. Inspectors had identified similar problems in 2019. Company officials suggested pausing production for the US to address the issues, according to a person familiar with the matter who declined to be identified discussing sensitive matters. The FDA, this person said, feared the fallout of even more shortages and advised against it.

In November, after Bloomberg News asked an agency spokesperson about the decision, the FDA banned some exports from the plant to the US. But the ban didn't apply to more than two dozen generics, including tacrolimus and 16 cancer drugs.

Robert Califf, The FDA Commissioner, donned a garland of pink flowers on the steps of the US Embassy in New Delhi in September, smiling broadly for a photo with the American ambassador as he embarked on a trip to meet with government

officials, drug company executives and academics. His subsequent blog post walked a line between pep talk and tough talk for India's embattled generic drug industry. While noting the "global attention focused on serious instances of quality failures," he said he'd also visited firms that are doing "a tremendous and reliable job" in a country that remains a critical partner.

Califf, who also led the FDA during the last year of the Obama administration, has returned to an agency in crisis. He and other officials were called before Congress last year to explain the FDA's slow response to evidence of contamination in baby formula made in Michigan that was linked to infant deaths. Before that came its approval, in 2021, of a potentially lucrative drug for Alzheimer's disease over the objections of a scientific advisory panel that questioned the drug's effectiveness. The agency didn't make him available to comment for this story.

The revolving door at the FDA, as at many other branches of government, is well-worn. At least four former chiefs of its office of compliance later became consultants to generic drugmakers. The head of its Center for Drug Evaluation and Research, Patrizia Cavazzoni, previously held senior positions at the drug giants Pfizer Inc. and Eli Lilly & Co. Like nine of ten of his predecessors, Califf, a cardiologist, went on to work for drug companies or serve on their boards. Between his stints as FDA chief, Califf worked for Google parent Alphabet Inc.'s Verily Life Sciences unit and had advisory or board roles for at least seven other companies, including one developing Alzheimer's treatments. (He has quit all of them since returning to the regulator.)

But the person who most shaped the modern FDA is Cavazzoni's mentor, Janet Woodcock, 75, who said last month that she's retiring after a 37-year career that included running the drug evaluation center and serving as acting commissioner, for a year until Califf's appointment. Now principal deputy, she's known to people in the industry as "shadow commissioner." As the regulator has lurched from controversy to controversy in recent years, it is Woodcock's mindset that has been pre-eminent. It boils down to encouraging manufacturers to fix problems themselves. "You cannot test products into compliance," she said in an email. "The best quality is assured when manufacturers are dedicated to high quality."

Some former agency officials say this approach leaves the FDA reacting to problems instead of anticipating them. It also allows officials to shift blame, said Frank Yiannas, the former deputy commissioner for food policy and response, who described the baby formula crisis as a preventable tragedy exacerbated by the agency's own mistakes. "There's a fear at the FDA where nobody wants to be responsible for the supply chain," he said. "The American public expects the government to do all that they can."

Woodcock laid out the agency's "risk-based approach" two decades ago in a regulatory framework called "Pharmaceutical Quality for the 21st Century." Ideally, the FDA would do as little as possible. She envisioned "a maximally efficient, agile, flexible manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight."

The offshoring of US pharmaceutical manufacturing to India and China was then just getting started, but some had already warned about losing control. A 1998 report by what's now called the Government Accountability Office cited concern about the FDA's "ability to ensure the safety and quality of the increasing volume of foreign-produced drugs imported daily into the United States."

Those worries materialized a decade later, when a contaminated blood thinner made in China led to hundreds of deaths in the US. That same year, the FDA opened its first offices in Beijing and New Delhi. The agency opened a second India office in Mumbai the following year, and had plans to hire 19 staffers in the country.

In a case that again jolted the generics market, the US unit of India's Ranbaxy Laboratories Ltd. in 2013 pleaded guilty to felony charges of selling adulterated drugs and lying about it to the FDA. Ranbaxy paid \$500 million to settle the case, which further exposed the flaws of an FDA inspection regime organized to monitor a domestic manufacturing base that was rapidly disappearing. While surprise inspections were easy to do in the US, the overseas inspectors had to announce their arrival weeks or months in advance.

The next year, following the Ranbaxy scandal, the FDA started a pilot program for unannounced inspections in India. It uncovered more troubling signs that factories there weren't just dirty and under-equipped; workers were routinely hiding sensitive documents.

But the program lasted only about a year, until a July 2015 email from Alonza Cruse, then acting director of the FDA's Office of Pharmaceutical Quality Operations. "The pilot will end immediately," Cruse wrote in the email, obtained by Bloomberg. No explanation. The agency later told the GAO, the investigative arm

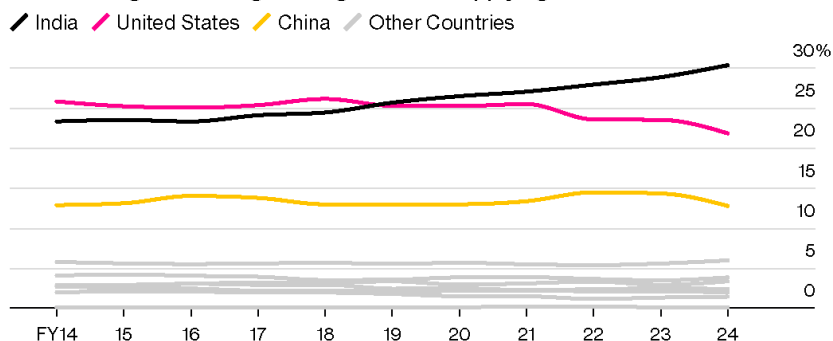
of Congress, that its staff hadn't developed any metrics on which to evaluate the pilot's success.

Two former employees, who didn't want to be identified discussing internal matters, said FDA leaders were also concerned that unannounced inspections could undermine efforts to deepen relations with India, a year after the nationalist government of Prime Minister Narendra Modi came to power. Asked about those claims, FDA spokesperson Kahn said the agency's "collaboration with India highlights continued advancement of the production and availability of medical products that both countries and the entire world rely upon."

By 2019, India's manufacturing clout had grown to the point that the country had more FDA-registered generic drug facilities than the US, according to a Bloomberg analysis of agency data. (India had 30 percent as of Oct. 1, compared with 22 percent for the US and 13 percent for China.) Yet the FDA's footprint in the country has shrunk. After closing the Mumbai office in 2016, it had a drug inspection staff that recently numbered four in New Delhi. The office primarily focuses on building relationships in government and industry rather than compliance.

India Captures America's Medicine Cabinet

Percent of generic drug-making facilities supplying the US



Source: US Food and Drug Administration

Note: The data includes makers of active ingredients as well as final products

Just before the pandemic, Valisure, a tiny lab in New Haven, Connecticut, started gaining customers—and embarrassing the FDA—by doing something people expect the regulator already does: test drugs.

The lab's co-founder, Adam Clark-Joseph, had suffered complications from an anticonvulsant drug he was taking. He'd connected with a friend from Yale University, a molecular biologist named David Light, and they'd become convinced there was a business in screening medications. (Bloomberg commissioned Valisure this year to test Indian-made cough syrups obtained from six countries; one test found unsafe levels of toxic chemicals in a cold medication sold in Iraq and prompted a recall.)

The FDA doesn't regularly test either ingredients or the finished products. During inspections, it primarily checks to see how well companies follow manufacturing procedures rather than conduct its own sampling. When the regulator does find problems, it typically relies on the company to voluntarily take action to address the root cause.

At first, Valisure operated as a pharmacy and tested the medications it dispensed. Light said about 10 percent had problems, such as contamination or the lack of an active ingredient. Then came a bombshell finding in 2019 that Zantac, the widely used heartburn drug, was contaminated with a chemical that likely causes cancer. A massive recall followed. Valisure also found leukemia-causing benzene in hand sanitizers, sunscreens and antiperspirants. Again, companies withdrew the products—and the FDA had to answer questions from Congress about how an obscure lab had sounded the alarm first.

Months after the Zantac revelation, the pandemic forced a near-halt in the FDA's inspections. Agency officials still found time, in May 2021, to send a team into Valisure's offices. In public statements about the lab, the regulator had grown increasingly critical, telling reporters its own testing revealed discrepancies from

Valisure's. Though the agency also found unsafe levels of the probable carcinogen NDMA in Zantac, it said the lab's tests had inflated them.

The inspection had been ordered by "HQ," agency headquarters in Silver Spring, Maryland, a high-ranking FDA investigator wrote in an email obtained through a public records request.

Staffers on the ground appeared mystified by the assignment. Over the following weeks, according to the emails, the FDA team repeatedly conveyed to top officials that nothing at the lab indicated the testing it did was subject to agency oversight. Valisure doesn't make drugs, and its contracts with clients say none of its testing should be used for any regulatory purpose. Twice, the team tried to close the inspection. They suggested that a discussion about some technical violations they'd spotted, not an official admonition, would suffice. But Francis Godwin, head of the Office of Manufacturing Quality, insisted on a tougher report, the emails show. (Godwin didn't respond to a request for comment.)

Nineteen months after the initial inspection, the FDA published an eight-page letter enumerating flaws in data collection and equipment that applied if Valisure were to do regulatory work—which, the letter acknowledged, it didn't. The letter said Valisure hadn't documented the "accuracy" and "repeatability" of its results, among other concerns. The FDA's Kahn said the agency isn't opposed to additional screening of drugs but added that such measures must be "backed by validated testing methods, scientific research and expertise."

In the view of some current and former staffers, who requested anonymity to protect their careers, the episode amounted to a hit job meant to clip the momentum of a company whose tests had called into question the regulator's effectiveness. Others who have raised concerns about drugs say they've often been met with silence. "The FDA has a story and the story is: 'We're the FDA, we know what we're doing. Trust us,'" said Joe Graedon, co-founder of the People's Pharmacy, a consumer health organization that publishes complaints about generics. "Anything that interferes with that story or criticizes that story is generally not welcome."

All of this helps to explain why independent testing, and Victor Suarez's collaboration with Valisure at the Department of Defense in particular, touched off such an intense bureaucratic struggle this year.

As tension with China has increased, India, which accounts for one-fifth of the world's generic drug exports, is seen by US officials as a more secure source of supply. "We've done a big push with India," said Neera Tanden, President Joe Biden's domestic policy adviser. After Modi met with Biden at the White House in June, they issued a joint statement welcoming "deeper collaboration" in pharmaceuticals and calling their two countries "among the closest partners in the world."

The relationship has survived some recent stress. A year ago, FDA inspectors issued a 36-page report describing the efforts of employees at the first Intas factory they visited to hide test results from them. One employee "rushed and tore apart" printouts and threw them into a trash bag, then poured acid onto them.

The company makes about 50 percent of the US supply of cisplatin, a widely used chemotherapy drug. After Intas ceased production at that factory to address issues raised by the inspectors, it led to a shortage of both cisplatin and another chemotherapy drug called carboplatin. That left cancer patients across the country scrambling to find hospitals able to secure the drugs, or even delaying treatment.

The shortages have embarrassed an administration that promised an ambitious "cancer moonshot" to cut death rates in half and now finds itself simply trying to ensure access to existing drugs. Early this year, Biden officials led by Susan Rice, then his domestic policy adviser, began crafting a \$25 billion package to restore US drug manufacturing and improve visibility into supplies, modeled on the CHIPS Act for semiconductors, according to people familiar with the matter who asked for anonymity to share plans that were not public. Among the steps to improve quality, they consulted with the FDA about implementing third-party testing of the type Valisure does.

After Bloomberg later reported the Pentagon's plans to test drugs with Valisure, FDA officials told the White House they felt betrayed, according to these people. The agency's leadership suggested that the testing, though still only a pilot, was a direct assault on its reputation and performance, sowing distrust in the products it clears, the people said. It was an awkward moment because Rice, the official who'd been most focused on policing supplies from India and China, had just left her post. Momentum for sweeping action stalled. Rice didn't respond to requests for comment.

Tanden, who replaced Rice in the role, said the administration continues working with the FDA to ensure the availability and quality of medicines and is open to various ideas, including different measures of quality. She added that the White House tried to interest lawmakers in investing billions to shore up the pharmaceutical sup-

ply chain, but congressional interest waned. The FDA's Kahn said it's open to "meaningful solutions" in "collaboration with our cross-government partners."

In August, Suarez, 50, went on stage with Valisure's Light at a conference of medical supply experts in Orlando. Congress had told the Pentagon a year ago to identify threats to its pharmaceutical supplies. Suarez got involved in the project as something of a swan song to a career of supporting vaccine development and managing medical acquisition and logistics for 25 military facilities. He retired last week and is now a consultant who advises health-care clients on product and supply chain issues. As Suarez announced the pact with Light that day in Orlando, he said it would help end what's in effect an "honor system" that leaves consumers in the dark.

That same month, Suarez said, he heard of blowback through his command chain. Califf met with one of his superiors, Assistant Secretary of Defense for Health Affairs Lester Martinez-Lopez, and raised concerns about the Pentagon study and Valisure's testing methods. Martinez-Lopez informed Califf the Pentagon would move forward, according to Suarez. Nicole Schwegman, a Defense Department spokesperson, said it "appreciates the FDA's insight" and noted that Martinez-Lopez is required to report on risks to the pharmaceutical supply chain. The FDA's Kahn didn't respond to questions about the meeting.

To sustain support, Suarez also briefed Pentagon leaders about Valisure's preliminary results for a few medications, including the flawed tacrolimus. A chart that compared prices alongside quality scores showed how cheap isn't always best. "It was just a jaw-dropping moment," he said. The Valisure pilot is testing a dozen drugs, each with multiple manufacturers, among them blood pressure medicines and antidepressants. The lab uses commercial samples obtained from distributors, not manufacturers. The tests measure dosages, as well as potential contaminants. Results are graded by an outside panel of experts, who assign quality scores.

Doctors had expressed doubts about some generic versions of tacrolimus soon after they were introduced in 2009. The FDA responded 2 years later by designating it a "narrow therapeutic index drug," signaling that small differences in dosages can have a big impact on patients. Over the next several years, the agency has said, it funded "a number of studies" to continue investigating. Finally, in September, the agency said the Intas version isn't equivalent—but let it stay on the market.

Last month, the Pentagon gave the Valisure project another vote of confidence by transferring it to the Uniformed Services University of the Health Sciences, which conducts research for the military. The institution will add dozens of additional medicines to the study and analyze the results over the next 2 years. Suarez said he hopes big drug buyers like Medicare and the Veterans Administration adopt the same approach—which might finally change the economics of the generic drug market to reward quality. "Hopefully the FDA will become part of that," Valisure's Light said, "but it's happening without them anyway."

In the European Union, independent testing has long been standard, with a network of 70 labs that sample medications both before they're released and after they're in use. The FDA's Woodcock said European authorities also rely on inspections and work closely with the FDA. Tests might motivate "certain manufacturers to make sure their products at least pass," she wrote in an email. "But people who know a lot about this will tell you that testing per se is not a magic bullet."

After abandoning pursuit of the \$25 billion legislative package, the Biden administration last week tapped the Defense Production Act to enable some domestic investment in essential medicines, starting with \$35 million for sterile injectable drugs. It also added a new post outside the FDA for a "supply chain resilience and shortage coordinator." Biden adviser Tanden said the administration is exploring other ways of using the clout of the US Government "as a giant purchaser of drugs" to encourage manufacturers to prioritize quality and availability. Prompted by Congress, the FDA resumed unannounced inspections in India last year and China more recently.

What's missing is a shift in the mindset of the regulator. Not long after FDA commissioner Califf returned from India, he spoke at an October conference for the generic drug industry in North Bethesda, Maryland. Asked about the idea of health systems doing independent tests, he responded: "I might say there are better ways to spend your money."

-With assistance from Laura Bejder Jensen, Ike Swetlitz, and Swati Gupta