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INSPECTOR GENERAL

U.S. Department of Defense

SEPTEMBER 20, 2021

Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain

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Results in Brief

Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain

September 20, 2021

Objective

(U) The objective of this evaluation was to determine whether the DoD mitigated the risks of disruptions to the pharmaceutical supply chain, which is heavily reliant on foreign suppliers, in accordance with DoD Instruction (DoDI) 4140.01.

Background

(U) The United States has increased its reliance on foreign pharmaceuticals over the past two decades. In August 2019, the U.S. Food and Drug Administration estimated that 72 percent of active pharmaceutical ingredient (API) manufacturers supplying the U.S. market were foreign and 13 percent of those were in China.

(U) The DoD does not manufacture pharmaceuticals and is dependent on the commercial market for pharmaceuticals that the DoD provides to Service members and DoD beneficiaries.¹ Therefore, the DoD is dependent on the increasingly foreign sources used by the U.S. commercial pharmaceutical market.

(U) DoDI 4140.01 requires the DoD to identify, monitor, and assess the security and potential disruptions within and outside of the DoD supply chain to mitigate risk to supply chain operations.² DoD Manual (DoDM) 4140.01 Volume 1

¹ Principal Deputy Assistant Director for Healthcare Operations, Defense Health Agency, testimony before the U.S.-China Economic and Security Review Commission, July 31, 2019.

² DoDI 4140.01, "DoD Supply Chain Materiel Management Policy," March 6, 2019.

Background (cont'd)

(U) requires DoD Components to reduce exposure to potential supply chain risk management (SCRM)-identified disruptions by monitoring the supply chain to provide early warning and mitigating the effects of problems that occur.³

Finding

(CUI) [REDACTED]

Specifically:

- (U) The Defense Logistics Agency (DLA) identified the DoD's reliance on foreign suppliers in the pharmaceutical supply chain as a risk, but did not conduct a formal assessment of the risk to develop mitigation strategies.
- (CUI) For military operations, the DLA established contingency contracts to guarantee access to pharmaceuticals. [REDACTED]
- (U) For routine Military Treatment Facility (MTF) operations, the Defense Health Agency (DHA) and the Military Services did not proactively assess risks of unexpected supply disruptions, in accordance with DoD Manual 4140.01, Volume 1. The risks include those posed by the DoD's reliance on the commercial pharmaceutical market, which is increasingly reliant on foreign sources. The DHA and the Military Services used "just-in-time" ordering for pharmaceuticals and did not store extra finished drug products to use in the event of a supply disruption because it was not required.

(U) As a result, pharmaceutical supply disruptions could compromise the standard of care to DoD beneficiaries. A disruption of the supply of foreign-made APIs to domestic

³ DoD Manual 4140.01, Volume 1, "DoD Supply Chain Materiel Management Procedures: Operational Requirements," December 13, 2018.



Results in Brief

Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain

Finding (cont'd)

(U) 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 Service members and DoD beneficiaries.⁴ Implementing measures to mitigate the risks of a pharmaceutical supply disruption would provide a defensive capability and mitigate public health and national security risks.

Recommendations

(U) We recommend that the Under Secretary of Defense for Acquisition and Sustainment:

- Develop and issue implementing guidance for DoD supply chain risk management for DoD materiel, which includes pharmaceuticals.
- Pursue Federal legislation requiring pharmaceutical manufacturers to include APIs and final drug product country of origin information of the pharmaceuticals' lot on the pharmaceuticals' packaging.

(U) We recommend that the Director of the Defense Health Agency:

- Develop and publish implementing guidance for supply chain risk management specifically for pharmaceuticals.
- Create a chartered work group to assess risks to the pharmaceutical supply chain, identify the pharmaceuticals most critical to beneficiary care at DoD MTFs, and establish policy for allocating scarce pharmaceutical resources in case of a supply disruption.

(U) We recommend that the Director of the Defense Logistics Agency modify DLA Instructions 5025.03 and 3110.01 to:

- Require DLA Troop Support to coordinate annually with Military Service customers to conduct responsiveness testing of the DLA's contingency contracts for pharmaceuticals.
- Include the contract responsiveness testing results, as reported by the Military Service customers, in the Warstopper Program annual reports.⁵

Management Comments and Our Response

(U) Based on management comments, we revised and renumbered Recommendations 3.b and 3.c from the draft report as Recommendations 1.b and 1.c in this final report, and redirected them to the Under Secretary of Defense for Acquisition and Sustainment; therefore, the recommendations are unresolved and open.

(U) We request that the Under Secretary of Defense for Acquisition and Sustainment provide comments in response to this report.

(U) We verified that actions taken by the DLA fully addressed the recommendation to establish written agreements with the Pharmacy Prime Vendors to maintain the transaction information, transaction history, and transaction statements in accordance with the Drug Supply Chain Security Act; therefore, we consider this recommendation resolved and closed.

⁴ Drug Shortages Task Force, "Drug Shortages: Root Causes and Potential Solutions," October 2019, updated February 21, 2020.

⁵ The Warstopper Program, which is managed by the DLA, mitigates shortfalls in critical supplies during the transition from peacetime to wartime and funds the Industrial Capabilities Program, including military go-to-war requirements.



Results in Brief

Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain

Comments (cont'd)

(U) The Deputy Assistant Secretary of Defense for Industrial Policy, responding for the Under Secretary of Defense for Acquisition and Sustainment; the DHA Deputy Director, responding for the DHA Director; and the DLA Acquisition Director, responding for the DLA Director, addressed all the other recommendations presented in the report. We consider all other recommendations in the report resolved and open. We will close the recommendations after we verify the actions taken fully addressed the recommendations.

(U) Please see the Recommendations Table on the next page for the status of recommendations.

Recommendations Table

Management	Recommendations Unresolved	Recommendations Resolved	Recommendations Closed
Under Secretary of Defense for Acquisition and Sustainment	1.b, 1.c	1.a	None
Director, Defense Health Agency	None	2.a., 2.b.1, 2.b.2, 2.c.1, 2.c.2	None
Director, Defense Logistics Agency	None	3.b.1, 3.b.2, 3.b.3	3.a

Please provide Management Comments by October 20, 2021.

Note: The following categories are used to describe agency management's comments to individual recommendations.

- **Unresolved** – Management has not agreed to implement the recommendation or has not proposed actions that will address the recommendation.
- **Resolved** – Management agreed to implement the recommendation or has proposed actions that will address the underlying finding that generated the recommendation.
- **Closed** – OIG verified that the agreed upon corrective actions were implemented.



**INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
4800 MARK CENTER DRIVE
ALEXANDRIA, VIRGINIA 22350-1500**

September 20, 2021

MEMORANDUM FOR UNDER SECRETARY OF DEFENSE FOR ACQUISITION AND SUSTAINMENT
DIRECTOR, DEFENSE HEALTH AGENCY
DIRECTOR, DEFENSE LOGISTICS AGENCY

SUBJECT: Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain (Report No. DODIG-2021-126)

This final report provides the results of the DoD Office of Inspector General's evaluation. We previously provided copies of the draft report and requested written comments on the recommendations. We considered management's comments on the draft report when preparing the final report. These comments are included in the report.

This report contains recommendations that are considered unresolved because we redirected Recommendations 1.b and 1.c to the Under Secretary of Defense for Acquisition and Sustainment based on management comments. Therefore, as discussed in the Recommendations, Management Comments, and Our Response section of this report, the recommendations remain open. We will track these recommendations until we receive documentation showing that all agreed-upon actions to implement the recommendations are completed.

DoD Instruction 7650.03 requires that recommendations be resolved promptly. Therefore, please provide us within 30 days your response concerning specific actions in process or alternative corrective actions proposed on the unresolved recommendations. Send your response [REDACTED] if classified SECRET.

Management's comments and associated actions addressed Recommendation 3.a. in this report, and we consider the recommendation closed.

The Deputy Assistant Secretary of Defense for Industrial Policy, responding for the Under Secretary of Defense for Acquisition and Sustainment; the DHA Deputy Director, responding for the DHA Director; and the DLA Acquisition Director, responding for the DLA Director, addressed all the other recommendations presented in the report; therefore, we consider the recommendations resolved and open. As described in the Recommendations, Management Comments, and Our Response section of this report, we will close the recommendations when we receive documentation showing that all agreed-upon actions to implement the recommendations are completed. Therefore, please provide us within 90 days your

response concerning specific actions in process or completed on the recommendations.
Send your response [REDACTED] if
classified SECRET.

If you have any questions or would like to meet to discuss the evaluation, please contact me at (703) 699 5469. We appreciate the cooperation and assistance received during the evaluation.



Bryan Clark
Acting Assistant Inspector General, Evaluations
Programs, Combatant Commands, and
Overseas Contingency Operations

Contents

Introduction

Objective	1
Background	1

Finding. The DoD Did Not Mitigate the Risks of Disruptions to Its Pharmaceutical Supply Chain, Which Is Reliant Upon Foreign Suppliers, in Accordance With DoD Instruction 4140.01

10

The DoD Did Not Mitigate the Risks of Disruptions to the Pharmaceutical Supply Chain Which Is Reliant on Foreign Suppliers	13
The DoD Did Not Have Implementing Guidance on SCRM for DoD Materiel	18
The DoD's Reliance on Foreign Suppliers for Pharmaceuticals Is a Public Health, Readiness, and National Security Risk	30
Recommendations, Management Comments, and Our Response	31

Appendix

Appendix A. Scope and Methodology	38
Use of Computer-Processed Data	40
Use of Technical Assistance	41
Prior Coverage	41

Management Comments

Undersecretary of Defense for Acquisition and Sustainment	44
Director, Defense Health Agency	48
Director, Defense Logistics Agency	52

Acronyms and Abbreviations

56

Glossary

57



Introduction

Objective

(U) The objective of this evaluation was to determine whether the DoD mitigated the risks of disruptions to the pharmaceutical supply chain, which is heavily reliant on foreign suppliers, in accordance with DoDI 4140.01. See the Glossary for definitions of technical terms used in this report.

Background

(U) The DoD's reliance on foreign suppliers for pharmaceuticals is a public health, readiness, and national security risk. According to a February 2020 Drug Shortages Task Force report, the United States increased its reliance on foreign pharmaceuticals over the past two decades as companies located more production overseas and increased the use of contract manufacturers.⁶ The reasons for the U.S. shift to overseas pharmaceutical manufacturing include facility space availability, environmental liability concerns, and low-cost labor. The DoD does not manufacture pharmaceuticals and is reliant upon commercial suppliers of pharmaceuticals and finished drug products that use active pharmaceutical ingredients (API), which are largely foreign in origin.⁷ For example, in 2019, 230 Chinese manufacturing facilities made APIs to supply the U.S. market, more than double the number in 2010.⁸

(U) As of August 2019, the U.S. Food and Drug Administration (FDA) estimated that there were 1,788 API manufacturing sites supplying the U.S. market, with 510 located in the United States (28 percent), 552 (31 percent) in China and India, and 726 (41 percent) in other foreign countries.⁹ This poses a potential national security risk because foreign countries could prohibit the exports of APIs. For example, in March 2020, India's Directorate General of Foreign Trade temporarily prohibited the export of ventilators, sanitizers, and hydroxychloroquine APIs and formulations made from hydroxychloroquine, which was initially thought to reduce the effects of coronavirus disease-19 (COVID-19). In October 2019 Testimony before the House Committee on Energy and Commerce, the Director of the FDA Center for Drug Evaluation and Research stated that

⁶ Drug Shortages Task Force, "Drug Shortages: Root Causes and Potential Solutions," October 2019, updated February 21, 2020. The Drug Shortages Task Force was chaired by the FDA and included senior FDA officials and partner Federal agencies, including the DoD.

⁷ An active pharmaceutical ingredient is any substance intended for incorporation into a finished drug product and is intended to furnish pharmacological activity.

⁸ Commissioner of Food and Drugs, Food and Drug Administration, testimony before the House Committee on Energy and Commerce, Subcommittee on Health, October 30, 2019.

⁹ Commissioner of Food and Drugs, Food and Drug Administration, testimony before the House Committee on Energy and Commerce, Subcommittee on Health, October 30, 2019.

(U) although the FDA knows where foreign API manufacturing facilities are located, it cannot determine the volume of APIs entering the U.S. market, either directly or indirectly by incorporation into finished drugs, from foreign sources.

Drug Shortage Concerns

(U) According to the FDA's drug shortage website, drug shortages can occur for many reasons, including manufacturing and quality problems. In 2008, the FDA found that the heparin supply with an active pharmaceutical ingredient sourced from China caused acute hypersensitivity reactions in patients undergoing dialysis.¹⁰ The contaminated heparin, which killed 246 patients, was a result of intentional adulteration to reduce the cost of production at the Chinese manufacturing facility. On July 13, 2018, the FDA announced the voluntary recall of several medicines containing the high blood pressure and heart failure medication valsartan due to a probable cancer-causing chemical identified in the API of the drug, which was manufactured in China.

(U) Natural disasters have also caused shortages in several pharmaceuticals used in the United States. For example, the Fukushima Daiichi nuclear disaster caused by the Japan earthquake and tsunami of 2011 reduced the U.S. supply of doxycycline, an antimalarial drug developed by the DoD and its partners to prevent malaria in military units deployed to endemic areas. In addition, Hurricane Maria damaged a large number of pharmaceutical manufacturers in Puerto Rico, causing significant pharmaceutical shortages of intravenous fluids and other pharmaceuticals.

Buy American Act and Trade Agreements Act

(U) Pharmaceuticals and pharmaceutical supplies offered through the Defense Logistics Agency's (DLA's) Prime Vendor Program must comply with the Buy American Act and the Trade Agreements Act (TAA).¹¹ The Acts require Government-purchased products to be manufactured in the United States or a designated country unless an exception applies under the Federal Acquisition Regulation or Defense Federal Acquisition Regulation Supplement.¹²

¹⁰ Heparin is an anticoagulant drug that prevents the formation of blood clots and is used to treat and prevent blood clots caused by medical conditions or procedures. Heparin is used before certain types of surgery.

¹¹ Sections 8301-8305, title 41, United States Code (41 U.S.C. §§ 8301-8301) and sections 2501-2582, title 19, United States Code (19 U.S.C. §§2501-2582), respectively.

¹² Federal Acquisition Regulation Part 25, "Foreign Acquisition," Subpart 25.1, "Buy American-Supplies," Section 25.103, "Exceptions;" Subpart 25.4, "Trade Agreements;" and Defense Federal Acquisition Regulation Supplement Part 225, "Foreign Acquisition," Subpart 225.1, "Buy American – Supplies," 225.103, "Exceptions;" and Subpart 225.4, "Trade Agreements."

(U) The Buy American Act restricts the purchase of supplies that are not domestic end products. According to this statute, the supply article must be manufactured in the United States, and the cost of domestic components must exceed 50 percent of the cost of all the components. Exceptions include public interest, non-availability, and unreasonable cost. In accordance with 41 U.S.C. 1907, the component test of the Buy American statute is waived for an end product that is a commercially available off-the-shelf item. DLA officials stated that most pharmaceuticals it purchases are commercially available off-the-shelf items.

(U) The TAA governs trade agreements negotiated between the United States and other countries. The TAA provides the authority for the President to waive the Buy American statute for eligible products, including pharmaceuticals, from countries that have signed an international trade agreement with the United States or that meet certain other criteria, such as being a least developed country.

Executive Orders and Congressional Actions to Reduce Reliance on Foreign Pharmaceutical Suppliers

(U) In August 2020 and February 2021, the President issued Executive Orders 13944 and 14017, respectively, to reduce the reliance on foreign pharmaceutical suppliers. The National Defense Authorization Act (NDAA) for Fiscal Year 2021 also outlined steps to reduce the reliance on foreign pharmaceutical suppliers.

Executive Orders

(U) The President issued Executive Order 13944 on August 6, 2020, to reduce U.S. dependence on foreign manufacturers for essential medicines, medical countermeasures, and critical inputs to ensure sufficient and reliable long-term domestic production of these products, to minimize potential shortages, and to mobilize the nation's Public Health Industrial Base to respond to outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear threats.¹³

(U) Specifically, EO 13944 directs the Secretary of Defense to take the following actions.

- Consider a variety of actions to increase domestic procurement of essential medicines, medical countermeasures, and critical inputs, and identify vulnerabilities in U.S. supply chains for these products.

¹³ Executive Order 13944 (EO 13944), "Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States," August 6, 2020.

- Provide a list, updated periodically by the Secretary of Defense, of defense-specific essential medicines, medical countermeasures, and critical inputs that are medically necessary to have available for defense use in adequate amounts and in appropriate dosage forms.
- Within 180 days of the date of EO 13944 and with the Director of Office of Management and Budget, identify vulnerabilities in the supply chain for essential defense-specific medicines, medical countermeasures, and critical inputs and all lawful actions necessary to mitigate the identified vulnerabilities.

(U) The President also issued Executive Order 14017 on February 24, 2021, to require the Assistant to the President for National Security Affairs and the Assistant to the President for Economic Policy, in coordination with the heads of appropriate agencies, to complete a review of supply chain risks and submit the review reports to the President.¹⁴ It also requires follow-on reports that review the actions taken and make recommendations concerning steps to strengthen the resilience of America's supply chains. EO 14017 further requires a supply chain assessment of pharmaceuticals and APIs and a sector-focused supply chain assessment of the Defense Industrial Base. The reports are also required to include a review of the resilience and capacity of American manufacturing supply chains and the industrial base to support national and economic security and emergency preparedness. Finally, EO 14017 requires the Secretary of Defense to submit a report on supply chains for the Defense Industrial Base by February 24, 2022, that identifies areas where civilian supply chains are dependent upon competitor nations, as determined by the Secretary of Defense.

(U) The White House published the "100-Day Reviews under Executive Order 14017" to the President of the United States in June 2021.¹⁵ This report assessed supply chain vulnerabilities across the four key products directed by the President, including pharmaceuticals and APIs. The report stated that the stability and the resilience of the drug supply chain are highly influenced by market factors that have led to increasing reliance on foreign countries to manufacture the medicines, APIs, and the APIs' key starting materials. The report also stated that solutions to address the reliability of the pharmaceutical and API supply chain should address the following two priority objectives.

- Improve supply chain transparency and incentivize resilience.
- Increase the economic sustainability of U.S. and allied drug manufacturing and distribution.

¹⁴ Executive Order 14017 (EO 14017), "America's Supply Chains," February 24, 2021.

¹⁵ The White House, "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth: 100-Day Reviews under Executive Order 14017," June 2021.

National Defense Authorization Act for Fiscal Year 2021

(U) Section 713 of the FY 2021 NDAA requires the Secretary of Defense to submit a report by March 1, 2022, containing an assessment of gaps or vulnerabilities with respect to drugs, biological products, vaccines, and critical medical supplies. The report must also assess how those finished drugs, biological products, vaccines, and critical medical supplies impact combat readiness and protection of the Armed Forces. The NDAA also modified 10 U.S.C. 2501(a), “National Security Strategy for National Technology and Industrial Base,” and requires the Secretary of Defense to report the drugs, biological products, vaccines, and critical medical supplies required to enable combat readiness and protect the health of the Armed Forces.

The Drug Supply Chain Security Act

(U) The Drug Supply Chain Security Act (DSCSA), which is Title II of the “Drug Quality and Security Act,” enacted on November 27, 2013, outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as the drugs are distributed in the United States. The purpose of the Act was to improve the security of the U.S. pharmaceutical supply chain by creating a closed prescription drug distribution system to prevent harmful drugs from entering the supply chain, detect harmful drugs if they do enter the supply chain, and enable rapid response when such drugs are found. The DSCSA included the following provisions.¹⁶

- Beginning no later than 4 years after the date of enactment of the DSCSA, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce.^[17] Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.
- Beginning 6 years after the date of enactment of the DSCSA, a wholesale distributor may, with some exceptions, engage in transactions involving a product only if the product is encoded with a product identifier.

¹⁶ Public Law 113-54, “Drug Supply Chain Security Act,” November 27, 2013.

¹⁷ The term “product identifier” means a standardized graphic that includes the standardized numerical identifier, lot number, and expiration date of the product. This graphic must be presented in both human readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization.

- Dispensers:

shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.

DoD Supply Chain Risk Management

(U) DoD Instruction (DoDI) 4140.01 requires the DoD to identify, monitor, and assess the security and potential disruptions within and outside of the DoD supply chain to mitigate risk to supply chain operations.¹⁸ DoD supply chain risk management (SCRM) encompasses cybersecurity, software assurance, obsolescence, counterfeit parts, foreign ownership of sub-tier vendors, and other categories of risk that affect the supply chain.¹⁹ DoDI 4140.01 states that the Under Secretary of Defense for Acquisition and Sustainment (USD[A&S]) establishes DoD policy and develops implementing guidance on all matters relating to DoD materiel management.²⁰

(U) DoD Manual 4140.01 Volume 1 assigns responsibilities and provides procedures for DoD materiel managers consistent with DoDI 4140.01.²¹ DoDM 4140.01 Volume 1 also states that DoD Components must perform SCRM in the same manner prescribed by DoDI 4140.01. This includes identifying potential disruptions as a result of terrorism, attacks, insufficient product quality, unreliable suppliers, and natural disasters. Additionally, DoDM 4140.01 Volume 1 requires DoD Components to reduce exposure to potential SCRM-identified disruptions by monitoring the supply chain to provide early warning and mitigating the effects of problems that occur.

Roles and Responsibilities Within the DoD's Pharmaceutical Supply Chain

(U) The DoD's Medical Materiel Executive Agent is the DLA Director.²² The Defense Health Agency (DHA) collaborates with the DLA Director to integrate medical logistics processes. The military treatment facilities (MTFs) and the military

¹⁸ DoDI 4140.01, "DoD Supply Chain Materiel Management Policy," March 6, 2019.

¹⁹ According to DoDI 4140.01, SCRM is the process for managing risk by identifying, assessing, and mitigating threats, vulnerabilities, and disruptions to the DoD supply chain from beginning to end to ensure mission effectiveness.

²⁰ DoDI 4140.01 defines materiel as all items necessary to equip, operate, maintain, and support military activities without distinction as to their application for administrative or combat purposes, excluding real property, installations, and utilities.

²¹ DoD Manual 4140.01, Volume 1, "DoD Supply Chain Materiel Management Procedures: Operational Requirements," December 13, 2018.

²² DoD Directive 5101.09E, "Class VIIIA Medical Materiel Supply Management," September 29, 2015 (Incorporating Change 2, September 12, 2019), designates the DLA Director as the DoD Executive Agent (DoD EA) for Medical Materiel.

(U) unit level organizations order pharmaceuticals through the Defense Medical Logistics Standard Support system, Electronic Catalog, or through the Government Purchase Card program.

Chief Information Security Officer for Acquisition and Sustainment

(U) The Office of the Deputy Assistant Secretary of Defense for Industrial Policy (ODASD[INDPOL]) reports to the USD(A&S). The Chief Information Security Officer for Acquisition and Sustainment (CISO[A&S]) is responsible for the Supply Chain Risk Management program. In January 2021, CISO(A&S) was integrated into ODASD(INDPOL), which is the enterprise level office in charge of SCRM policies. ODASD(INDPOL) leads efforts to secure the defense supply chain and synchronizes these efforts across the DoD and other Federal agencies.

Defense Logistics Agency

(U) The DLA manages the global supply chain for the Army, Navy, Air Force, Marine Corps, Space Force, combatant commands, other Federal agencies, and partner and allied nations. DLA Troop Support is one of the DLA's major subordinate commands. DLA Troop Support provides medical supplies and equipment, including pharmaceuticals, to customers. The DLA relies on the FDA to dictate and enforce quality assurance provisions and requires FDA approval or Emergency Use Authorization of all pharmaceuticals that it procures.

(U) In 1993, the DoD established and funded the Warstopper Program as a result of key industrial base vulnerabilities demonstrated during the Gulf War in 1991.²³ The DLA has managed the Warstopper Program since 1993 to ensure a sustainable industrial base and to mitigate variable demand patterns, technology inhibitors, skill retention, and general industry issues that may exist for DLA-managed, go-to-war items. The Warstopper Program Manager may use funds allocated to the DLA under the Program Element 0708011, "Industrial Preparedness," to mitigate shortfalls in critical supplies during the transition from peacetime to wartime.

(U) The DLA partners with manufacturers, distributors, and prime vendors to gain access to commercial inventory. For example, the DLA Pharmaceutical Prime Vendor Program supports the day-to-day orders for the MTFs and Preplanned Surge, Deferred Procurement, and War Readiness Materiel requirements for the DLA and the Services. The different requirements in the Pharmaceutical Prime Vendor contract are distinct contract line items funded by the Services.

²³ DLA Instruction 5025.03, "Manage the Warstopper Program," October 31, 2019, provides guidance on budgeting and outlay of yearly appropriated Operations and Maintenance and Procurement funds controlled under Program Element 0708011, Industrial Preparedness.

(U) Two prime vendors, the Primary Supplier and the Secondary Supplier, support the day-to-day normal requirements of the MTFs. Only the Primary Supplier supports the Preplanned Surge, Deferred Procurement, and War Readiness Materiel requirements for the Services.

Defense Health Agency

(U) The DHA is a joint, integrated Combat Support Agency that supports the Military Departments. As the health care delivery arm of the Military Health System, the DHA supports the DoD's integrated system of readiness and health.

(U) The DHA Pharmacy Operations Division monitors drug usage and cost trends and supports DoD drug formulary management, national pharmaceutical contracts, and clinical practice guidelines. The DHA Pharmacy Operations Division works with the DLA and the Department of Veterans Affairs' Pharmacy Benefits Management Strategic Health Group and National Acquisition Center to establish national pharmaceutical contracts. The DHA Medical Logistics Division is a joint activity under the direction, authority, and control of the DHA. The mission of the DHA Medical Logistics Division is to recommend clinical, logistics, and program policy and support medical materiel development and acquisition processes across the Services.

Military Services

(U) The Military Services, along with the DHA Pharmacy Operations Division, continue to manage the MTF pharmacies until the transition of administration and control to the DHA is complete.²⁴ In operational healthcare units, the Services submit annual requirements for medical materiel, including pharmaceuticals, medical and surgical supplies, and medical equipment, to the DLA through a Medical Contingency File, and the DLA determines how best to meet the Services' needs.²⁵

(U) The Commander of the U.S. Army Medical Materiel Agency, a subordinate unit of the Army Materiel Command and the Army Medical Logistics Command, plans, programs, and budgets for all materiel and care of supplies in storage requirements

²⁴ According to the Deputy Secretary of Defense Memorandum, "Continuing Implementation of the Reform of the Military Health System," October 25, 2019, effective on the date of the memo, the authority, direction, and control of continental U.S.-based MTFs, and those in Alaska, Hawaii, and Puerto Rico, will transfer from the Military Departments to the DHA. The management of these MTFs in FY 2020 will be executed through Direct Support agreements, currently in effect, between the DHA and the Military Departments, and the DHA will establish objective conditions that demonstrate the DHA's capability and capacity for management of MTFs in FY 2020 and FY 2021.

²⁵ The Medical Contingency File is a repository of the Services' medical materiel shortfalls needed for contingencies.

(U) for the medical materiel portion of the Army Pre-Positioned Stock. The U.S. Army Medical Materiel Agency manages the medical materiel within the Army Pre-Positioned Stock program.

(U) The Navy Bureau of Medicine and Surgery (BUMED) is the headquarters for the Navy Medicine enterprise. Led by the Navy Surgeon General and Chief, BUMED develops policy and guidance and manages manpower, personnel, and resources throughout Navy Medicine. The Navy's Expeditionary Medical Support Command maintains the equipment and supplies for the Navy's deployable medical systems, the Expeditionary Medical Facilities, and Forward Deployable Preventative Medicine Units.

(U) The Air Force Surgeon General develops medical readiness policy and issues guidance and procedures to implement policy, obtains and allocates resources for medical readiness activities, and interfaces with the DHA on Air Force Medical Service readiness requirements. The Air Force Medical Readiness Agency, Medical Logistics Division, is responsible for establishing policy and procedures for managing medical materiel for peacetime and wartime support to the Air Force Medical Service. The Medical Logistics Division supports the management of contingency response assemblages, including War Reserve Materiel; Pandemic Influenza; and Medical Counter-Chemical, Biological, Radiological, and Nuclear assemblages.

(U) The Medical Officer to the Marine Corps advises the Commandant and Headquarters staff on all matters regarding healthcare and serves as the functional expert in working with the appropriate headquarters agencies for determining requirements. The Medical Officer makes recommendations on all medical and dental matters supporting the Marine Corps.

U.S. Food and Drug Administration

(U) The FDA is the U.S. Department of Health and Human Services (HHS) agency responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. The scope of FDA's regulatory authority is broad and the list of traditionally-recognized product categories that fall under the FDA's regulatory jurisdiction includes prescription (both brand-name and generic) and non-prescription (over-the-counter) drugs and biologics.²⁶ The FDA is responsible for quality assurance of pharmaceuticals. The FDA shares drug information with the DLA, DHA, and Services through notifications and has a drug shortage website and a drug recall webpage that the DLA and the DHA monitor continuously.

²⁶ Biologics includes vaccines for humans, blood and blood products, cellular and gene therapy products, tissue and tissue products, and allergenics.

Finding

The DoD Did Not Mitigate the Risks of Disruptions to Its Pharmaceutical Supply Chain, Which Is Reliant Upon Foreign Suppliers, in Accordance With DoD Instruction 4140.01

(CUI)

Specifically, the DLA identified the DoD's reliance on foreign suppliers in the pharmaceutical supply chain as a risk in 2019, but the DLA did not conduct a formal assessment of the risk to develop mitigation strategies. Additionally, the DLA did not routinely monitor the country of origin of pharmaceuticals purchased by the DoD to assess the risks posed by foreign suppliers.

(CUI)

29

(U) For routine MTF operations, the DHA and the Military Services did not proactively assess risks of potential supply disruptions, such as those posed by the DoD's reliance on foreign suppliers, in accordance with DoD Manual 4140.01 Volume 1. The DHA and the Military Services used "just-in-time" ordering for pharmaceuticals. The DHA and the Military Services did not store extra finished drug products to use in the event of a supply disruption because it was

²⁷ For this evaluation, we did not interview U.S. Space Force personnel because a senior Air Force medical official stated that the Air Force provided Medical Logistics, Pharmacy, and Medical Readiness support for the U.S. Space Force. According to Joint Publication 3-0, "Joint Operations," January 17, 2017 (Incorporating Change 1, October 22, 2018), military operation is a set of actions intended to accomplish a task or mission.

²⁸ The Warstopper Program, which is managed by the DLA, mitigates shortfalls in critical supplies during the transition from peacetime to wartime and funds the Industrial Capabilities Program, including military go-to-war requirements.

²⁹ WRM assemblages contain equipment and supplies used in deployments of medical units and are maintained in a constant state of readiness.

(U) not required. The DoD had processes to respond to pharmaceutical shortages, but only after the shortage was identified or the pharmaceutical became unavailable.³⁰ For example, the DHA attempted to identify alternative vendors for unavailable drugs or identify appropriate therapeutic substitutes for drugs when they became unavailable.

(U) The problems with pharmaceutical supply chain management occurred because:

- 1) The DoD did not develop implementing guidance for SCRM for DoD materiel, which includes pharmaceuticals, as required by DoDI 4140.01.³¹ A 2018 internal review of DoD SCRM by the Logistics Management Institute identified the need for a single department-level SCRM lead organization to provide SCRM implementation guidance to DoD components.³² In August 2020, the CISO(A&S) office was assigned responsibility for supply chain risk management policies at the DoD enterprise level. In 2020, the CISO(A&S) began drafting a DoD Instruction to establish implementing guidance for SCRM, but as of June 16, 2021, it had not been published.
- 2) The DoD did not, and is not required to, aggregate and analyze available country of origin data for finished drug products and APIs to assess the magnitude of its reliance on foreign suppliers and the gaps in its country of origin information. The DLA received country of origin information from the FDA, from vendors entering into Joint National Contracts, and from vendors entering into other types of contracts when requested. According to senior DLA officials, the DLA did not maintain this country of origin information for finished drug products and APIs in a database because the DLA was not required to maintain such a database, and it would provide little value since the commercial pharmaceutical market was always changing. However, Air Force and Marine Corps representatives stated that the personnel who select items to be included in WRM assemblages could make informed decisions when selecting pharmaceuticals for their assemblages if the Defense Medical Logistics Standard Support system had information about the pharmaceuticals' supply chain risk.³³
- 3) The DoD did not identify the pharmaceuticals most critical to routine MTF operations and did not quantify the amount of critical (important) pharmaceuticals needed to mitigate the risk of supply disruptions

³⁰ According to title 32 Code of Federal Regulations (CFR) section 199.21, (2020) “TRICARE Pharmacy Benefits Program,” therapeutic class is a group of pharmaceutical agents that are similar in chemical structure, pharmacological effect, or clinical use.

³¹ DoD Instruction 4140.01, “DoD Supply Chain Materiel Management Policy,” March 6, 2019.

³² LMI Report, “DoD Supply Chain Risk Management: Assessment and Recommendations,” March 2018.

³³ WRM assemblages contain equipment and supplies used in deployments of medical units and are maintained in a constant state of readiness.

because it was not required. DHA officials stated that most medications have a therapeutic equivalent that could be used in case of a supply disruption. The DLA maintained a Medical Contingency File that listed critical pharmaceuticals with quantities needed for military operations to mitigate the risk of supply disruptions, based on requirements developed by the Services. However, the DHA did not provide the DLA with a similar list that identified the quantity of critical pharmaceuticals needed for routine MTF operations to mitigate the risk of supply disruptions. The DoD Pharmacy and Therapeutics Committee reviewed new drugs to determine how they would impact deployment readiness but did not assess criticality as part of its review process for drugs added to the uniform formulary.³⁴

- 4) The DLA did not test the responsiveness of its Pharmaceutical Prime Vendor contract, as allowed in the statement of work, to ensure the contractors could meet the Services' readiness contingency requirements for pharmaceuticals. Testing the DLA's contingency contracts was not required, and DLA officials stated that monitoring the prime vendors' responsiveness in meeting its peacetime orders was sufficient to project the prime vendors' ability to respond to and meet its readiness contingency requirements. Based on the inability of the Prime Vendor to meet contractual fill rate requirements during the Air Force's April 2019 test of its portion of the Pharmaceutical Prime Vendor contract, we determined that the DLA's method of testing prime vendor responsiveness during peacetime is insufficient. Additionally, according to a senior official at the U.S. Army Medical Materiel Agency, the type and quantity of pharmaceuticals needed for war readiness are different from peacetime requirements.

(U) As a result, pharmaceutical supply disruptions could compromise the standard of care to DoD beneficiaries. A disruption of the supply of foreign-made active pharmaceutical ingredients 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 commercial pharmaceutical market, which is dependent on ingredients from foreign suppliers, the drug shortages would ultimately compromise the standard of care for Service members and DoD beneficiaries.³⁵ Ensuring the DoD pharmaceutical supply chain has protective measures in place to mitigate the risks of a pharmaceutical supply disruption would provide a defensive capability and mitigate public health and national security risks.

³⁴ According to the TRICARE Pharmacy Program website, the uniform formulary is a list of the covered generic and brand-name drugs.

³⁵ Based on the Drug Shortages Task Force, "Drug Shortages: Root Causes and Potential Solutions," October 2019, updated February 21, 2020.

The DoD Did Not Mitigate the Risks of Disruptions to the Pharmaceutical Supply Chain, Which Is Reliant on Foreign Suppliers

(CUI) [REDACTED]

[REDACTED] For routine MTF operations, the DLA and the DHA did not proactively assess and mitigate the risks of potential pharmaceutical supply chain disruptions.

The DoD Did Not Mitigate the Risks Directly Associated With Its Reliance on Foreign Suppliers

(CUI) [REDACTED]

[REDACTED]. DoDI 4140.01 and DoD Manual 4140.01 Volume 1 require the DoD to identify, assess, and mitigate potential supply chain risks, including potential risks posed by foreign suppliers in the supply chain. DLA and DHA officials identified the DoD's reliance on pharmaceuticals that use ingredients from foreign suppliers as a risk in 2019, and DLA personnel were aware that the DoD's reliance on the commercial market made it reliant on foreign-manufactured finished drug products and APIs. The DLA also conducted an industrial capability risk assessment that identified shortfalls in medical materiel. [REDACTED]

(U) In the FY 2020 Medical Readiness Annual Industrial Capability Risk Assessment, the DLA identified challenges such as pharmaceutical shortages of raw materials and pharmaceutical production delays; however, the assessments did not specifically address the risks posed by foreign pharmaceutical suppliers or planned actions to mitigate the risks. Additionally, DLA officials stated that the DLA did not conduct a formal assessment of the risk of foreign suppliers in the supply chain. Although DoDI 4140.01 requires the DoD to assess potential supply chain risks, including potential risks posed by foreign suppliers, it does not require a formal assessment. DLA officials further stated that the DLA did not routinely monitor

(U) the country of origin of pharmaceuticals. DLA Troop Support officials stated that the DLA's reliance on the commercial pharmaceutical market, and the fact that the DLA did not have the resources, authority, or responsibility to manufacture pharmaceuticals, meant there was little the DLA could do to avoid foreign pharmaceutical suppliers. However, DLA officials stated that the DLA would support a formal study of risks to the supply chain posed by foreign manufacturers.

The DoD Did Not Mitigate the Risk of Supply Disruptions for Military Operations

(CUI) The Military Services stored finished drug products as part of their WRM programs to meet initial military operational requirements but not to maintain operations until mission completion. The DLA maintained Warstopper Program contingency contracts to sustain military operations, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(U) DoDI 3110.06 requires the DoD Components to acquire and maintain, in peacetime, war materiel inventories sufficient to attain and sustain strategic objectives, as prescribed in the Secretary of Defense Guidance for Employment of the Force, within authorized funding.³⁶ Officials from the Services stated that pharmaceuticals stored worldwide as WRM could mitigate pharmaceutical supply chain disruptions for military operations. Based on the FY 2019 Annual Report on the Status of Department of Defense Programs for Pre-Positioned Materiel and Equipment, we created a "stoplight" classification for WRM pharmaceutical fill status to compare the dollar value of WRM pharmaceuticals in on-hand inventory held by the Services to the dollar value of WRM pharmaceuticals required by the Services. We defined the fill status as:

- "Green" when the dollar value of on-hand inventory is greater than 90 percent of the requirement,
- "Yellow" when the dollar value of on-hand inventory is between 70 and 90 percent of the requirement, and
- "Red" when the dollar value of on-hand inventory is less than 70 percent of the requirement.

(CUI) Based on the dollar value of the pharmaceuticals held in WRM, we compared the amount of on-hand pharmaceutical inventory held by the Services to the amount required by the Services as of January 2021. We found that [REDACTED]

³⁶ DoDI 3110.06, "War Reserve Materiel (WRM)," January 7, 2019.

{CUI} [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(U) The Services identified their medical materiel shortfalls needed for military operations in the Medical Contingency File. The Medical Contingency File includes the quantity of pharmaceuticals that each Service projected it would need for 6 months. The DLA Medical Directorate works with vendors to add the necessary items to Warstopper Program-funded contingency contracts to meet the Services' shortfalls. DLA officials stated that the DLA had 91 percent of Services' Medical Contingency File pharmaceutical requirements on contingency contract and regularly attempted to increase coverage using Warstopper Program funds.

(U) Despite its efforts to establish contingency contracts, the DLA previously experienced problems with access to certain drugs. In the 2020 Drug Shortages Task Force report, the DLA stated that 1,334 drugs were unavailable due to manufacturer backorder and 238 were experiencing availability problems due to manufacturer allocation.

(U) Additionally, the Air Force and the Navy experienced problems accessing pharmaceuticals that met the delivery and fill-rate requirements established in the Pharmaceutical Prime Vendor Contract. The Pharmaceutical Prime Vendor Contract includes options for Prime Vendor War Readiness Materiel funded by the Warstopper Program designed to provide contractual coverage of pharmaceuticals in support of Service-identified shortfalls. The Air Force funded contract line items in the Pharmaceutical Prime Vendor contract for War Readiness Materiel to establish a Deferred Procurement Program to rapidly acquire pharmaceuticals for military operations.

{CUI} In April 2019, the Air Force tested the Deferred Procurement Program to evaluate the Pharmaceutical Prime Vendor's ability to fulfill the Air Force portion of the contract for 81 line items in two of its WRM assemblages using the DLA contingency contract. [REDACTED]

[REDACTED]

[REDACTED] The Air Force after action report concluded that the results of the test implied a higher risk of materiel availability when leveraging DLA contingency contracts and recommended that the Air Force Medical Readiness Agency, Medical Logistics Division, reassess whether the deferred procurement strategy was viable based on the continued issues with fill rates.

(CUI) The Air Force conducted another test in March 2021 to test and evaluate the effectiveness of the deferred procurement ordering process and to assess the delivery lead time and fill rates relative to contractual terms and conditions of the Prime Vendor War Readiness Materiel Supplier. According to the Air Force after action report, the Air Force unit placed the orders on March 3, 2021, for a total of 43 lines in one WRM assemblage covered by the contingency contracts. [REDACTED]

[REDACTED] The fill rate for the accepted line items was 100 percent. All accepted lines and quantities were delivered within 3 business days after receipt of the order in accordance with the contractual terms of the contract. According to the Air Force after action report, Air Force personnel coordinated with the DLA and identified the root cause [REDACTED] [REDACTED] and initiated actions to resolve the problems.

(U) The Air Force conducted a followup deferred procurement order exercise in May 2021 to test and evaluate the resolution by the prime vendor to prevent rejection of duplicate lines of the same National Drug Code (NDC) item in an order against the DLA Prime Vendor War Readiness Materiel contracts.³⁷ According to the Air Force after action report, the Air Force unit ran a “small scale” deferred procurement order for three lines in a WRM assemblage, and all lines and quantities ordered were accepted. Delivery occurred the next day with a 100 percent fill rate on all lines ordered. The after action report concluded that the exercise demonstrated that the deficiency identified from the March 2021 deferred procurement exercise was resolved and the programming changes the prime vendor implemented were functioning as intended.

(CUI) In April 2020, the Navy packaged and transported an Expeditionary Medical Facility in response to COVID-19 operations in Guam and requested support from the DLA for its pharmaceutical procurements. The DLA notified the Navy Expeditionary Medical Support Command (NEMSCOM) that it would not support procurement of pharmaceuticals for the operation, though NEMSCOM staff did procure pharmaceuticals through DLA Prime Vendors. The DLA did support procurement of non-pharmaceutical medical-surgical consumables for the activation. [REDACTED]
[REDACTED]
[REDACTED]

³⁸ The NEMSCOM’s point paper concluded that current packaging and production

³⁷ According to the FDA, the National Drug Code is a unique, three-segment number used as a universal product identifier for human drugs manufactured, prepared, propagated, compounded, or processed by registered drug establishments for commercial distribution.

³⁸ NEMSCOM Point Paper, “Pharmaceutical Push Block Assessment/Recommendation,” December 14, 2020.

(CUI) operations were not conducive to support rapid deployment operations and recommended procuring additional pharmaceuticals to maximize support, achieve flexibility, and support initial phases of operations.

The DoD Did Not Mitigate the Risk of Supply Disruptions for Routine MTF Operations

(U) For routine MTF operations, the DLA and the DHA did not proactively assess and mitigate the risks of potential pharmaceutical supply disruptions, such as the risks posed by foreign suppliers in the DoD supply chain. The DLA maintains contingency contracts to mitigate the risk of pharmaceutical shortages during military operations; however, there was no comparable contracted supply of pharmaceuticals for peacetime use that would help mitigate the risk of pharmaceutical supply disruptions for routine MTF operations.

(U) DoDI 4140.01 and DoD Manual 4140.01 Volume 1 require the DoD to identify, assess, and mitigate potential supply chain risks by identifying, assessing, and mitigating potential threats, vulnerabilities, and disruptions. Potential risks and potential threats are those that may not have occurred yet, but could occur in the future. DoD Manual 4140.01, Volume 1, further requires Components to monitor the supply chain to provide as much early warning as possible.

(U) MTFs use “just-in-time” ordering for purchasing pharmaceuticals. The Pharmaceutical Prime Vendor contract requires delivery of routine orders by the next business day. Additionally, Service policies direct MTF pharmacies to store limited amounts of pharmaceuticals. The Army, Navy, and Air Force imposed maximum limits on the days of pharmaceutical supply held at MTF pharmacies of 15 days, 30 days, and 14 days, respectively. According to the “100-Day Reviews under Executive Order 14017” report, the pharmaceutical industry often uses a just-in-time approach to keep costs low, but just-in-time inventory management practices that limit inventory and reduce the ability to respond to surges in demand contribute to risk in the pharmaceutical supply chain.

(U) The DLA and the DHA monitor shortages of pharmaceuticals on the MTF uniform formulary and react to shortages by identifying alternative vendors or therapeutic substitutes.³⁹ These mitigating actions are in response to shortages that the DLA or the DHA identify through its supply chain monitoring activities. DLA risk assessments of the pharmaceutical supply chain also identifies shortages of raw materials and pharmaceuticals on backorder as risks that lead to shortages. However, based on the DLA’s FY 2020 Annual Industrial Capabilities Risk

³⁹ According to the TRICARE Pharmacy Program website, the uniform formulary is a list of the covered generic and brand-name drugs. According to 32 CFR sec. 199.21, (2020), “TRICARE Pharmacy Benefits Program,” therapeutic class is a group of pharmaceutical agents that are similar in chemical structure, pharmacological effect, or clinical use.

(U) Assessment Report and interviews with DLA and DHA officials, we determined the DoD did not proactively assess potential threats to the MTFs' pharmaceutical supply chain.⁴⁰

(U) DLA officials stated that the process to review MTF pharmaceutical requirements is different than the process to review contingency requirements because the MTFs have a different supply operation and process to meet MTF requirements. The DLA maintains contingency contracts to mitigate the risk of pharmaceutical shortages for military operations; however, there is no contracted supply of pharmaceuticals to mitigate the risk of pharmaceutical supply disruptions for routine MTF operations. A senior official from the U.S. Army Medical Materiel Agency stated that if there is a sudden global shortage for pharmaceuticals that traditionally would not be in shortage, they do not mitigate against it. According to the "100-Day Reviews under Executive Order 14017" report, one pillar of supply chain resilience strategy is to build emergency capacity to ensure that the United States does not have shortfalls of critical drugs during times of crisis.

The DoD Did Not Have Implementing Guidance on SCRM for DoD Materiel

{CUI} [REDACTED]

For example, although the DoD had information about the country of origin for pharmaceuticals, the DoD did not aggregate and analyze the available country of origin data because it was not required. The DoD did not identify the quantity of critical pharmaceuticals needed for routine MTF operations because it was not required. Additionally, the DLA did not test the responsiveness of its Pharmaceutical Prime Vendor contract because testing the DLA's contingency contracts was not required.

The DoD Did Not Have Implementing Guidance on SCRM for DoD Materiel, Including Pharmaceuticals

{CUI} [REDACTED]

[REDACTED] DLA Troop Support assessed the industrial capability risk in FY 2020 and identified pharmaceutical shortages of certain raw materials and backorders as a confirmed risk, with the recommendation to "maintain

⁴⁰ DLA Troop Support Medical Readiness, "Annual Industrial Capability Risk Assessment Report," FY 2020.

(CUI)-awareness and adjust strategies accordingly.” However, the report did not specifically identify which strategies must be adjusted to mitigate the identified risk of pharmaceutical shortages. Furthermore, DHA representatives stated that they were not aware of any risk assessments performed on either the Defense Medical Logistics programs or the pharmaceutical programs under the purview of the Defense Health Agency Medical Logistics.

The Chief Information Security Officer for Acquisition and Sustainment Office Is Responsible for SCRM at the DoD Enterprise Level

(U) DoDI 4140.01 states that the DoD identifies, monitors, and assesses the security and potential disruptions within and outside of the DoD supply chain to mitigate risk to supply chain operations.⁴¹ DoD SCRM encompasses all sub-sets of SCRM, such as cybersecurity, software assurance, obsolescence, counterfeit parts, foreign ownership of sub-tier vendors, and other categories of risk that affect the supply chain. DoDI 4140.01 states that the USD(A&S) establishes DoD policy and develops implementing guidance in appropriate DoD issuances on all matters relating to DoD materiel management.

(U) A 2018 internal review of DoD SCRM identified the need for a single department-level SCRM lead organization to provide SCRM implementation guidance to DoD components.⁴² In August 2020, the CISO(A&S) office under the USD(A&S) was assigned responsibility for supply chain risk management at the DoD enterprise level and for setting the overarching terms, requirements, standards, and policies. A senior official from the CISO(A&S) office stated that the DHA should be responsible for setting SCRM policies for the pharmaceutical supply chain. According to the DHA-Procedural Instruction 6430.02, the Director of the DHA exercises management responsibility for Enterprise Activities in the Military Health System, including the Defense Medical Logistics Enterprise Activities. Therefore, the DHA should be responsible for setting SCRM policies for the pharmaceutical supply chain.⁴³

DoD Did Not Have Implementing Guidance on How to Perform SCRM for DoD Materiel

(U) The CISO(A&S) office did not issue implementing guidance for SCRM for DoD materiel to ensure that every DoD program office performed supply chain risk management in a similar manner. Senior officials from the Office of the Deputy

⁴¹ DoD Instruction 4140.01, “DoD Supply Chain Materiel Management Policy,” March 6, 2019.

⁴² LMI Report, “DoD Supply Chain Risk Management: Assessment and Recommendations,” March 2018.

⁴³ DHA-Procedural Instruction 6430.02, “Defense Medical Logistics (MEDLOG) Enterprise Activity (EA),” September 27, 2018.

(U) Assistant Secretary of Defense for Logistics stated that the DoD would benefit from establishing a SCRM governance structure and that a “how-to guide” for anything SCRM-related would be beneficial. The CISO(A&S) office personnel were drafting a DoD Instruction for implementing guidance for SCRM, but as of the publication date of this report, the draft was not ready for distribution.

The Defense Health Agency Did Not Fully Implement Its Drug Supply Chain Security Act Compliance Strategy

(U) Based on information we received from the DHA and the Services regarding the DHA’s compliance with the DSCSA, we found that the DHA did not fully implement its DSCSA Compliance Strategy. In 2018, the Medical Logistics and Pharmacy Joint DSCSA Work Group prepared the “Drug Supply Chain Security Act (DSCSA) Compliance Strategy.” Senior Service representatives reviewed this strategy, and the DHA Pharmacy Operations Division Chief approved the strategy in September 2018. The DSCSA Work Group made the following four conclusions and recommendations.

- Rely on Pharmacy Prime Vendor websites for DSCSA information instead of investing in a DoD information technology storage and retrieval solution for DSCSA compliance because the system would only duplicate the data.
- Recommend the pharmacy community take the lead to establish the appropriate policy and procedure for drugs purchased with Government Purchase Cards or local contracts.
- Recommend that DLA Troop Support take the lead for additional analysis and recommendations for DLA-managed processes, including DLA Depot Stock, Direct Vendor Delivery, and DLA Electronic Catalog.⁴⁴
- Recommend that business requirements documents for drug label scanning and capture be reviewed and approved by the Pharmacy Work Group and then forwarded to the Joint Medical Logistics Functional Development Center for development.

(U) We requested information from the DLA, DHA, and the Services about the status of the DSCSA Work Group conclusions and recommendations. As of June 2021, we found that the recommendations were not fully implemented.

⁴⁴ DLA Managed Procurements represents about 2.5 percent of all pharmaceutical purchases. This includes pharmaceutical products where the DLA plays a more central role in the procurement of drugs, such as purchases from the DLA Electronic Catalog, DLA Direct Vendor Delivery (DVD), and DLA depots.

- The DHA did not have written agreements with the Pharmacy Prime Vendors to maintain the transaction information, transaction history, and transaction statements in accordance with the DSCSA.⁴⁵ After we discussed this with DHA and DLA senior officials, on May 13, 2021, DLA Troop Support modified the DLA Pharmacy Prime Vendor contract for the primary supplier to maintain the required transaction information in accordance with the DSCSA. According to a DLA official, the primary supplier accounts for about 95 percent of the DoD's pharmaceutical prime vendor transactions, and DLA officials are modifying the contracts for the secondary suppliers.
- According to DHA officials, as of February 1, 2021, the Supply Special Interest Group (SIG) of the DHA MTF Pharmacy Advisory Board was still drafting the policy for drugs purchased with Government Purchase Cards or local contracts.
- On October 5, 2020, the DLA Customer Pharmacy Operations Center team distributed a Situation, Background, Assessment, Recommendation (SBAR) report to the field providing pharmacies the relevant information about the DSCSA.⁴⁶ However, the SBAR report did not include guidance on DLA-managed processes such as DLA Depot Stock, Direct Vendor Delivery, and DLA Electronic Catalog.
- On October 23, 2020, the FDA announced a 3-year delay in enforcement of the requirement for product identifier portions of the DSCSA until November 27, 2023. The DHA released the "DHA MTF Pharmacy Advisory Board (DPAB) SIG Briefing," January 20, 2021, which showed that funding was set aside for modifications for the Defense Medical Logistics Standard Support system to be able to scan and keep documents in accordance with DSCSA requirements, with a projected launch in 2023.

The DoD Did Not Aggregate and Analyze Available Country of Origin Data for Finished Drug Products and API

{CUI} [REDACTED]

According to senior DLA officials, the DLA did not store the finished drug product or API country of origin information in a database because the DLA was not required to maintain such a database. DLA officials also stated

⁴⁵ Public Law 113-54 November 27, 2013, Title II, 127 STAT 616 (d) Dispenser Requirements (1)(B) states that "a dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser must maintain a copy of the written agreement and must not be relieved of the obligations of the dispenser under this subsection."

⁴⁶ DLA Customer Pharmacy Operations Center, "Drug Supply Chain Security Act (DSCSA) Compliance for Dispensers" (SBAR Report), October 5, 2020.

{CUI} that the commercial pharmaceutical market is always changing, so maintaining a database would provide little value to the supply chain. However, Air Force and Marine Corps representatives stated that if the Defense Medical Logistics Standard Support system contained information about the pharmaceuticals' supply chain risk, then personnel who select items to be included in WRM assemblages could make informed decisions when selecting pharmaceuticals for their assemblages.

The DLA Contracting Officers Received Country of Origin Information for Pharmaceuticals From Vendors

(U) The DLA contracting officers receive a limited amount of country of origin information for pharmaceuticals from the vendors. According to DLA officials, the DLA required an offeror to self-certify that the pharmaceutical products are TAA compliant or reveal the country of origin of its products when they enter into a Distribution and Pricing Agreement or Joint National Contract with the DLA. According to DLA officials, the DLA has requested country of origin information from the offeror for certain pricing vehicles, but this information is not specifically required by the TAA clause and provision. The DLA contracting officers considered the country of origin information for the finished drug products and APIs before adding the finished drug products to the DLA's Medical Master Catalog as part of its review process.

The DLA Received Country of Origin Information for Pharmaceuticals From the FDA

(U) In 2019, the FDA began sharing information with the DLA about where finished drug products and APIs were manufactured; however, DLA officials stated that the FDA country of origin data was incomplete. A senior official from the DHA Pharmacy Operations Division stated that the U.S. pharmaceutical market was grappling with the problem of where the APIs were coming from because that information was not flowing from the manufacturers to the FDA. The "100-Day Reviews under Executive Order 14017" report identified information gaps and included a recommendation for the HHS to 1) develop and make recommendations

(U) to Congress seeking statutory authorization to increase FDA and HHS ability to collect information and 2) require that API and finished drug labels identify original manufacturers.

(U) We requested from the DLA a list of pharmaceuticals purchased by the DoD in FYs 2019 and 2020 along with the country of origin data that the DLA received from the FDA for each finished drug product. We reviewed data provided by the DLA and found that the FDA country of origin data was incomplete and difficult to interpret. Based on our analysis of the data, the file included 24,880 unique finished drug products, representing \$10.6 billion in spending, and only \$7.3 billion (68.7 percent) of the total spending on those drugs were associated with a drug that had a listed API country of origin. However, \$3.9 billion of the \$7.3 billion (46.8 percent) spent on drugs with a listed API country of origin referenced multiple countries, making it impossible to determine what percentage of total pharmaceutical spending was associated with any single country.

(U) We reviewed the FDA's data, which included a National Drug Code (NDC) to represent each pharmaceutical item.⁴⁷ According to FDA officials, the NDCs could not be used to identify the country of origin of the pharmaceuticals because each NDC could be associated with multiple countries of origin. Based on our analysis, we determined that the data that the FDA provided to the DoD would be more useful if the country of origin information was linked to the lot numbers from each manufacturer.⁴⁸ Each manufacturer lot number would then be associated with only one country of origin.

(U) According to FDA officials, the FDA did not capture lot numbers for NDCs. Although there would be advantages for drug quality evaluations, including the ability to match lot numbers reported in quality defects to the country of origin, the burden on industry to report this level of detailed information would likely be significant. FDA officials stated that the FDA would prioritize closing other supply chain information gaps before requesting this level of detail from the pharmaceutical industry. The FDA and the supply chain personnel were working toward developing enhanced distribution security under the DSCSA by November 2023. The product identifier requirement included encoding a barcode on the packages with the NDC, serial number, lot number, and expiration date. However, Federal requirements do not require country of origin information in the barcode of drug products.

⁴⁷ According to the FDA, the National Drug Code is a unique, three-segment number used as a universal product identifier for human drugs manufactured, prepared, propagated, compounded, or processed by registered drug establishments for commercial distribution.

⁴⁸ According to 21 CFR sec. 210.3, (2020), a lot number is any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

The DoD Received the Pharmaceuticals' Manufacturing Address in the Transaction History in Accordance With the Drug Supply Chain Security Act

(U) The DSCSA requires dispensers (pharmacies) to maintain the transaction history of pharmaceuticals for at least 6 years after the transaction. The transaction history includes "the business name and address of the person from whom ownership is being transferred" for each prior transaction going back to the manufacturer of the product.

(U) To determine whether the address of the manufacturers would provide the country of origin for the finished drug products, we asked each of our points of contact at the DHA and the Services to provide us one transaction history for a recent purchase of insulin for an MTF pharmacy. The transaction histories received from the officials from the DHA and the Services showed that the manufacturer addresses were the addresses of the manufacturers' corporate offices. Technically, "the business name and address of the person from whom ownership is being transferred" could be the corporate name and address of the manufacturer. Since the address does not need to be the address of the manufacturing site, we determined that this data field would not be a reliable source of information for the pharmaceuticals' country of origin. However, we determined that it could be useful if combined with other data points.

The DLA's Country of Origin Data Could be Valuable if Aggregated and Analyzed

(U) We observed that the multiple sources of data through which the DLA obtained country of origin information were incomplete. The DLA obtained country of origin information from the FDA, from vendors to assess TAA compliance, and from vendors when the DLA requested it. The DLA also required API country of origin information from pharmaceutical vendors that used the Joint National Contract.

(U) A senior official from the DLA Medical Customer Pharmacy Operations Center stated that the pharmaceutical market was not transparent about where the pharmaceuticals were manufactured, so it was almost impossible for a purchaser to have full visibility of where a pharmaceutical was manufactured. However, the data could be valuable if the available country of origin information for finished drug products and APIs were aggregated and analyzed.

{CUI} For example, we combined the DLA's list of pharmaceuticals purchased by the DoD in FYs 2019 and 2020 with the country of origin data that the DLA received from the FDA for each finished drug product. [REDACTED]

[REDACTED]

{CUI}

[REDACTED]⁴⁹ The DLA could also identify pharmaceuticals with a single point of failure, single or dual suppliers, or limited resilience and annotate that risk in its Medical Master Catalog.

(U) The personnel who select items to be included in WRM assemblages could use the supply chain information when they select pharmaceuticals for their assemblages. A senior official from the Air Force Medical Readiness Agency, Medical Logistics Division, stated that the personnel who select items to be included in WRM assemblages could select alternate pharmaceuticals by way of pharmaceutical substitution if the Defense Medical Logistics Standard Support system had information about the supply chain. A senior official from the U.S. Marine Corps Expeditionary Medical Systems stated that there could be multiple National Stock Numbers for the same pharmaceutical item, so if there was information about the origin of the pharmaceuticals, the Marine Corps could decide to select the National Stock Number for the pharmaceutical that was made in the United States, instead of other National Stock Numbers of the same item that were made outside the United States.

(U) Although the information about country of origin was limited, we determined that there are benefits to aggregating and analyzing the information that the DLA already has. DLA officials could better assess the magnitude of its reliance on foreign suppliers. Based on the DLA officials' expertise, DLA officials could also assess the gaps in its country of origin information and determine whether there are options the DLA could use to obtain more complete information to assess risks associated with foreign suppliers in the supply chain.

The DoD Did Not Identify the Quantity of Critical Pharmaceuticals Needed for Routine MTF Operations to Mitigate the Risk of Supply Disruptions

{CUI} [REDACTED]

The DLA had a Medical Contingency File that listed critical pharmaceuticals with quantities needed for military operations to mitigate the risk of supply disruptions.

⁴⁹ Executive Order 14017, "America's Supply Chains," February 24, 2021.

(CUI) However, the DHA did not have a similar list that identified the quantity of critical pharmaceuticals needed for routine MTF operations to mitigate the risk of supply disruptions.

The DoD Did Not Identify Critical Pharmaceuticals Needed for Routine MTF Operations

(U) For routine MTF operational requirements, the DoD Pharmacy and Therapeutics Committee manages the uniform formulary in accordance with 32 CFR sec. 199.21(2020) "TRICARE Pharmacy Benefits Program."⁵⁰ The uniform formulary includes two subsets, the Basic Core Formulary and the Extended Core Formulary. The Basic Core Formulary is a mandatory component of formularies at all full-service MTF pharmacies. The Extended Core Formulary is a list of pharmaceuticals that MTF Pharmacy and Therapeutics Committees could add to the individual MTF formularies based on the scope of health care services provided at the respective MTFs. The DoD Pharmacy and Therapeutics Committee reviewed new drugs to determine how they would impact deployment readiness but did not assess criticality as part of its review process for drugs added to the uniform formulary.

(U) We reviewed a copy of the Basic Core Formulary and the Extended Core Formulary. The Basic Core Formulary had 24,017 NDCs and the Extended Core Formulary had 228 NDCs. The formularies did not mark any individual pharmaceuticals as more critical than others.

(U) Senior DHA officials stated that there was no value added to identify critical pharmaceuticals because most medications have a therapeutic equivalent that could be used in case of a supply disruption. DHA officials provided two examples where the DHA used other medications in the same drug class or medications used to treat the same conditions when the preferred medications were unavailable.

(U) Although there is no requirement to identify any pharmaceuticals as more critical than others, we determined there is still value to identifying critical pharmaceuticals. For example, the University of Minnesota's Resilient Drug Supply Project identified a list of 156 critical acute drugs and reported on February 22, 2021, that 33 of the 156 critical acute drugs (21.2 percent) were on the list of drug

⁵⁰ According to 32 CFR sec. 199.21, (2020), the purpose of the DoD Pharmacy and Therapeutics Committee is to assure that the selection of pharmaceutical agents for the uniform formulary is based on broadly representative professional expertise concerning relative clinical and cost effectiveness of pharmaceutical agents and accomplishes an effective, efficient, integrated pharmacy benefits program.

(U) shortages reported by the FDA.⁵¹ The list of drugs critical for the DoD could be different, but we determined that a list of 33 of 156 critical drugs would be a more manageable list to focus on than 24,017 drugs in the Basic Core Formulary.

The DoD Did Not Identify the Quantity of Critical Pharmaceuticals Needed for Routine MTF Operations to Mitigate the Risk of Supply Disruptions

(U) The DoD did not identify the quantity of critical finished drug products needed for routine MTF operations to mitigate the risk of supply disruptions. The uniform formulary (Basic Core Formulary and Extended Core Formulary) did not include the quantity of drugs needed to meet Service member and beneficiary demand in case of supply disruptions.

(U) Senior DHA officials stated that there is no one correct answer for what quantity of any of the medications are necessary for routine MTF operations since demand fluctuates wildly. But according to a senior official at the U.S. Army Medical Materiel Agency, the U.S. pharmaceutical distributors know what the hospitals use on a daily basis because of known usage rate based on historical demand. We determined that if the Services could estimate their military operations requirements for the Medical Contingency File, then the DHA should be able to estimate its requirements for routine MTF operations in case of a supply disruption, based on historical demand for the pharmaceuticals for routine MTF operations.

(U) According to the FY 2019 Annual Report on the Status of DoD Programs for Pre-Positioned Materiel and Equipment, the DoD continues to evaluate the pre-positioned capabilities and stocks to maximize its effectiveness in an increasingly constrained resource environment. Because of resource constraints, we determined that it would not be financially feasible or efficient to have guaranteed access to all the finished drug products on the Basic Core Formulary for an indefinite quantity. 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.⁵²

⁵¹ According to the University of Minnesota's Resilient Drug Supply Project, critical acute drugs are drugs that must be available and used within hours or days when medically needed in acute care or the patient may suffer serious outcomes which may include disability or death.

⁵² Based on a strategic recommendation in the American Society of Health-System Pharmacists, "Pharmacy Forecast 2021: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems," March 15, 2021.

The DLA Did Not Test the Responsiveness of Its Pharmaceutical Prime Vendor Contract, as Allowed in the Statement of Work

{CUI} [REDACTED]

[REDACTED] In the 2020

Drug Shortages Task Force report, the DLA reported that 1,334 NDCs were unavailable due to manufacturer backorder and 238 NDCs were unavailable due to manufacturer allocation.⁵³ Additionally, in April 2019, the Air Force tested the ability of the Pharmaceutical Prime Vendor to fulfill the Air Force portion of the DLA contingency contract. The Air Force after action report concluded that the results of the test implied a higher risk of materiel availability when leveraging DLA contingency contracts. Based on this information, we determined that the DLA could not be reasonably assured that the contractors on the DLA's contingency contracts could meet the readiness contingency requirements when needed.

The DLA Did Not Conduct Responsiveness Tests on Its Prime Vendors

(U) The DLA's Pharmaceutical Prime Vendor Program contract statement of work states that the Government may test the primary supplier's responsiveness by placing simulated or actual orders against the contract, with or without prior notification, up to twice a year for simulated orders.⁵⁴ However, according to the DLA officials, the DLA did not perform these responsiveness tests allowed in the Pharmaceutical Prime Vendor contract. Although DLA Troop Support Medical reserves the contractual option to test its prime vendors' responsiveness, the DLA would only do so if it noted an issue in its vendors' ability to provide material or lack of responsiveness in performing their daily distribution commitments.

(U) DLA officials stated that the products on prime vendors' war readiness lists were also provided during peacetime, so monitoring the prime vendors' responsiveness in meeting its peacetime orders was sufficient to accurately project their abilities to respond to and meet their readiness contingency requirements. In addition, the prime vendors submitted on-hand inventory reports for their readiness items every 2 weeks to their respective DLA contracting officers. Since all of the items contained in the prime vendors' readiness programs were

⁵³ Drug Shortages Task Force, "Drug Shortages: Root Causes and Potential Solutions," October 2019, updated February 21, 2020.

⁵⁴ According to the DLA's Pharmaceutical Prime Vendor Program contract statement of work, these tests go by different names: DLA-War Readiness Materiel Testing; Army-Surge Testing; and Air Force-Responsiveness Testing.

(U) normally carried by the prime vendors in quantities sufficient to meet their readiness commitments, the DLA stated that there was no reason to conduct a redundant test.

(U) The DLA's Pharmaceutical Prime Vendor Program contract is one of many contingency contracts the DLA Warstopper Program invests funds in. When we asked if DLA officials tested the vendors' ability to respond to requests for pharmaceuticals by placing orders against the DLA's contingency contracts, including the Prime Vendor War Readiness Materiel, Corporate Exigency Contracts, and Vendor Managed Inventory contracts, DLA officials stated that the DLA tested its prime vendors' ability to respond to pharmaceuticals orders daily as it places orders from readiness customers against the Prime Vendor War Readiness Materiel, Corporate Exigency Contracts, and Vendor Managed Inventory contracts.⁵⁵ However, according to a senior official at the U.S. Army Medical Materiel Agency, the type and quantity of pharmaceuticals needed for war readiness are different from peacetime requirements.

(U) Based on the DLA's finding in the 2020 Drug Shortages Task Force report, the Air Force's responsiveness testing results, and the Navy's experience with the DLA's medical support during the Navy's response to COVID-19 operations in Guam, it appears that the DLA cannot meet the Services' readiness requirements when needed. Therefore, we determined that conducting responsiveness tests would not be redundant because it would help the DLA identify the exact points of failure in the process to obtain pharmaceuticals through DLA contingency contracts.

The DLA Is Not Required to Conduct Responsiveness Tests or Report the Results

(U) Although responsiveness tests are allowed in the Pharmaceutical Prime Vendor contract, DLA Instructions 5025.03 and 3110.01 did not require the DLA's contingency contracts to be tested and did not require test results to be included in the DLA's Warstopper Program Annual Report.⁵⁶

(U) The National Defense Authorization Act for FY 2021, section 732, "Department of Defense pandemic preparedness," requires the Secretary of Defense to develop a strategy for pandemic preparedness and response that includes a review of the effectiveness of the Warstopper Program of the DLA. The results from the responsiveness tests could be part of the effectiveness metrics.

⁵⁵ According to the DLA Troop Support Medical Readiness website, the primary types of contingency contract vehicles are Prime Vendor War Readiness Materiel, Vendor Managed Inventory contracts, and Corporate Exigency contracts.

⁵⁶ DLA Instruction 3110.01, "War Reserve Materiel (WRM)," April 24, 2018; and DLA Instruction 5025.03, "Manage the Warstopper Program," October 31, 2019.

The DoD's Reliance on Foreign Suppliers for Pharmaceuticals Is a Public Health, Readiness, and National Security Risk

(U) The DoD's reliance on foreign suppliers for pharmaceuticals is a public health, readiness, and national security risk. A senior official from the CISO(A&S) office stated that the United States needs a national strategy and a "whole of government approach" that provides incentives for companies to manufacture pharmaceuticals in the United States to mitigate the risks posed by foreign suppliers. The DoD could identify the foreign pharmaceutical manufacturers it relies on and assess the risks of this reliance; however, because the DoD purchases less than 2 percent of U.S. pharmaceuticals, it must continue to rely in large part on commercial suppliers and other Government agencies to enact national strategies for protecting the entire pharmaceutical supply chain.

(U) Furthermore, a senior official from the DLA Medical Customer Pharmacy Operations Center stated that the risk with pharmaceutical supply disruptions was really a national problem and not just a DoD problem. The senior official stated that the DLA Troop Support addressed this from a holistic (entire commercial market) perspective by collaborating with the FDA.⁵⁷

(U) Senior officials from the DLA Medical Pharmaceutical Prime Vendor Division stated that if some countries decide to stop producing APIs or shipping them to domestic manufacturers in the United States, the results could be catastrophic for the entire U.S. pharmaceutical industry. During July 31, 2019, testimony before the U.S.-China Economic and Security Review Commission, a Senior Advisor at the Hastings Center stated that the United States has virtually no manufacturing capability left in the United States to make generic antibiotics, a class of drugs commonly prescribed to active duty Service members. Ensuring the DoD pharmaceutical supply chain has protective measures in place would provide a defensive capability against potential disruptions in the supply of these drugs.

(U) According to the 2020 Drug Shortages Task Force report, drug shortages affect every level of the health care system, ultimately compromising the standard of care, producing waste, and increasing costs. Drug shortages can also worsen patients' health outcomes by causing delays in treatment or changes in treatment

⁵⁷ Drug Shortages Task Force, "Drug Shortages: Root Causes and Potential Solutions," October 2019, updated February 21, 2020.

(U) regimens, such as substituting less effective therapies when a drug of choice is not available. Inability to access specific drugs in a forward deployed location could also increase the requirements for aeromedical evacuation from theater.⁵⁸

(U) A senior official from the DHA Medical Logistics Plans and Readiness Division stated that failure to mitigate actual or rumored pharmaceutical supply disruptions could lead to major health care consequences. For example, during the COVID-19 pandemic, MTFs and medical centers hoarded anti-bacterial medications used for upper respiratory infections. Actions such as this could create an artificial shortage and force the supply chain to shift to a less clinically effective agent.

Recommendations, Management Comments, and Our Response

Revised, Renumbered, and Redirected Recommendations

(U) As a result of management comments, we revised draft report Recommendation 2.c. In addition, we revised and renumbered draft report Recommendations 3.b. and 3.c. as 1.b. and 1.c., and redirected the recommendations from the Defense Logistics Agency Director to the Under Secretary of Defense for Acquisition and Sustainment. We revised and renumbered draft Recommendation 3.d. as Recommendation 3.b. to clarify the recommendations.

Recommendation 1

(U) We recommend that the Under Secretary of Defense for Acquisition and Sustainment:

- a. Develop and issue implementing guidance for DoD supply chain risk management for DoD materiel in accordance with DoD Instruction 4140.01.**

Under Secretary of Defense for Acquisition and Sustainment Comments

(U) The Deputy Assistant Secretary of Defense for Industrial Policy, responding for the Under Secretary of Defense for Acquisition and Sustainment, agreed with the recommendation, stating that he is reviewing all current supply chain policies across the DoD and determining where modifications can be made to better align DoD policies and procedures to the modern, complex, globally-integrated supply chains of the 21st century. He further stated that he agrees with the DoD OIG assessment that the lack of transparency within the pharmaceutical supply chain related to country of origin information for active pharmaceutical ingredients

⁵⁸ According to a senior official from Air Force Operational Medical Logistics.

(U) poses a significant foreign dependency risk for the DoD, the U.S. government, and the general public. He highlighted DLA and DHA efforts to share country of origin information with the FDA and stated that the root cause of transparency challenges is the lack of available, authoritative data relating to the sourcing of pharmaceutical ingredients. He stated that efforts to address foreign dependency must begin with standardizing sourcing data requirements and may require Congressional action. He recommended that recommendations made by the DoD OIG incorporate a coordinated whole-of-government approach to addressing the challenges.

Our Response

(U) Comments from the Deputy Assistant Secretary addressed all specifics of the recommendation; therefore, the recommendation is resolved, but will remain open. We will close the recommendation when the DoD publishes implementing guidance for DoD supply chain risk management for DoD materiel, in accordance with DoD Instruction 4140.01. We also agree with the Deputy Assistant Secretary's assessment that our recommendations should incorporate a coordinated whole-of-government approach to addressing data transparency challenges. We have directed Recommendations 1.b. and 1.c. to the Under Secretary of Defense for Acquisition and Sustainment to help the DoD address pharmaceutical foreign dependency risk through a whole-of-government approach, rather than a unilateral approach, since the DLA Director is the DoD's Medical Materiel Executive Agent and ODASD(INDPOL) is the enterprise level office in charge of SCRM policies.

Revised and Redirected Recommendation

(U) As a result of management comments, we revised and renumbered draft report Recommendations 3.b. and 3.c. as 1.b. and 1.c., respectively, and redirected the recommendations to the Under Secretary of Defense for Acquisition and Sustainment, who has the authority to implement the recommendation.

- b. Coordinate with the U.S. Department of Health and Human Services to communicate the importance of the Food and Drug Administration implementing the recommendation outlined in the 100-Day Reviews under Executive Order 14017 to "Seek Additional Authority Through Which FDA Can Collect Additional Data and Take Action to Improve Surveillance, Oversight, and Resilience of the Supply Chain."**

- c. Pursue Federal legislation requiring pharmaceutical manufacturers to include active pharmaceutical ingredients and final drug product country of origin information of the pharmaceuticals' lot on the pharmaceuticals' packaging through modification of the Drug Quality and Security Act, Public Law 113-54 §582(b)(2)(A), or through development or modification of other statutes.

Defense Logistics Agency Comments

(U) The DLA Acquisition Director, responding for the DLA Director, agreed with the intent of the recommendations for the DLA to seek complete and reliable country of origin data, but did not agree with the directed actions in draft report Recommendations 3.b. and 3.c. The DLA Acquisition Director stated that the DLA is ready to support and contribute to ongoing efforts of the current administration to increase transparency in the pharmaceutical supply chain. However, the Director stated that an effective approach to data aggregation should be standardized as part of a whole-of-government review, with the FDA in a lead role. The Director stated that seeking complete and reliable country of origin data by requesting the information through a modification of pharmaceutical contracts would establish a requirement that only the DLA could enforce, rather than a Government-wide or industry-wide statutory reporting requirement, increasing the likelihood that contractors would refuse to provide the data or provide the data at significant cost to the Government. The Director stated that the DoD has no leverage to influence commercial behavior because the DoD accounts for only a small portion of global pharmaceutical spending. Enacting uniform standards for pharmaceutical suppliers would prevent costly Government-unique contractual requirements.

(U) The Director suggested that recommendations to establish regulatory requirements for pharmaceutical data be directed to the Office of the Secretary of Defense, which is better positioned to impact the DoD's ability to obtain reliable country-of-origin data through modifications to Federal law, coordination with the FDA, and as part of ongoing critical defense supply chain initiatives.

Our Response

(U) Comments from the DLA Acquisition Director addressed Recommendations 3.b. and 3.c. from our draft report. We revised the recommendations, redirected them to the USD(A&S), and renumbered them as Recommendations 1.b. and 1.c.; therefore, the recommendations are unresolved. We request that the Under Secretary of Defense for Acquisition and Sustainment provide comments on Recommendations 1.b. and 1.c. in the final report.

(U) We agree with the DLA Director that seeking complete and reliable country of origin information through coordination with the Department of Health and Human Services and through the pursuit of regulatory or statutory changes meets the intent of the recommendation that the DoD seek ways to obtain complete and reliable pharmaceutical country of origin data. We also agree that the Office of the Secretary of Defense is better able to coordinate with other Federal agencies and pursue new or modified Federal legislation. We revised the recommendations to ensure that the DoD has a role in the whole-of-government efforts to obtain more complete and reliable information about pharmaceutical country of origin data from pharmaceutical manufacturers, rather than recommending that the DoD attempt to obtain the data unilaterally through contract modifications. Because the DLA Director is the DoD's Medical Materiel Executive Agent and ODASD(INDPOL) is the enterprise level office in charge of SCRM policies and leads efforts to secure the defense supply chain, we redirected the recommendations to the Under Secretary of Defense for Acquisition and Sustainment, who oversees both the DLA and ODASD(INDPOL) and is best positioned to pursue these actions.

Recommendation 2

(U) We recommend that the Director of the Defense Health Agency:

- a. After the new DoD implementing guidance for supply chain risk management is published, develop and publish implementing guidance for supply chain risk management specifically for pharmaceuticals, that includes the Component responsible for policy execution.
- b. Complete the implementation of its Drug Supply Chain Security Act Compliance Strategy by:
 1. Establishing policies and procedures for drugs purchased with Government Purchase Cards or local contracts to comply with the Drug Supply Chain Security Act.
 2. In coordination with the Commander of Defense Logistics Agency Troop Support, establishing policy and procedures for drugs purchased with Defense Logistics Agency-managed processes, including Defense Logistics Agency Depot Stock, Direct Vendor Delivery, and Defense Logistics Agency Electronic Catalog.

Defense Health Agency Director Comments

(U) The Deputy Director of the Defense Health Agency, responding for the Director of the Defense Health Agency, agreed with Recommendations 2.a., 2.b.1., and, 2.b.2.

Our Response

(U) The DHA Deputy Director addressed these recommendations; therefore, these recommendations are resolved. We will close Recommendations 2.a., 2.b.1, and 2.b.2 when the Director provides documentation that the guidance policies and procedures addressing the recommendations have been established and implemented.

Revised Recommendation

(U) As a result of management comments, we revised Recommendation 2.c.

c. **Create a chartered work group to:**

1. **Meet at least quarterly to assess risks to the pharmaceutical supply chain and identify the pharmaceuticals most critical to beneficiary care at DoD Military Medical Treatment Facilities that are affected by those risks.**
2. **Establish policy for allocating scarce pharmaceutical resources in case of a supply disruption.**

Defense Health Agency Director Comments

(U) The DHA Deputy Director, responding for the Director of the Defense Health Agency, disagreed with the draft report Recommendation 2.c.1, although the DHA agrees with the intent of the recommendation. The Deputy Director stated that a critical drug list would not be beneficial if developed unilaterally by the DHA at a single point in time; rather, it should be part of a larger effort to continuously evaluate and manage the risks to the pharmaceutical supply chain. The Deputy Director agreed with draft report Recommendation 2.c.2, but recommended establishing a working group to address concerns like quickly identifying needed medications and determining how to allocate scarce resources during supply chain disruptions.

Our Response

(U) As a result of management comments, we revised Recommendation 2.c. by recommending that the DHA Director establish a chartered work group to identify the pharmaceuticals most critical to beneficiary care at DoD MTFs and establish policy for allocating scarce pharmaceutical resources in case of a supply disruption. The DHA Deputy Director addressed the specifics of the recommendation;

(U) therefore, the recommendation is resolved, but will remain open. We will close Recommendation 2.c. when the Director provides documentation, including the charter and meeting minutes, verifying that the work group has been established and the recommendation has been addressed. Although the recommendation was revised, the DHA Deputy Director's response sufficiently addressed the specifics of the revised recommendation; therefore, no additional comments are required in response to the final recommendation.

Recommendation 3

(U) We recommend that the Director of the Defense Logistics Agency:

- a. Establish written agreements with the Pharmacy Prime Vendors to maintain the transaction information, transaction history, and transaction statements in accordance with the Drug Supply Chain Security Act.

Defense Logistics Agency Director Comments

(U) The DLA Acquisition Director, responding for the DLA Director, agreed with the recommendation, stating that the DLA issued bilateral modifications to all awardees under the global prime vendor contract in July 2021 to ensure that the transaction information, transaction history, and transaction statements remain available and accessible in accordance with the Drug Supply Chain Security Act.

Our Response

(U) Comments from the DLA Acquisition Director addressed all specifics of the recommendation. We reviewed the contract modifications and verified that the information provided and actions taken fully addressed the recommendation; therefore, the recommendation is closed.

Revised and Renumbered Recommendation

(U) As a result of management comments, we revised and renumbered draft Recommendation 3.d. as Recommendation 3.b. to clarify that the Military Services perform the recommended responsiveness testing instead of the DLA.

- b. modify Defense Logistics Agency Instructions 5025.03 and 3110.01 to:
 1. Require DLA Troop Support to coordinate annually with Military Service customers to conduct responsiveness testing of the Defense Logistics Agency's contingency contracts for pharmaceuticals by placing simulated or actual orders against the contracts.

2. Provide a Standard Operating Procedure or similar guidelines to DLA's Military Service customers on how to conduct responsiveness testing.
3. Include the contract responsiveness testing results, as reported by the Military Service customers, in the Warstopper Program annual reports.

Defense Logistics Agency Comments

(U) The DLA Acquisition Director, responding for the DLA Director, agreed with the intent of the recommendation for responsiveness testing, but disagreed with the recommended method. The DLA Acquisition Director stated that the proper manner to test the contracts is for the Military Services to test the orders. The DLA will provide guidelines for conducting annual responsiveness testing to the DLA's Military Service customers. The estimated completion date for these guidelines is November 1, 2021. After the tests, the DLA will include the results in the Warstopper Program annual reports.

Our Response

(U) We agree with the DLA Acquisition Director's comments that the Military Services can perform the responsiveness testing instead of the DLA. We revised the recommendation based on management comments to state that the DLA should update policy to require the DLA to coordinate with the Services to conduct annual responsiveness testing. Comments from the DLA Acquisition Director addressed the specifics of the recommendation; therefore, the recommendation is resolved, but will remain open. We will close this recommendation when the Director provides comments and supporting documentation verifying that the modified DLA Instructions 5025.03 and 3110.01 have fully addressed the recommendation. Although the recommendation was revised, the DLA Acquisition Director's response sufficiently addressed the specifics of the revised recommendation; therefore, no additional comments are required in response to the final recommendation.

Appendix

Scope and Methodology

(U) We conducted this evaluation from September 2020 through July 2021 in accordance with the “Quality Standards for Inspection and Evaluation,” published in January 2012 by the Council of Inspectors General on Integrity and Efficiency. Those standards require that we plan and perform the evaluation to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings, conclusions, and recommendations based on our objectives. We believe that the evidence obtained provides a basis for a reasonable person to reach the findings, conclusions, and recommendations based on our review.

Criteria

(U) To address the objective for this report, we reviewed executive orders; public laws and regulations; DoD, DLA, DHA, and Service policies; and reports to Congress related to DoD supply chain risk management and pharmaceutical supply chain, including the following.

- 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,” August 6, 2020
- Executive Order 14017, “America’s Supply Chains,” February 24, 2021
- Public Law 113-54, “Drug Supply Chain Security Act,” November 27, 2013
- Federal Acquisition Regulation (FAR) Part 25, “Foreign Acquisition,” Subpart 25.1, “Buy American-Supplies,” and Subpart 25.4, “Trade Agreements.”
- DoD Directive 3110.07, “Pre-positioned War Reserve Materiel (PWRM) Strategic Policy,” March 7, 2017 (Incorporating Change 1, June 18, 2018)
- DoD Directive 5101.09E, “Class VIIIA Medical Materiel Supply Management,” September 29, 2015 (Incorporating Change 2, September 12, 2019)
- DoD Instruction 3110.06, “War Reserve Materiel (WRM),” January 7, 2019
- DoD Instruction 4140.01, “DoD Supply Chain Materiel Management Policy,” March 6, 2019
- DoD Manual 4140.01, Volume 1, “DoD Supply Chain Materiel Management Procedures: Operational Requirements,” December 13, 2018

- DoD Instruction 5101.15, “DoD Medical Materiel Executive Agent (MMEA) Implementation Guidance,” May 4, 2012 (Incorporating Change 2, August 31, 2018)
- DoD Instruction 6200.03, “Public Health Emergency Management (PHEM) within the DoD,” March 28, 2019
- Chairman of the Joint Chief of Staff Instruction 4310.01E, “Logistics Planning Guidance for Pre-positioned War Reserve Materiel,” January 13, 2020
- DLA Instruction 3110.01, “War Reserve Materiel (WRM),” April 24, 2018
- DLA Instruction 5025.03, “Manage the Warstopper Program,” October 31, 2019

Review of Documentation and Interviews

(U) To conduct this evaluation, we interviewed DoD policy makers, pharmacists, and medical logisticians. We interviewed personnel from the CISO(A&S) office, DLA Troop Support, the DHA, and the Military Services. From November 2020 to February 2021, we conducted interviews with stakeholders and key personnel responsible for the DoD’s supply chain risk management and the pharmaceutical supply chain. We interviewed and obtained information from personnel at the following organizations.

- CISO(A&S) Office
- Office of the Deputy Assistant Secretary of Defense for Logistics
- DLA – DLA Troop Support, DLA Acquisition Directorate, and DLA Office of the Inspector General
- DHA – DHA Medical Logistics Division, DoD Pharmacy Operations Division, and the Defense Healthcare Management Systems Program Executive Office
- Army – Assistant Secretary of the Army for Manpower and Reserve Affairs, U.S. Army Medical Command and Office of the Surgeon General, U.S. Army Medical Materiel Agency, and the Army Medical Logistics Command
- Navy – Bureau of Medicine and Surgery (BUMED) Operations, Plans, and Readiness; Fleet Support and Logistics; Logistics Policy; Pharmacy; and Medical Operations
- Air Force – Air Force Operational Medical Logistics, and Air Force Medical Readiness Agency, Medical Logistics Division

- Marine Corps – Headquarters Marine Corps Health Services, Clinical Support Services; Marine Corps Systems Command, Expeditionary Medical Systems; and Marine Corps Systems Command, Operations, and Programs Directorate

(U) We also requested information from the CISO(A&S) office, DLA Troop Support, the DHA, the Military Services, and the FDA. To determine whether the DoD mitigated the risks of disruptions to the pharmaceutical supply chain, which relies on foreign suppliers, we compared the actions DoD officials described to the public laws and DoD-provided plans and policies, such as the guidance titled, "Drug Supply Chain Security Act (DSCSA) Compliance Strategy." We obtained formularies from DLA and DHA staff that identified pharmaceuticals for various DoD requirements. We also obtained inventory data from the DLA Troop Support and the Military Services staff that identified their on-hand pharmaceutical inventory held in reserves for military operations and routine MTF operations. We did not physically observe DoD operations at the MTFs or warehouses due to DoD COVID-19 travel restrictions. Rather, we conducted interviews with CISO (A&S) office, Office of the Deputy Assistant Secretary of Defense for Logistics, DLA, DHA, and Military Services personnel. We also reviewed the DoD policies, plans, and other documentation described in this report.

Use of Computer-Processed Data

{CUI} We used computer-processed data to perform this evaluation. The DLA provided us a list of pharmaceuticals and associated spending for those pharmaceuticals, purchased by the DoD in FYs 2019 and 2020 with the country of origin data that the DLA received from the FDA for each finished drug product. The DLA obtained the pharmaceutical sales data from its Enterprise Business Support System using the Customer Demand Management Information Application. The DLA received the pharmaceutical country of origin data from the FDA, which is maintained by the FDA's Center for Drug Evaluation and Research in its Site Catalog of all manufacturing facilities making drugs for the U.S. market. The DLA merged the sales data with country of origin data to assign the FDA-derived country of origin to every drug purchased by the DLA in FYs 2019 and 2020. We used this dataset to determine that, among those pharmaceuticals with APIs supplied from a single country, [REDACTED] contained APIs supplied from non-Trade Agreements Act (TAA) countries.⁵⁹

⁵⁹ According to the FDA, the National Drug Code is a unique, three-segment number used as a universal product identifier for human drugs manufactured, prepared, propagated, compounded, or processed by registered drug establishments for commercial distribution.

(CUI) The OIG Data Analytics Team assessed the reliability of the DLA pharmaceutical spending and country of origin data. [REDACTED]

[REDACTED] By comparing the API country of origin included in the DLA data with API country of origin data provided to us by the FDA in August and November 2020, we determined that [REDACTED] of the DLA pharmaceutical spending on single country API sourced pharmaceuticals was sufficiently reliable for the purposes of this evaluation. The remaining \$326 million (8.4 percent) of spending was of undetermined reliability. We determined the data provided a reasonable basis for our analysis based on the following factors.

- 1) (U) In our professional judgement, the data are reasonably valid measures for analyzing the reliance on foreign pharmaceutical suppliers.
- 2) (U) The datasets are large and widely used for tracking pharmaceutical inventory.
- 3) (CUI) About [REDACTED] of DLA spending on pharmaceuticals with a single country API source fully matched the API country of origin in the data obtained from the FDA.

Use of Technical Assistance

(CUI) The Data Analytics Division assisted this evaluation by combining the DLA's list of pharmaceuticals purchased by the DoD in FYs 2019 and 2020 with the country of origin data the DLA received from the FDA for each finished drug product. The Data Analytics team found that, out of a total of 24,880 unique NDCs, pharmaceuticals with API from a single country contained [REDACTED] unique NDCs. Among the 5,486 NDCs with APIs supplied from a single country, [REDACTED] contained APIs supplied from non-TAA countries. Based on this analysis, we determined that there are benefits to aggregating and analyzing the information that the DLA has access to.

Prior Coverage

(U) During the last 5 years, the Government Accountability Office (GAO) issued two reports discussing actions needed to enhance oversight of the DoD's pharmaceutical processes and prepositioned war materiel. The DoD Office of Inspector General (DoD OIG) issued two recent reports discussing the DoD's SCRM policies and the DoD's pharmaceutical processes.

Unrestricted GAO reports can be accessed at <http://www.gao.gov>. Unrestricted DoD OIG reports can be accessed at <http://www.dodig.mil/reports.html>.

GAO

(U) Report No. GAO-19-244, "Prepositioned Stocks – DoD Needs Joint Oversight of the Military Services' Programs," January 31, 2019

The report focused on the DoD's fragmented management approach and limited Joint oversight of the DoD's prepositional stock program. The GAO determined that the DoD did not fully address four of the seven elements for managing its prepositioned stock program, as required by FY 2014 NDAA section 321. The GAO further determined that the DoD did not fully implement a Joint oversight approach for managing prepositioned stock program. The report listed prepositioned stock programs within each Service and highlighted the need for the DoD to have a comprehensive list of prepositional materiel. The report recommended that the DoD improve Joint oversight of the prepositional stock program.

(U) Report No. GAO-21-265, "COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention," January 28, 2021

Provisions within the CARES Act directed the GAO to provide monitoring and oversight of the efforts related to the COVID-19 pandemic. The GAO report made 13 additional recommendations to a previous GAO report, which had 31 recommendations regarding COVID-19 oversight. The GAO report highlighted its concern that the directed agencies did not act on recommendations that addressed critical gaps in the medical supply chain. The GAO report detailed recommendations for agencies to have a specified plan to coordinate and communicate pharmaceutical processes and identified that incomplete drug manufacturing data inhibits Federal efforts to identify supply chain vulnerabilities. The GAO report also recognized the greater U.S. reliance on foreign manufacturing of many drugs and the importance of ensuring a secure supply chain for pharmaceuticals.

DoD OIG

(U) Report No. DODIG-2017-076, "The Missile Defense Agency Can Improve Supply Chain Security for the Ground-Based Midcourse Defense System," April 27, 2017

The report addressed supply chain risk management as it pertains to the Ground-Based Midcourse Defense System. This report provided a background understanding on the DoD's supply chain risk management policy, which requires the Defense agencies to identify critical information and communications components, purchase components from trusted suppliers,

and test and evaluate critical components for malicious threats. The report's recommendations include development of a plan for oversight of the program, including testing and evaluation to detect vulnerabilities within the critical components.

(U) Report No. DODIG-2020-120, "Audit of Management of Pharmaceuticals in Support of the U.S. Central Command Area of Responsibility," August 28, 2020

The report found that the Military Departments did not fully account for or safeguard pharmaceuticals within the U.S. Central Command of responsibility. This occurred because existing guidance did not provide a unifying method to account for and safeguard pharmaceuticals in accordance with theater, Service, and unit-level processes. The report recommended that the U.S. Central Command Theater Pharmacist establish policies and procedures for conducting pharmaceutical inventories, develop tracking mechanism for deficiencies, and update the checklist for inventories.

Management Comments

Undersecretary of Defense for Acquisition and Sustainment



OFFICE OF THE UNDER SECRETARY OF DEFENSE
3000 DEFENSE PENTAGON
WASHINGTON, DC 20301-3000

ACQUISITION
AND SUSTAINMENT

MEMORANDUM FOR ASSISTANT INSPECTOR GENERAL (ACQUISITION, CONTRACTING AND SUSTAINMENT)

SUBJECT: Response to Office of Inspector General Draft Report "Evaluation of the DoD's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain" (Project No. D2020-DEVOPB-0175.000)

The Office of the Deputy Assistant Secretary of Defense for Industrial Policy (ODASD(IndPol)) appreciates the opportunity to review and comment on the entirety of the report. We agree with the Department of Defense Office of Inspector General's (DoD(OIG)) assessment that the current lack of transparency within the pharmaceutical supply chain, particularly related to country-of-origin information for active pharmaceutical ingredients, poses a significant foreign dependency risk not only for DoD, but for the entire U.S. Government and the general public.

IndPol will continue to support the Department of Health and Human Services (HHS), the lead U.S. government agency for pharmaceutical supply chains. We work closely with HHS, particularly the Food and Drug Administration (FDA), in providing supply chain information to help in their efforts to secure pharmaceutical supply chains, and we will continue to support them in their efforts.

IndPol has been a vocal advocate of reforms in supply chain management, and has supported our counterparts at the Defense Logistics Agency (DLA) and the Defense Health Agency (DHA). Noteworthy is their efforts to highlight the need for regulatory requirements that compel and standardize the submission of country-of-origin information to the FDA. IndPol has expressed the need to share such data with federal buying organizations as they develop mitigations and alternatives in response to foreign dependency risks. While implementing guidance for DoD Instruction 4140.01 will help create standard processes and expectations for risk management performance within the pharmaceutical supply chain, the root cause of transparency challenges is the lack of available, authoritative data relating to the sourcing of advanced pharmaceutical ingredients. Efforts to address foreign dependency must begin with standardizing sourcing data requirements and may require Congressional action.

With the humanitarian toll caused by the pandemic and the need to mitigate such crisis in the future, IndPol or DoD efforts alone will not suffice. However, as IndPol works with other government agencies that are currently analyzing and developing recommendations related to this issue in response to Executive Orders 14001 and 14017, we offer that any recommendations by your office incorporate a coordinated whole-of-government approach to addressing the challenges.

Undersecretary of Defense for Acquisition and Sustainment (cont'd)

Thank you again for the opportunity to comment and share our perspective on this very important issue. The point of contact for this audit is [REDACTED]
[REDACTED]

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E.A. [REDACTED] SALAZAR,JESSE A. [REDACTED]
Date: 2021.08.18 11:46:40 -04'00'

Jesse Salazar
Deputy Assistant Secretary
for Industrial Policy

Attachment:
Requested corrections and individual response to the report recommendation

Undersecretary of Defense for Acquisition and Sustainment (cont'd)

DOD OIG DRAFT REPORT DATED JULY 6, 2021 "EVALUATION OF THE DEPARTMENT OF DEFENSE'S MITIGATION OF FOREIGN SUPPLIERS IN THE PHARMACEUTICAL SUPPLY CHAIN" (PROJECT NO. D2020-DEVOPB-0175.000)

Final Report Reference

OFFICE OF INDUSTRIAL POLICY'S RESPONSE TO THE DOD OIG RECOMMENDATIONS

REQUEST FOR CORRECTION: Page 4, paragraph 3 of the draft report states "(U) The Secretary of Defense submitted a report titled "100-Day Reviews under Executive Order 14017" to the President of the United States in June 2021. This report assessed supply chain vulnerabilities across the four key products directed by the President, including pharmaceuticals and APIs."

This statement is inaccurate. The Secretary of Defense did not submit the report. The White House published the report, which included an assessment of four sectors:

1. Semiconductors, led by Department of Commerce;
2. High-capacity batteries, led by Department of Energy;
3. Strategic and critical materials, led by Department of Defense (DoD); and
4. Pharmaceuticals and active pharmaceutical ingredients (APIs), led by the Department of Health and Human Services (HHS).

While DoD provided input to the report on pharmaceuticals and APIs, DoD did not lead the assessment. It was led by the Food and Drug Administration within HHS. The division of sectors is described in the Executive Order itself as well as in the White House's 100-day report, which includes the compilation of all four agencies' sector assessments.

Recommended correction: "(U) The White House published Secretary of Defense submitted a report titled "100-Day Reviews under Executive Order 14017" to the President of the United States in June 2021. This report assessed supply chain vulnerabilities across the four key products directed by the President, including pharmaceuticals and APIs, which was led by the Department of Health and Human Services (HHS). DoD provided support to HHS' report, but was not the lead agency."

Revised

REQUEST FOR CORRECTION: Page 7, paragraph 1 of the draft report states: "(U) The Chief Information Security Officer for Acquisition and Sustainment (CISO[A&S]) is the enterprise level office in charge of SCRM policies. The CISO(A&S) leads efforts to secure the Defense Supply Chain and synchronizes these efforts across the DoD and other Federal agencies."

Recommended correction: With the integration of the CISO(A&S) organization into the Office of Industrial Policy, request the following correction: "(U) The Office of the Deputy Assistant Secretary of Defense for Industrial Policy (ODASD(IndPol)), Chief Information Security Officer for Acquisition and Sustainment (CISO[A&S]) is the enterprise level office in charge of SCRM policies. ODASD(IndPol)The CISO(A&S) leads efforts to secure the Defense Supply Chain and synchronizes these efforts across the DoD and other Federal agencies."

Revised

RECOMMENDATION 1: (U) We recommend that the Under Secretary of Defense for Acquisition and Sustainment develop and issue implementing guidance for DoD supply chain risk management for DoD materiel in accordance with DoD Instruction 4140.01.

Undersecretary of Defense for Acquisition and Sustainment (cont'd)

DOD OIG DRAFT REPORT DATED JULY 6, 2021 "EVALUATION OF THE DEPARTMENT OF DEFENSE'S MITIGATION OF FOREIGN SUPPLIERS IN THE PHARMACEUTICAL SUPPLY CHAIN" (PROJECT NO. D2020-DEVOPB-0175.000)

OFFICE OF INDUSTRIAL POLICY'S RESPONSE TO THE DOD OIG RECOMMENDATIONS

ODASD(IndPol) RESPONSE: Concur. As part of our efforts in response to Executive Order 14017, which are still underway, IndPol is reviewing all current supply chain policies across DoD and determining where modifications can be made to better align our policies and procedures to the modern, complex, globally-integrated supply chains of the 21st century.

Director, Defense Health Agency



DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

08/17/2021

Mr. Thomas Bickett
Evaluations Component
U.S. Department of Defense
Office of Inspector General
4800 Mark Center Dr
Alexandria, VA 22350

Dear Mr. Bickett:

I am in receipt of the Department of Defense Inspector General's (DoD IG's) Draft Report No. D2020-DEV0PB-0175.000, "Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain." The Defense Health Agency (DHA) concurs with Recommendations (2.a): After the new DoD implementing guidance for supply chain risk management is published, develop and publish implementing guidance for supply chain risk management specifically for pharmaceuticals, that includes the Component responsible for policy execution.; (2.b.1): Complete the implementation of its Drug Supply Chain Security Act Compliance Strategy by: Establishing policies and procedures for drugs purchased with Government Purchase Cards or local contracts to comply with the Drug Supply Chain Security Act; (2.b.2): In coordination with the Commander of Defense Logistics Agency Troop Support, establishing policy and procedures for drugs purchased with Defense Logistics Agency-managed processes, including Defense Logistics Agency Depot Stock, Direct Vendor Delivery, and Defense Logistics Agency Electronic Catalog; and (2.c.2): Mitigate the risks and potential impacts of pharmaceutical supply disruptions due to its reliance on foreign suppliers by: Establishing policy for allocating scarce pharmaceutical resources in case of a supply disruption. DHA non-concurs with Recommendation (2.c.1): Mitigate the risks and potential impacts of pharmaceutical supply disruptions due to its reliance on foreign suppliers by: Establishing a list of critical (important) pharmaceuticals with quantities needed to mitigate the risk of supply disruptions for military treatment facility operations.

Please see the attached response to recommendations document. Specifically, in response to Recommendation (2.c.1), while we agree with the intent of the recommendation, we do not feel a critical drug list would be beneficial if developed unilaterally by DHA at a single point in time and should be part of a larger effort to continuously evaluate and manage the risks to the pharmaceutical supply chain.

Director, Defense Health Agency (cont'd)

Thank you for the opportunity to review and respond to the draft report recommendations.
My point of contact for this topic is [REDACTED]
[REDACTED]

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Y.TOSHIMITSU KIYOKAWA.GUY.TOSHIM
ITSU [REDACTED]
[REDACTED]

RONALD J. PLACE
LTG, MC, USA
Director

Attachment:
As stated

Director, Defense Health Agency (cont'd)

Final
Report Reference

**DODIG DRAFT REPORT DATED JULY 6, 2021
PROJECT NO. D2020-DEV0PB-0175.000**

**"EVALUATION OF THE DEPARTMENT OF DEFENSE'S MITIGATION OF
FOREIGN SUPPLIERS IN THE PHARMACEUTICAL SUPPLY CHAIN"**

**DEFENSE HEALTH AGENCY AND DEFENSE LOGISTICS AGENCY COMMENTS
TO THE DOD IG RECOMMENDATIONS**

(U) RECOMMENDATION 2: We recommend that the Director of the Defense Health Agency:

RECOMMENDATION 2.a: After the new DoD implementing guidance for supply chain risk management is published, develop and publish implementing guidance for supply chain risk management specifically for pharmaceuticals, that includes the Component responsible for policy execution.

DHA RESPONSE: DHA concurs.

RECOMMENDATION 2.b: Complete the implementation of its Drug Supply Chain Security Act Compliance Strategy by:

RECOMMENDATION 2.b.1: Establishing policies and procedures for drugs purchased with Government Purchase Cards or local contracts to comply with the Drug Supply Chain Security Act.

DHA RESPONSE: DHA concurs.

RECOMMENDATION 2.b.2: In coordination with the Commander of Defense Logistics Agency Troop Support, establishing policy and procedures for drugs purchased with Defense Logistics Agency-managed processes, including Defense Logistics Agency Depot Stock, Direct Vendor Delivery, and Defense Logistics Agency Electronic Catalog.

DHA RESPONSE: DHA concurs.

RECOMMENDATION 2.c: Mitigate the risks and potential impacts of pharmaceutical supply disruptions due to its reliance on foreign suppliers by:

RECOMMENDATION 2.c.1: Establishing a list of critical (important) pharmaceuticals with quantities needed to mitigate the risk of supply disruptions for military treatment facility operations.

DHA RESPONSE: DHA non-concurs. While we agree with the intent of the recommendations, we don't feel that a critical drug list would be beneficial if developed unilaterally by DHA at a single point in time and should be part of a larger effort to continuously evaluate and manage the risks to the pharmaceutical supply chain.

Revised, Page 35

Director, Defense Health Agency (cont'd)

2

RECOMMENDATION 2.c.2: Establishing policy for allocating scarce pharmaceutical resources in case of a supply disruption.

DHA RESPONSE: DHA concurs. We recommend establishing a standing working group with subject matter experts positioned to address concerns such as quickly identifying the medications required in specific circumstances as they arise and how to allocate scarce resources during supply chain disruption.

Director, Defense Logistics Agency



DEFENSE LOGISTICS AGENCY
HEADQUARTERS
8725 JOHN J. KINGMAN ROAD
FORT BELVOIR, VIRGINIA 22060-6221

August 13, 2021

MEMORANDUM FOR ASSISTANT INSPECTOR GENERAL (ACQUISITION,
CONTRACTING AND SUSTAINMENT)

SUBJECT: Response to Office of Inspector General Draft Report "Evaluation of the DoD's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain" (Project No. D2020-DEVOPB-0175.000)

DLA appreciates the opportunity to review and comment on the entirety of the report. We agree with the DODIG's assessment that the current lack of transparency within the pharmaceutical supply chain, particularly related to country-of-origin information for active pharmaceutical ingredients, poses a significant foreign dependency risk not only for the Defense Department, but for the entire U.S. Government and the general public.

DLA has been a vocal proponent of reforms in the pharmaceutical supply chain and highlighted the need for regulatory requirements that compel and standardize the submission of country-of-origin information to the Food and Drug Administration. DLA has also expressed the need to share such data with federal buying organizations as they develop mitigations and alternatives in response to foreign dependency risks. While implementing guidance for DODI 4140.01 will help to create standard processes and expectations for the performance of risk management within the pharmaceutical supply chain, the root cause of transparency challenges is the lack of obtainable, authoritative data relating to sourcing of APIs. Efforts to address foreign dependency must begin with the standardization of sourcing data requirements and may require Congressional action. As various government entities are currently analyzing and developing recommendations related to this issue – for example in response to Executive Order 14017 – we offer that any recommendations by your office incorporate a coordinated Whole-of-Government approach to addressing the challenges. This is not a problem that DLA or the Defense Department can solve on its own. This is the perspective from which we developed our attached response to the draft report.

Thank you again for the opportunity to comment and share our perspective on this very important issue. The point of contact for this audit is Mr. Andrew Hagenow, DLA Office of the Inspector General, [REDACTED]

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ICHARD [REDACTED] BEEBE.MATTHEW.RICHARD [REDACTED]
MATTHEW R. BEEBE
Director, DLA Acquisition

Attachment:
Individual responses to each of the report recommendations

Director, Defense Logistics Agency (cont'd)

Final
Report Reference

DOD OIG DRAFT REPORT DATED JULY 6, 2021
“EVALUATION OF THE DEPARTMENT OF DEFENSE’S MITIGATION OF
FOREIGN SUPPLIERS IN THE PHARMACEUTICAL SUPPLY CHAIN”
(PROJECT NO. D2020-DEVOPB-0175.000)

DEFENSE LOGISTICS AGENCY’S RESPONSE TO THE DOD OIG RECOMMENDATIONS

RECOMMENDATION 3: We recommend that the Director of Defense Logistics Agency:

RECOMMENDATION 3.a: Establish written agreements with the Pharmacy Prime Vendors to maintain the transaction information, transaction history, and transaction statements in accordance with the Drug Supply Chain Security Act.

DLA RESPONSE: Concur. Bilateral modifications have been issued to all awardees under the global prime vendor contract (AmerisourceBergen, DMS Pharmaceuticals, and Dakota) to ensure that the transaction information, transaction history, and transaction statements remain available and accessible in accordance with the Drug Supply Chain Security Act. **Completed July 2021.**

RECOMMENDATION 3.b: Develop procedures to aggregate data on pharmaceuticals’ origin that the Defense Logistics Agency already collects into a database that enables data analysis.

DLA RESPONSE: Non-concur. While DLA understands the intent behind the recommendation for actionable country-of-origin data that could assist with buying decisions and risk mitigations, we non-concur with the specific directed action. Determining country-of-origin is a complex, resource-intensive process. Although DLA does have access to some vendor and FDA-provided data, we do not have the capability or authority to authenticate it or ensure it remains current. Additionally, aggregating incomplete and potentially inaccurate data for the purposes of making recommendations to customers could imply that DLA considers the resultant database viable and authoritative. As noted in our July 20 discussion with the DoDIG team, the various ongoing Administration reviews in supply chain risk are determining the types and sources of data necessary to most effectively increase transparency in the pharmaceutical supply chain. DLA stands ready to support and contribute to these efforts and will implement resulting regulations and policies as directed. However, we believe that an effective approach requires that measures to support data aggregation be standardized and the result of a Whole-of-Government review, with FDA in a lead role. We suggest that any recommendation related to establishing regulatory requirements for pharmaceutical data should be directed to OSD, as the Department is best positioned to impact DOD’s ability to obtain more reliable country-of-origin data through modifications to federal law, through coordination with the FDA, and in conjunction with ongoing reviews related to Executive Orders and other critical defense supply chain initiatives. DLA requests that this recommendation be removed.

Revised, redirected
and renumbered draft
Recommendations
3.b. and 3.c. as 1.b
and 1.c., Page 32-33

RECOMMENDATION 3.c: Conduct a review to determine whether the Defense Logistics Agency can obtain complete and reliable data on the pharmaceuticals’ origin from the manufacturers under the existing contracts and, if not, determine what contractual modification would be necessary for the agency to obtain this information. Additionally, if existing statutes or

Director, Defense Logistics Agency (cont'd)

Final
Report Reference

DOD OIG DRAFT REPORT DATED JULY 6, 2021
"EVALUATION OF THE DEPARTMENT OF DEFENSE'S MITIGATION OF
FOREIGN SUPPLIERS IN THE PHARMACEUTICAL SUPPLY CHAIN"
(PROJECT NO. D2020-DEVOPB-0175.000)

regulations prohibit the agency from obtaining complete and reliable data on pharmaceuticals' origin, identify potential regulatory or statutory changes that might permit the agency to obtain this information.

DLA RESPONSE: Non-concur. While DLA understands the intent behind the recommendation for actionable country-of-origin data that could assist with buying decisions and risk mitigations, we non-concur with the specific directed action. It is common knowledge, documented by the FDA and other authorities, that manufacturers consider their sources for active pharmaceutical ingredients and products as trade secrets and do not share them as routine practice. While DLA could request this information as part of the contract through modification or inclusion in new contracts, establishing a requirement that only DLA would enforce, rather than having a government-wide or industry-wide statutory reporting requirement, increases the likelihood that contractors would simply refuse or would agree to provide the information at a significant cost to the government. Either option would negatively impact readiness support to DLA customers. DOD represents approximately 2% of the global spend on pharmaceuticals and DLA has virtually no leverage to influence commercial behavior. Requiring uniform standards for pharmaceutical suppliers to provide certifiable country-of-origin data is necessary to prevent costly, government-unique contractual requirements. As with 3.b., we believe any recommendation related to establishing regulatory or statutory requirements for pharmaceutical data should be directed to OSD, as they are best positioned to impact DoD's ability to obtain more reliable country-of-origin data through modifications to federal law, through coordination with the FDA, and in conjunction with ongoing reviews related to Executive Orders and other critical defense supply chain initiatives. DLA requests that this recommendation be removed.

RECOMMENDATION 3.d: Modify Defense Logistics Agency Instructions 5025.03 and 3110.01 to:

RECOMMENDATION 3.d.1: Require annual responsiveness testing of the Defense Logistics Agency's contingency contracts for pharmaceuticals.

RECOMMENDATION 3.d.2: Include the contract responsiveness testing results in the Warstopper Program annual reports.

DLA RESPONSE: Partially concur. DLA agrees with the recommendations for responsiveness testing but non-concurs with the suggested method and instead, recommends an alternative. The issue with having DLA perform testing is that it would require the Operations & Maintenance (O&M)-funded Warstopper Program to purchase inventory without a specific contingency related requirement. Further, the Warstopper Program is designed to fund investments that ensure readiness rather than purchase specific items of inventory. Financial controls for Warstopper investments require 1) tracking use of funds and material to avoid supplementing the Defense-Wide Working Capital Fund (DWWCF), and 2) ensuring repayments resulting from the investment are used only for Warstopper purposes. Further, even if determined permissible to purchase inventory through the Warstopper Program for this purpose, it would likely create a wasteful scenario where the items purchased may not be sold or needed for any reason at the

Revised and
renumbered as
Recommendation 3.b.,
Page 36

Director, Defense Logistics Agency (cont'd)

**DOD OIG DRAFT REPORT DATED JULY 6, 2021
“EVALUATION OF THE DEPARTMENT OF DEFENSE’S MITIGATION OF
FOREIGN SUPPLIERS IN THE PHARMACEUTICAL SUPPLY CHAIN”
(PROJECT NO. D2020-DEVOPB-0175.000)**

time they're purchased. Therefore, having the Warstopper Program fund a test of actual product is questionable from a fiscal standpoint both as to the purpose of the purchase and also the associated *bona fide need*.

Additionally, any Warstopper funding used to purchase items for testing further takes away industrial readiness contract coverage for the very items that this report is attempting to preserve. This is a zero-sum issue as money used for purchasing items for testing will come directly from obtaining contract coverage. Depending on the amount of testing required, this may conservatively account for a 10%-20% reduction in medical surge readiness coverage.

The proper manner to test the contracts is for the military service to request, establish the parameters of the test, and fund the orders. In that scenario, DLA would coordinate with DLA's military service customers to provide guidelines for conducting annual responsiveness testing on a selected sample from DLA's contingency contracts for pharmaceuticals. The estimated completion date for these guidelines is November 1, 2021. After this testing, DLA would include the results in the Warstopper Program annual reports due each February.

Acronyms and Abbreviations

API	Active Pharmaceutical Ingredient
CISO (A&S)	Chief Information Security Officer for Acquisition and Sustainment
DHA	Defense Health Agency
DLA	Defense Logistics Agency
DoDI	DoD Instruction
DoDM	DoD Manual
DSCSA	Drug Supply Chain Security Act
EO	Executive Order
FDA	U.S. Food and Drug Administration
HHS	U.S. Department of Health and Human Services
MTF	Military Treatment Facility
NDAA	National Defense Authorization Act
NDC	National Drug Code
NEMSCOM	Navy Expeditionary Medical Support Command
ODASD (INDPOL)	Office of the Deputy Assistant Secretary of Defense for Industrial Policy
USD (A&S)	Under Secretary of Defense for Acquisition and Sustainment
SCRM	Supply Chain Risk Management
TAA	Trade Agreement Act
WRM	War Reserve Materiel

Glossary

Active pharmaceutical ingredient. Any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.

Critical Inputs. Active Pharmaceutical Ingredients (API), API Starting Material, and other ingredients of drugs and components of medical devices that the FDA Commissioner determines to be critical in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures.

Dispenser. A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor. This does not include a person who dispenses only products to be used in animals.

Domestic. When used to modify the term “registrant,” “manufacturer,” “repacker,” “relabeler,” “salvager,” “private label distributor,” or “establishment,” refers to a registrant, manufacturer, repacker, relabeler, salvager, private label distributor, or establishment within any state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

Finished drug product. A finished dosage form (for example, tablet, capsule, or solution) that contains at least one active pharmaceutical ingredient, generally, but not necessarily, in association with other ingredients in finished package form suitable for distribution to pharmacies, hospitals, or other sellers or dispensers of the drug product to patients or consumers.

Uniform formulary. A list of the covered generic and brand-name drugs in the TRICARE Pharmacy Program. The formulary also contains a third category of medications that are designated as non-formulary. Medications in the non-formulary category include any drug in a therapeutic class determined to be less clinically effective or less cost effective than other drugs in the same class.

Heparin. An anticoagulant drug that prevents the formation of blood clots in the veins, arteries, and lungs. It is used before certain types of surgery, including coronary artery bypass graft surgery; in kidney patients before they undergo dialysis; and to prevent or treat other serious conditions, such as deep vein

thrombosis and pulmonary emboli. Heparin is also used in medical devices—for example, blood oxygenators or catheters contain or are coated with heparin, and some diagnostic testing products, such as some capillary tubes, are manufactured using heparin.

Military operations. A set of actions intended to accomplish a task or mission. The range encompasses three primary categories: military engagement, security cooperation, and deterrence; crisis response and limited contingency operations; and large-scale combat operations. Some examples include defense support to civil authorities; countering weapons of mass destruction; chemical, biological, radiological, and nuclear response; homeland defense; and mass atrocities response.

Supply chain risk management. The process for managing risk by identifying, assessing, and mitigating threats, vulnerabilities, and disruptions to the DoD supply chain from beginning to end to ensure mission effectiveness. Successful SCRM maintains the integrity of products, services, people, and technologies, and ensures the undisrupted flow of product, materiel, information, and finances across the lifecycle of a weapon or support system. DoD SCRM encompasses all sub-sets of SCRM, such as cybersecurity, software assurance, obsolescence, counterfeit parts, foreign ownership of sub-tier vendors, and other categories of risk that affect the supply chain.

Transaction history. A statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product. The transaction information includes the:

- a. proprietary or established name or names of the product;
- b. strength and dosage form of the product;
- c. National Drug Code number of the product;
- d. container size;
- e. number of containers;
- f. lot number of the product;
- g. date of the transaction;
- h. date of the shipment, if more than 24 hours after the date of the transaction;
- i. business name and address of the person from whom ownership is being transferred; and
- j. business name and address of the person to whom ownership is being transferred.

Whistleblower Protection

U.S. DEPARTMENT OF DEFENSE

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For more information about DoD OIG reports or activities, please contact us:

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