Prepared Statement

of

Dr. Lester Martínez-López
Assistant Secretary of Defense (Health Affairs)

Regarding

The Department of Defense's Efforts to Ensure Service Members' Access to Safe, High-Quality Pharmaceuticals

Before the

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

The Department's primary mission is to defend the Nation. As codified in DOD policy on supply chain management[1], we focus on identifying, monitoring, and assessing the security risks and potential disruptions within and outside of the DOD supply chain to mitigate the risk to supply chain operations that may impact availability or quality of material solutions. As it relates to the pharmaceutical supply chain, fulfilling this mission means our MHS beneficiaries, including our warfighters, have ready access to quality pharmaceutical products to ensure their best health outcomes and to optimize the health readiness of the Force. Considering pharmaceutical supply chain vulnerabilities, and in line with our mission of maintaining a ready medical force, we have a responsibility to identify and evaluate these emerging threats and develop data informed solutions to mitigate them.

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

[1] DoDI 4140.01, March 6, 2019 (whs.mil)

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

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

Another effort to generate insights, led by the Uniformed Services University of the Health Sciences (USU), is evaluating six aspects of the MHS pharmaceutical supply chain, to include: domestic manufacturing capability, documentation of the supply chain, and supply chain security and resilience. Our objective, through our research initiative, is to generate meaningful and actionable information on drug and active pharmaceutical ingredient (API) supply chain resiliency. Using the MHS as a representative example, this study will conduct a thorough

environmental scan of the pharmaceutical supply landscape, including a risk assessment, analysis of the domestic manufacturing capacity, and examination of the pharmaceutical supply chain, analytical testing of drug products from various suppliers, and study of scoring systems and the associated policy considerations. This pilot study will generate data pertaining to essential drugs for military operations. Through this study the MHS will gain insights into which manufacturers, and associated supply chains meet reliability essential to the Department's Joint Deployment Formulary. By creating more transparent information concerning supply chains that are able to consistently deliver quality medications, this study may enable manufacturers to be able to better compete and allow major purchasers of drugs, like the DoD, to direct our purchasing to best value manufacturers.

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

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

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

The WRAIR conducts vaccine research in partnership with industry, other US government partners academic, and international research partners. At WRAIR, structural and computational biologists harness the latest generation in electron microscopy, the next generation in sequencing, monoclonal antibody generation, machine learning technologies and novel adjuvants to design innovative next-generation vaccine candidates, which are then tested in preclinical models.

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

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

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