PREPARED STATEMENT

OF

Terry M. Rauch, Ph.D., M.P.H., M.B.A.

Acting Deputy Assistant Secretary of Defense

Force Health Protection and Readiness

REGARDING

U.S. BIODEFENSE AND RESPONSE TO THE NOVEL CORONAVIRUS OUTBREAK

BEFORE THE

HOUSE COMMITTEE

ON OVERSIGHT AND REFORM

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Chairwoman Maloney, Ranking Member Jordan, and members of the Committee, thank you for this opportunity.

The Department's top priority is the health and safety of our personnel around the world. We responded to the coronavirus disease 2019 (COVID-19) outbreak immediately, by disseminating force health protection guidance early in the outbreak, and continuing to issue additional guidance as the situation evolves.

The Department remains aligned with guidance from the Centers for Disease Control and Prevention (CDC) while allowing limited location and command flexibility as required by mission or local circumstances. We remain vigilant as this outbreak unfolds. The Department continues the oversight role as we work to expand force health protection measures, increase diagnostic testing capabilities, and make progress on COVID-19 medical countermeasures research and development activities.

In the area of force health protection, the Department issued initial guidance on January 30, 2020, that addressed the current situation (at that time), the risk to DoD personnel, individual prevention and protection measures, healthcare information, patient screening and isolation information, and information on diagnosis, treatment, and reportable medical events. The guidance also listed the CDC travel advisory level for China and referred to the CDC criteria for

identifying a person at risk or under investigation for disease caused by the novel coronavirus. The guidance also directed personnel on actions to take if they suspect they have an increased risk of exposure due to travel or close contacts.

Healthcare providers should refer to previously issued Department guidance dated September 25, 2018 on the use of personal protective equipment related to potential exposure to infectious agents. The January 30, 2020 COVID-19 initial force health protection guidance also informs providers on patient screening and isolation actions including putting a facemask on the patient and placing the patient in an airborne infection isolation room, if available, and refers them to CDC guidance for updated information.

The Department issued additional force health protection guidance to address COVID-19 on February 7, 2020, for monitoring personnel returning from China during the novel coronavirus outbreak. This guidance remained in step with CDC and provided further measures to prevent the spread of the disease. The February guidance directed the identification of Service members, and imposed a 14-day restriction of movement and monitoring requirements for Service members returning from mainland China after February 2, 2020. It specified actions to be taken by the Service member during their restriction of movement to reduce the potential spread of disease. The guidance recommended that DoD civilian

employees, contractor personnel, and family members returning from China follow existing CDC guidance.

On February 25, 2020, the Department issued additional guidance providing a risk-based framework to guide commanders in implementing health protection measures based on local circumstances. In total, DOD has issued nine Force Health protection guidelines. The entire series of force health protection guidance may be found on our defense.gov website.

In addition to force health protection guidance, I provided interim recommendations to the Joint Staff to assist Combatant Command Surgeons in advising their commanders about the medical risk posed by COVID-19 during operational exercises, and provided a medical risk algorithm for planning, execution, and recovery from such exercises.

As the Department assesses and manages risk to personnel and missions, the capability to diagnose COVID-19 to better inform treatment decisions and help track disease spread is vital and one important factor is diagnostic testing capabilities. Currently, the Department has 13 laboratories (10 in the continental United States and 3 outside the continental United States) approved to perform COVID-19 diagnostic testing with the CDC 2019-Novel Coronavirus (2019-CoV)

Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel. Daily testing capacity is limited at this time.

The Department is also actively pursuing all avenues of accessing testing under the Food and Drug Administration's Emergency Use Authorization (EUA) mechanism. We have identified general timelines to implement laboratory developed tests under an EUA if this option is pursued by DoD laboratories and we have begun discussions and information gathering on host-nation diagnostic tests and specific instrument sponsors, to determine EUA feasibility. The Department has strong relationships with state and local public health laboratories, which may be utilized to conduct diagnostic testing of samples taken from our beneficiary patients. Relying on partnerships with state and local public health laboratories is routinely available and may be used at any time for diagnostic testing under applicable agreements if the treating physician determines that pathway is appropriate. We anticipate the Department's laboratories will leverage such relationships and the capability of high-throughput instrumentation diagnostic testing coming online in the commercial sector to provide the most rapid test results to our beneficiaries. As for the cost to our beneficiaries for these COVID-19 tests, generally, they will not be responsible for such costs except in certain situations such as when the test is provided via the purchased care system at an

out-of-network provider or charges are processed to private health insurance plans, which vary in their out-of-pocket costs.

Finally, we are pursuing additional types of diagnostic testing to include serologic testing that will assess the patient's blood for the presence of COVID-19 antibodies. This will assist us in determining whether the infected or recovered individuals have developed a strong immune response against COVID-19 and whether they are still shedding virus even though symptoms have passed. Together, this information could help public health officials make key decisions, such as determining when to separate individuals who may be shedding virus or identifying individuals with COVID-19 antibodies who may already be recovered and protected against subsequent infection.

No FDA-approved medical countermeasures are available to prevent or treat COVID-19. The Department is working quickly to develop these countermeasures with the interagency Medical Countermeasure (MCM) Task Force. Towards that end, our Department-wide MCM Task Force is charged with coordinating the accelerated development and approval of medical countermeasures, such as safe, effective, and readily scalable vaccines and therapeutics, across the Department. The Department is already leveraging existing knowledge on potential medical countermeasures, such as remdesivir, an antiviral being developed against Ebola. The Department's MCM Task Force is working to establish a baseline to better

understand of the current status, needs, and gaps for COVID-19 medical countermeasure development. This baseline will lead to an effective and directed approach towards countermeasure development.

The Department is leveraging its CONUS and OCONUS clinical trial network to learn more about COVID-19 infections and to provide wide use of promising antiviral therapeutics, such as remdesivir, for infected Service members and other beneficiaries. Many of these activities are conducted in coordination with National Institute of Allergies and Infectious Diseases (NIAID). Our medical researchers and subject matter experts are aggressively developing multiple COVID-19 vaccine candidates. These candidates include nanoparticle platforms and DNA-based vaccines, among others. As we did during the 2014 Ebola outbreak, it is essential to simultaneously develop multiple candidates to improve the chances of obtaining a safe and effective end product.

The Department is working collaboratively to develop COVID-19 countermeasures. Across the U.S. Government, the Department is aligned under the Interagency Medical Countermeasures Task Force, led by the HHS Assistant Secretary for Preparedness and Response (ASPR) to provide support and coordination of medical countermeasures development activities. The Department has representation on the working groups under this Task Force to provide subject matter expertise on prioritization of activities and strategy development.

I am grateful for the opportunity to provide further detail on our efforts to contain and mitigate this outbreak. Thank you to the members of this Committee for your commitment to the men and women of our Armed Forces, and the families who support them.