Crossing the Valley of Death: Bringing Promising Medical Countermeasures to Bioshield
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Testimony

Mr. Chairman, members of the subcommittee, thank you for the opportunity to appear here today and provide my views on ways to improve the capability of the U.S. Government to develop and acquire medical countermeasures urgently needed to protect our citizens against the bioterrorism. I am Dr. Philip Russell, a retired Army Medical Corps Major General. From November 2001 until August 2004, I served as a senior advisor to the Department of Health and Human Services. In that capacity I was deeply involved in the acquisition of several medical countermeasures including the ACAM 2000 smallpox vaccine, Intravenous Vaccinia Immune Globulin, Equine antitoxin for Botulism, the rPA (recombinant protective antigen) anthrax vaccine, anthrax treatment products as well as the H5N1 influenza vaccine. As acting Director of the Office of Research and Development Coordination within the Office of the Assistant Secretary for Public Health Emergency Preparedness I was responsible for coordination of the initial purchases made under Project BioShield.

Drawing on my recent experience with some successful and some less-than-successful acquisitions under project BioShield and earlier HHS acquisitions, as well as my previous experience with research development and acquisition in the Department of Defense, I have done an analysis of critical factors that determine the outcome of major medical countermeasure acquisition programs. That analysis is the basis of my testimony today. I am providing this perspective with the intent to inform future legislative efforts intended to improve the capability of the government to obtain the medical countermeasures essential to national security.

I have identified eight critical elements that are major determinants of success or failure of a major acquisition under the current process and rules governing BioShield acquisitions.

• A credible threat determination and threat analysis
• A defined deployment and utilization policy for the product
• Government-wide agreement on the requirement
• A mature science base demonstrating proof of principal and ability to manufacture
• Funds and funding mechanism for early and mid-stage industrial development
• Sufficient acquisition funds (obligation authority) to provide the incentive for industry
• Consultation and support for the manufacturer from the acquisition agency and the FDA to assist in meeting regulatory requirements
• Ability to indemnify the manufacturer

A generally accepted understanding of the threat and broad consensus on the policy for emergency use of the products was the basis for the successful acquisition of smallpox vaccine and enabled the botulism antitoxin and the rPA anthrax vaccine programs to proceed rapidly. Threat analyses and agreement on utilization policies are necessary to support and properly size product requirements and are lacking for the other agents on the CDC "A" list. Threat determination and threat analysis is the responsibility of the Department of Homeland Security. Utilization policy is the responsibility of HHS

A consensus among the three major departments, HHS, DHS, DOD and White House offices on the proposed utilization policy and the size of the requirement is necessary to initiate a purchase under the BioShield program. This requires a process of interagency consultation which may go as high as the Deputies Committee. It was possible, albeit not easy, to obtain such a consensus for the botulism antitoxin and anthrax countermeasures where the threat was very clear. For future products against other threat agents, such as plague, tularemia and hemorrhagic fever vaccines, where both the threat analysis, and the size of the requirement and utilization policy will be much more challenging, this process may fail.

The existing NIAID program is creating solid scientific bases for future potential products. The investments in the Regional Centers of Excellence will provide the research basis for the potential development of a large number of new vaccines and therapeutics. Whether the potential products are eventually developed depends on whether funding is available for industrial product development to the point where they are considered viable candidates for a BioShield acquisition.

Most of the biologic products now in advanced development and under contract for purchase required major investments by the government during the early and mid stages of development prior to the purchase contract. This includes the ACAM2000 smallpox vaccine and botulism antitoxin developed under CDC contracts, and rPA anthrax vaccine and the next generation MVA smallpox vaccine developed under NIAID cost–reimbursement contracts. When adequate government support of early and mid level development is lacking, products will not progress to the point where they can be purchased under BioShield. The present process does not fully meet the needs of the government as evidenced by the slow development of anthrax treatment products to the point where they are eligible for BioShield procurement. Most small biotech companies with promising products need government support in the preclinical and early clinical phases of the R&D. Many large companies need government funding to share the risk of initial development for products where the government is the only market. This transition between laboratory research and early industrial development is one of the more serious and controversial problem areas in the current federal program for developing and acquiring medical countermeasures.

The special reserve fund for purchases under BioShield is sufficient for the currently approved products but, looking to the future, it will certainly be insufficient for full ten years. The high cost of bringing new products through the development and licensing process plus the cost of maintaining or renewing stockpiles and surge capacity will

deplete the fund before the end of the decade. The permanent definite nature of the appropriation does provide confidence that the government acquisition agency will be able to honor the terms of contracts.

Differences in policy regarding buying products prior to FDA licensure, in addition to Economy Act requirements and issues of indemnification will make it difficult and may make it impossible to make joint HHS-DOD acquisitions of future important products such as botulism, plague and tularemia vaccines. The high cost of product development and economies of scale in production make joint acquisition highly desirable for certain products but experience indicates it probably cannot be done under existing policies for acquisition and indemnification.

Small and medium sized companies that are attempting to develop and license a new vaccine or therapeutic product need substantial consultation and support from the acquisition agency and from the FDA to succeed in meeting regulatory requirements. The requirements of the "Animal Rule" are a special challenge for small companies. Providing effective support and guidance requires a large commitment of qualified technical personnel especially from the FDA.

Indemnification of the manufacturer when products such as vaccines are used in a government program is essential. It is a major issue with every acquisition and manufacturers cannot be expected to deliver products to the stockpile without reasonable protection from liability. Inability of the acquisition agency to provide assurance of indemnification at the initiation of a contract is a very strong disincentive to large corporate manufacturers.

In summary, there are many improvements that should be made in the processes used to develop and stockpile medical countermeasures. Probably the most important is the need to address the gap between laboratory-based research and advanced industrial development under BioShield. A program based on prioritized requirements that carries out a systematic technology watch and provides adequate funds for early and mid stage development of promising new products would greatly enhance the effectiveness of the BioShield program.

Perhaps equally important is a solution to the indemnification issue that would greatly simplify the contracting process for both the acquisition agency and the manufacturer. The current processes are cumbersome, expensive, and slow, a very strong disincentive to large corporations and a burden to the small companies.

A simplified process for determining requirements for products may be needed to address the very complex problem of obtaining the necessary government wide agreement on the need and utilization policy for such products as botulism, plague and viral hemorrhagic fever vaccines.

Thank you very much for the opportunity to provide this testimony. I will be happy to answer any questions.