Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain (DODIG-2021-126)

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Objective

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

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.

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. Therefore, the DoD is dependent on the increasingly foreign sources used by the U.S. commercial pharmaceutical market.

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. DoD Manual (DoDM) 4140.01 Volume 1 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.

Finding

[REDACTED]. Specifically:

- 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.
- For military operations, the DLA established contingency contracts to guarantee access to pharmaceuticals. [REDACTED]
- 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.

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 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. 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

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.

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.

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.

Management Comments and Our Response

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.

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

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.

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.

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