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**Statement of**
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**Before the Senate Committee on Armed Services**
**Subcommittee on Personnel**

**Hearing on**
**The Department of Defense's**
**Efforts to Ensure Servicemembers' Access to**
**Safe, High-Quality Pharmaceuticals**

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

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

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

The Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services (HHS) regulates the U.S. commercial medical products, including pharmaceuticals. DoD leverages commercial pharmaceutical supply chain capabilities. DoD is supported by the commercial medical industrial base and provides medical treatment and care for the U.S. Military. Within DoD, DHA manages the personnel, facilities, treatment protocols, and requirements of the military healthcare system. In turn, DLA supports DHA and other defense customers by procuring the pharmaceutical supplies and services needed by the Department, based upon the requirements and specifications defined by its customers.

The issue of foreign dependency in pharmaceuticals has been a recognized risk for some years. A 2021 DoD Inspector General report, "Evaluation of the Department of Defense's Mitigation of Foreign Suppliers in the Pharmaceutical Supply Chain," found that "[a] disruption of the supply of foreign-made APIs to domestic manufacturers could cause a drug shortage that affects every level of the U.S. health care system. Since the DoD is a consumer of the U.S. commercial pharmaceutical market, which is dependent on ingredients from foreign suppliers, these potential drug shortages could ultimately compromise the standard of care for Military 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."

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

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

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

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

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

The information provided by PPS has enhanced DLA's ability to share information with customers and other stakeholders to develop risk mitigations and actions to address potential shortages and issues of availability. Additionally, DoD participates in the HHS Joint Supply Chain Resilience Working Group. The formal Working Group operates under the authority of the

Critical Infrastructure Partnership Advisory Council and facilitates engagements between government representatives at the federal, state, local, tribal, and territorial levels and representatives from critical infrastructure owners and operators to conduct deliberations and form consensus positions to assist the Federal Government in developing resiliency.

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

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