[redacted]

[redacted]

Statement of Dr. Gerald W. Parker, Jr.

Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense

on

Medical Countermeasures

before

Emergency Preparedness, Response, and Communications Subcommittee,

Committee on House Homeland Security

U.S. House of Representatives

April 13, 2011

Introduction

Chairman Bilirakis, Ranking Member Richardson, and members of the Subcommittee, thank you for giving me this opportunity to discuss Department of Defense efforts to develop medical countermeasures to protect the Warfighter and the Nation.

DoD has to confront the growing and evolving risk of chemical, biological, radiological, and nuclear threats, and emerging infectious disease. Our national security is challenged to both accurately identify and rapidly respond to an attack or naturally occurring outbreak with countermeasures that limit impacts and loss of life. DoD is responding to this challenge by building an end-to-end, integrated capability to respond to the threat through enhanced diagnostics, detection, and biosurveillance; and through innovative industrial capacity for advanced development and adaptive manufacture of medical countermeasures for rapid response.

The potential threats today are much more difficult to plan against. We face a broad array of both natural and manmade challenges. The world is smaller so global pandemics come to our shores faster, and DoD personnel are deployed around the world coming into contact with endemic diseases unlikely to be seen in North America. The emergence and rapid advance of synthetic biology will make it easier over time for an adversary, whether state or non-state, to develop modified pathogens. These challenges will only increase with the exponential growth in the field of biotechnology, global industrialization, and the wealth of scientific information becomes even more available through mass communications.

Our over-arching goal, of course, is to prevent an attack or infectious disease outbreak in the first place. The Department has expanded prevention efforts underway that include international scientific engagements to promote a culture of laboratory responsibility, enhance scientific collaboration, and to secure dangerous pathogens. Should a crisis occur, however, we will have to act swiftly and decisively with the capability to rapidly indentify and characterize the threat, activate response plans, and rapidly distribute and disseminate medical countermeasures in sufficient quantities.

Before addressing medical countermeasure development challenges and solutions, I want to take the opportunity to emphasize the strong and productive collaboration we share with the Department of Health and Human Services and the Department of Homeland Security on many levels, and particularly through the Public Health Emergency Medical Countermeasures Enterprise. Through this Medical Countermeasures Enterprise, we have developed the Integrated Portfolio for CBRN Medical Countermeasures to develop medical countermeasures required for National and Homeland Security. Our relationship with HHS and DHS through the Enterprise is synergy at its best—we team our expertise, avoid duplicating efforts, and participate in joint acquisition and stockpiling when possible.

As a former laboratory director, I want to mention that the Department of Defense has an incomparable set of laboratory assets and scientific expertise based throughout the United States and around the globe engaging in basic and applied research, advanced technology development to prove concepts for medical products and information, and response to threats against health and performance. These include medical research and technology aimed at endemic disease threats, chemical and biological warfare threats, environmental hazards, battle sequelae, systems hazards, operational stressors, and combat injuries.

Our overseas laboratories are national assets that advance US diplomacy through the study of infectious diseases of critical regional public health importance. By contributing to the health infrastructure of another country, we contribute to that country's security and by extension to US security as well. The laboratory missions also include the evaluation of vaccines, therapeutic agents, diagnostic assays, and vector control measures. New international collaborations include the Republic of Georgia-US Biosurveillance and Research Center which engages scientists in diagnostic and epidemiological studies, and medical countermeasures research. DoD endeavors with coalition partners are exemplified by the work in the Republic of South Korea where diagnostic, detection, biosurveillance, and laboratory capabilities to protect US forces are tested and deployed. This work is done in collaboration with the Republic of Korea Defense, Health, and other Ministries to improve our collective preparedness and response posture to emerging infectious disease threats of any origin in this critical geographic region.

Challenges to Progress on Medical Countermeasures

The December 2010 *National Strategy for Countering Biological Threats* highlighted the significant threat posed by especially dangerous pathogens to our people, forces, and coalition partners. The Department of Defense must have the ability to fight and win in an environment that might be compromised by diseases or threat of a bioattack. This includes the timely provision of safe and effective vaccines and treatments for our Joint Service Members and our coalition partners.

The events of the 2009 H1N1 pandemic, along with the ongoing challenges and costs associated with development of chemical, biological, radiological, and nuclear medical countermeasures, revealed major gaps in advanced development and access to domestic surge manufacturing capacity. These and other challenges underscored by the Public Health Emergency Medical Countermeasures Enterprise Review in August 2010, revealed the need for a whole of government approach.

Factors that have limited progress for developing biodefense vaccines include the inability to leverage the expertise and capabilities of larger, experienced biopharmaceutical companies due to the high opportunity costs of entering the limited chemical, biological, radiological, and nuclear medical countermeasure market. The result is a reliance on small biotechnology firms that are engines of innovation and critical for discovery and early development of medical countermeasure candidates, but they have limited advanced development and regulatory experience and limited manufacturing capabilities. This is a costly, inefficient, and risky approach to meet critical biodefense and public health needs.

The cost and time required to develop and obtain Food and Drug Administration approval to market a new biologic and/or drug is costly, takes years, and is a risky endeavor even for large, experienced pharmaceutical companies or for medical countermeasure candidates that have well established regulatory and development pathways and a commercial market.

The Department's needs for medical countermeasures are variable in number, ranging from tens of thousands to a few million doses, owing to unique operational vaccine and treatment

requirements due to our global presence. The potential spectrum of CBRN threats and emerging infectious diseases is diverse, and we have too many gaps and unmet requirements for medical countermeasure vaccines and treatments.

It is crucial that we close the vaccine, antimicrobial and antiviral drug gaps. We cannot afford to take the average 12 to 15 years to develop a medical countermeasure against a single threat, nor can we afford to use the traditional and costly "one bug–one drug" development paradigm. This national security challenge requires new approaches for medical countermeasure advanced development and manufacturing to counter anticipated and unanticipated threats from an attack or naturally occurring infectious disease threats. The DoD approach to overcome some of these challenges is to bring innovation to manufacturing processes in an analogous way that the Transformational Medical Technology program brought innovation to discovery and early development. The approach will capitalize on platform technologies that can be multi-use and give us an ability to quickly characterize the pathogen and promptly develop a countermeasure.

Integrated Biodefense Approach

The Department will address these gaps holistically and as an integrated set of capabilities including establishment of critical industrial capacity to respond swiftly and effectively to these evolving threats. These capabilities focus on the need to quickly and precisely detect, diagnose, and identify the threat, develop or refine a medical countermeasure, and manufacture quickly those countermeasures in useful quantities.

Detection and Initial Response

The first step in this integrated set of functions is detection, and includes the entire system and processes that can quickly determine the nature of the infectious disease or emerging threat. Our ability to obtain early warning about the emergence and progression of new and/or particularly dangerous threats feeds directly into our ability to prepare effective vaccines and therapeutics.

Detection capabilities are a priority for DoD and include pursuit of research, development, and acquisition of medical diagnostics, environmental detection, and data fusion, management, and decision tools.

One diagnostic capability currently fielded with our forces in over 300 locations worldwide is the Joint Biological Agent Identification and Diagnostic System. It is capable of rapidly identifying multiple biological agents, such as anthrax, plague, and avian influenza. In response to the 2009 H1N1 pandemic, genomic signatures and assays obtained from the CDC were quickly ported to the JBAID system under FDA Emergency Use Authorization enabling use of this deployed platform for both military and public health needs. The utility of this genomic based diagnostic system has been very successful, enough to warrant investments and a new development thrust in next-generation diagnostics.

We are also working closely with the Department of Homeland Security and the Department of Health and Human Services on biosurveillance, diagnostics, environmental detection, laboratory capabilities, integrating operations and data systems, and participating in joint exercises in support of a national biomonitoring architecture. In BioWatch cities, for example, military installations are included in the local emergency management and public health incident command centers enabling shared situational awareness through local, state, and national operations centers. We are also integrated through the National Biosurveillance Integration System, which serves as the platform for information exchange between agencies and facilitates the early recognition of biological events, including natural disease outbreaks, accidental or intentional use of biological agents, and emergent biohazards. DoD also collaborates with the DHS National Biodefense Analysis and Countermeasures Center for biological risk assessments and bioforensic analysis to support attribution.

DoD global biosurveillance activities are enhanced by establishing strategic research partnerships and scientific cooperation efforts with partner nations. Global biosurveillance initiatives and medical diplomacy through overseas labs foster ongoing communication, collaboration, and information networks among the US government agencies, non-governmental organizations, academia and international partners. The Armed Forces Health Surveillance Center Global Emerging Infections Surveillance and Response System is a centralized communication hub to help coordinate DoD resources and link with other US and international disease surveillance efforts. This center links DoD laboratories, research facilities, and the

military health system to facilitate rapid recognition and response to protect the health of the forces and national security. Within DoD, a new laboratory information and communications system, the Electronic Integrated Disease Surveillance System, can link together the different levels of a national disease surveillance network within a country providing near real time information flow that can be disseminated to the appropriate organizations in a timely manner. DoD's overarching interest is to improve the capability for international surveillance, countering biological threats, and responding to emerging infectious diseases of intentional or natural origins. This is done in close collaboration with CDC global disease detection efforts.

DoD supports civil authorities in chemical, biological, radiological, and nuclear consequence management operations to save lives and reduce the effects of a weapon of mass destruction attack. We recognize the importance of maintaining a force that is ready and able to respond to these special threats and is prepared to rapidly support civil authorities in response to an event. The Department has established elements to provide forces as soon as possible to support any consequence management scenario that may occur. This includes command and control, decontamination of personnel and equipment, hazardous material handling and disposal, air and land transportation, aerial evacuation, emergency medical treatment, and sustainment. Other units provide casualty/patient decontamination, emergency medical support, and casualty search and extraction. We are continually looking for ways to improve support to civil authorities, increasing life saving capabilities and reducing response times. By the end of 2012 there will be 10 Homeland Response Force units capable of responding within hours in each of the FEMA regions to provide more life saving capabilities faster using the same approximately 18,000 personnel assigned to this mission.

Medical Countermeasures Discovery and Development

The second step of our integrated biodefense enterprise includes the entire scope of efforts to discover and develop a medical countermeasure candidate to a chemical, biological, radiological, and nuclear threat or new pathogen. These countermeasures must be rapidly demonstrated to be safe and effective through streamlined, but still rigorous, techniques. The Transformational Medical Technologies program, established as a DoD Initiative in 2006, focuses on the discovery

and refinement of medical countermeasures in response to emerging threats and has been so successful it is now becoming the base approach for the entire medical discovery program.

The Transformational Medical Technologies program addresses novel threats, biologically engineered pathogens, or emerging infectious diseases by developing new detection and therapeutic capabilities. The goal is to provide a rapid response capability to identify and characterize an unknown, and then apply a broad spectrum medical countermeasure. If none exist, a therapeutic platform will discover and develop medical countermeasure candidates quickly.

For example, in 2009 we redirected a therapeutic platform focused on developing therapeutics for hemorrhagic fever viruses to discover and refine medical countermeasures against an outbreak of an unknown pathogen. Our systems quickly indentified the unknown sample as the H1N1 virus, and a new antiviral was synthesized within 14 days. This is a revolutionary change from traditional discovery methods which can take years. However, traditional advanced development and manufacturing is not rapid, and will require further innovation. Even so, the H1N1 antiviral showed great promise in animal studies and is now entering clinical trials. Still, we must bring innovation to advanced development and manufacturing as well.

Advanced Development and Manufacturing

The essential third step is access to critical industrial capacity and expertise for the agile development and manufacturing of medical countermeasures in quantities to treat affected populations rapidly. We are preparing to implement the Medical Countermeasures Initiative through a cooperative partnership with industry. One of the innovation drivers will be the ability to manufacture medical countermeasures in a flexible fashion to include "on-demand" surge capacity for specific products in the event of a national security emergency or change manufacturing runs on different products as the need arises. The Medical Countermeasures Initiative encompasses two components: science and technology, and advanced development and manufacturing. A related component is the planned national test and evaluation facility for animal studies necessary for FDA approval. The science and technology component will concentrate on three areas: novel platform/expression systems, advancement of regulatory

science, and advancements in flexible manufacturing technologies. The advanced development component will concentrate on integrating novel platform/expression systems into a production process and establishing a Technical Center of Excellence to provide advanced development core services and a flexible manufacturing capability for DoD and national security needs. Ultimately, the Medical Countermeasures Initiative will coalesce to provide a "one-stop" shop for all future DoD medical countermeasure development.

Although platform and new manufacturing technologies coupled with new facility design make this approach technically feasible, it is not without risks and challenges. The technologies are new and the underpinning regulatory science will have to be developed in parallel as the products develop.

DoD intends to engage the most capable performer(s) to integrate innovative manufacturing technologies and to perform advanced development using scalable commercial manufacturing processes for meeting the Department's medical countermeasure requirements. Developing the right industry partnerships, small biotechnology endeavors generating new innovations needed for the revolutionary breakthroughs and larger companies with advanced development and licensure experience, will require the right incentives. We anticipate the need to motivate entry into the MCM niche, possibly cost-sharing, intellectual property rights, indemnification, or other attributes deemed necessary to generate interest.

Interagency Collaboration

The FDA has already started promoting regulatory innovation and investment in regulatory science in order to provide private sector partners with more access to regulators and greater clarity about the pathways to product approval. We are collaborating with the FDA and our other interagency, private sector, and academic partners to explore solutions to complex scientific regulatory problems and to identify situations in which the application of new science could simplify or speed product development and streamline the FDA regulatory approval process for medical countermeasures. Regulatory science is a critical enabling factor, particularly for unique challenges of developing biological defense medical countermeasures where pivotal efficacy studies must be done in animal model systems. Together, we will develop

strategies and assemble new tools for mutual success. Whether it is a member of our Armed Forces in the field or a fellow citizen in our neighborhood, safe and effective FDA approved medical countermeasures are needed when an event occurs.

Collaboration with the Department of Health and Human Services is essential to the successful implementation of the DoD Medical Countermeasures Initiative. Not only does this include the FDA, but the DoD advanced development and manufacturing capability must complement the parallel, but distinct, Biomedical Advanced Research and Development Authority work to establish Centers of Excellence for Advanced Development and Manufacturing. Leveraging the regulatory sciences component of the DoD's Medical Countermeasures Initiative will aid in surmounting these challenges by supporting the FDA in developing new methods for regulatory assessments so those assessments will not hamper moving advanced development programs forward. By working closely with HHS, we expect to provide one part of a national advanced development and manufacturing capability to support national security and meet unique DoD operational requirements.

Our nation must have the nimble, flexible capability to produce medical countermeasures in a more cost effective manner and rapidly in the face of any attack or threat, whether known or unknown, novel or reemerging, natural or intentional. President Obama called for this in last year's State of the Union Address. Our effort, along with the complementary manufacturing efforts within the Department of Health and Human Services, will provide surge production when necessary and will address the science and technology efforts to develop the next-generation medical countermeasure platform technologies, critical industrial manufacturing systems and regulatory science technologies. DoD has to commit to flexible manufacturing technologies because of the breadth of medical countermeasures we need to protect our troops and support global operations, and because of the varying numbers of doses required for each of these. We do not need to give every service member every vaccine, but we do need to be prepared to provide the levels of protection required.

There is no way to draw a line between national security and public health so we coordinate closely with our public health colleagues. We have a great partnership with other US agencies

and are careful to maintain our focus on national security to avoid overlap with established US public health efforts.

The Department of Defense has a long and proud history in infectious disease medical research and development. The DoD played a significant role in developing eight of the 15 adult vaccines licensed in the United States since 1962. Currently used worldwide, these include vaccines for influenza, meningococcal disease, hepatitis, rubella, adenovirus, typhoid, and Japanese encephalitis. In the high-risk business of vaccine production, experience breeds proficiency and efficiency, curbing the scientific, regulatory, and financial risk that can stifle product development. Since 2000, biodefense efforts have resulted in eight FDA approvals for diagnostics and medical countermeasures (including licensed medical countermeasures for anthrax, smallpox, and nerve agents) generated in our pipeline. Still in the advanced development pipeline are 14 candidates for next-generation countermeasures against anthrax, smallpox, botulism, alphaviruses, plague, influenza, and other emerging infectious diseases; chemical agents; and radiological threats. We anticipate more FDA approvals in the next five years.

DoD brings a unique capability to the national biodefense portfolio: detection and diagnostics sound the alarm, the Transformational Medical Technologies program or similar rapid response efforts generate new medical countermeasure candidates, and the Medical Countermeasures Initiative will establish the critical industrial capacity and expertise for advanced development and manufacture of medical countermeasure.

Conclusion

We are putting more emphasis on biodefense, particularly medical biodefense, leveraging the rapid growth in new technologies for our purposes. These threats on our troops or citizens are very real and ever changing in the 21st century. The Department of Defense must develop a nimble and agile program to respond. My organization is working to strengthen our capabilities to effectively prevent, deter, and defeat these threats. We are working with interagency partners, to include the Departments of Homeland Security and Health and Human Services, to better detect threats and protect the nation from harm before an event occurs: we are changing the way

we address research and development so we can be better stewards of the pipeline that we share with HHS, and we are becoming more responsive and proactive. I appreciate the opportunity to testify today and would be pleased to answer your questions.