RECORD VERSION

STATEMENT BY

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Chairman Pitts, Ranking Member Green, and distinguished members of the Subcommittee, thank you for the opportunity to testify on Department of Defense (DoD) efforts to partner with industry to develop medical countermeasures to prevent or mitigate the health effects of chemical, biological, radiological, and nuclear (CBRN) threats to the Armed Forces. For the last three years, I have led the Joint Project Management Office for Medical Countermeasure Systems (JPM MCS), the organization within DoD's Chemical and Biological Defense Program that is ultimately responsible for the advanced development, procurement, and sustainment of Food and Drug Administration (FDA) approved diagnostics, vaccines, and therapeutics needed to protect warfighters against CBRN threats on the battlefield. JPM MCS is one of five joint project managers within DoD's Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD). During my tenure at JPM MCS, we have instituted a range of improvements intended to enhance our ability to deliver capabilities to the force; however, there are some fundamental challenges that require assistance which the DoD cannot provide. I therefore greatly appreciate the opportunity to discuss incentives that will improve the ability of the DoD to deliver medical countermeasures against CBRN hazards.

Available economic and regulatory incentives have not succeeded in encouraging industry to partner with DoD on the development of medical countermeasures against CBRN threats. In general, medical countermeasures against CBRN hazards will be used in rare, emergency situations. The market for these medical countermeasures is small and is unlikely to yield an acceptable return-on-investment (ROI) for our industry partners. Industry performers have indicated that ROI is their top priority and there is simply little or no benefit to targeting these low-likelihood, high-impact CBRN threats. Further narrowing the potential ROI for industry is the limited size of the military population versus the entire U.S. population. Accordingly, I believe incentives are needed to inspire additional innovation in this market. There are a variety of potential incentives that could be used to encourage this investment, and DoD recognizes that the

development of incentives will require a careful assessment of risks and benefits that extend beyond DoD.

Make no mistake, however, we are not idle in the face of this challenge. JPM MCS is taking steps to increase DoD's ability to more rapidly develop and field medical countermeasures against CBRN hazards. For instance, in order to make it easier for non-traditional defense contractors such as pharmaceutical companies to partner with DoD, we recently announced the award of an Other Transaction Authority (OTA) consortium for the development of medical countermeasures against CBRN threats. An OTA is a special contracting vehicle with flexibility regarding certain procurement regulations and statutes and is available to federal agencies for the purpose of obtaining or advancing their research and development priorities. On behalf of JPM MCS, the U.S. Army Contracting Command has entered into an OTA with the National Chemical and Biological Defense Consortium for a period of 20 years.

Additionally, JPM MCS is establishing the DoD Medical Countermeasures Advanced Development & Manufacturing Capability (MCM ADMC), a dedicated and enduring capability to conduct advanced development and manufacturing of medical countermeasures for distribution to meet warfighter needs. In coordination with the Department of Health and Human Services Centers for Innovation in Advanced Development and Manufacturing, the DoD MCM ADMC will promote competition and incentivize businesses to compete by making it more likely small innovator biopharmaceutical companies that lack the FDA regulatory and production experience can and will succeed at fulfilling DoD requirements. This broadens the community of potentially capable and potentially interested performers.

DoD depends on small contractors to address our requirements for medical countermeasures, because, as noted, large pharmaceutical companies have been unwilling to join in ventures with the Government to address the DoD requirement

given the limited market potential for the resulting end products. DoD's MCM ADMC effort will be a place where small innovators can access expertise and technology to navigate the complex processes and challenges of medical countermeasure development and production. This $205 million project was undertaken in response to a directed requirement from the White House in 2010.[i]

DoD is determined to fulfill validated warfighter requirements for medical countermeasures against CBRN threats. I applaud the conversation now ongoing as to which incentives are best to generate innovation and results. DoD is an essential participant in the discussion and is well positioned to take advantage of improvements in this challenging market. The National Chemical and Biological Defense Consortium OTA and the Medical Countermeasures Advanced Development & Manufacturing Capability are just two examples of actions we are taking now to remain as ready as possible in an uncertain world. Thank you again for the opportunity to provide my perspective. I look forward to continued Congressional efforts to achieve results for the warfighter and taxpayer.

[i] Brennan, John O. (2010, December 29) *Medical Countermeasures Against Biological and Other Public Health Threats* [Memorandum]. Washington, DC: The White House.