



**Testimony**  
**Before the Subcommittee on Health**  
**Committee on Energy and Commerce**  
**United States House of Representatives**

**HHS Implementation of Project  
BioShield**

*Statement of*

**Alex M. Azar, II**

*Deputy Secretary*

*U.S. Department of Health and Human Services*



**For Release on Delivery**  
**Expected at 1:00 PM**  
**Thursday, April 6, 2006**

Good afternoon Chairman Deal and Members of the Subcommittee. I am pleased to be here today to update you on the steps the Department of Health and Human Services (HHS) has taken to implement the Project BioShield Act of 2004 (P.L.108-276). Project Bioshield, as announced by President Bush in his State of the Union address on January 28, 2003, was proposed to accelerate the process of research, development, purchase, and availability of effective countermeasures against agents of bioterror. Then HHS Secretary Tommy Thompson and Department of Homeland Security (DHS) Secretary Tom Ridge jointly transmitted the "Project BioShield Act of 2003" to Congress on February 26, 2003 and it was signed into law by President Bush on July 21, 2004.

Project BioShield enables the Government to develop, procure, and make available countermeasures to chemical, biological, radiological, and nuclear agents for use in a public health emergency that affects national security. Pharmaceutical research and development historically has focused on development of products likely to attract significant commercial interest. Many countermeasures for potential agents of terrorism realistically have no market other than the government and thus have not generated a great deal of manufacturer interest. Because the market for developing countermeasures is speculative, without government interest, private companies have not invested and engaged in developing the countermeasures that the current situation warrants. Project BioShield was intended to provide such an assurance of a

market. I want to acknowledge the important role of this Committee in enactment of Project BioShield and thank you for your continued support of the program.

Project BioShield is a critical part of a broader strategy to defend America against the threat of weapons of mass destruction. It provides HHS with several new authorities to speed the research, development, acquisition, and availability of medical countermeasures to defend against chemical, biological, radiological and nuclear (CBRN) threats. Defending against such threats is a top priority for the Bush Administration and having an appropriate armamentarium of medical countermeasures is a critical element of the response and recovery component of the President's "21<sup>st</sup> Century Strategy for Biodefense." HHS acts to accomplish this mission through integrated efforts of several components, including: research and development at the National Institutes of Health (NIH); regulatory activities related to medical countermeasure development and availability at the Food and Drug Administration (FDA); acquisition of medical countermeasures through the Office of Public Health Emergency Preparedness (OPHEP); and storage and deployment in an emergency by the Centers for Disease Control and Prevention.

### **NIH BioShield Authorities**

HHS's National Institutes of Health (NIH) is assigned the lead role in the research and early development of medical countermeasures to prepare for and respond to CBRN agents and in the conduct of research to expand our understanding of

the human health impact of these agents. The National Institute of Allergy and Infectious Diseases (NIAID) is the NIH institute with primary responsibility for carrying out this assignment. Thus far, NIAID has used Project BioShield authorities to award \$35.6 million in grants and contracts. These awards will promote development of countermeasures toward possible future procurement with Project BioShield funds. Twelve grants and two contracts have been awarded to support research directed against the Category A agents that cause anthrax, smallpox, tularemia, plague, botulism, and viral hemorrhagic fevers. NIAID has awarded 4 grants and 3 contracts to support research on medical countermeasures against radiological or nuclear terrorist attacks, including countermeasures to protect the immune system against radiation and improved treatments for the elimination of internal radionuclide contamination that can be given by mouth rather than intravenously.

### **Medical Countermeasure Acquisition**

The Office of Research and Development Coordination (ORDC) within OPHEP exercises and coordinates the procurement authorities utilizing the Special Reserve Fund authorized under Project BioShield. ORDC works with NIH, CDC, and FDA to coordinate the transitions between medical countermeasures development at NIH, procurement by ORDC, storage and development by CDC, and approval/licensure/clearance by FDA. Prioritization and development of requirements for medical countermeasures acquisition programs is coordinated by the Weapons of Mass Destruction Medical Countermeasures (WMD MCM)

Subcommittee. By defining requirements for medical countermeasures the Subcommittee enables policy makers to identify and evaluate acquisition options to address immediate and future needs.

In setting priorities for medical countermeasure acquisition under Project BioShield, the WMD MCM Subcommittee considers a number of factors. The credibility and immediacy of the specific threats are driving factors and are informed by Material Threat Assessments (MTAs) conducted by the DHS. Other factors include an evaluation of the availability of appropriate countermeasures, both current and projected, and the target population for which the medical countermeasure would be used. In addition, logistical issues are considered such as the feasibility of deployment in a public health emergency, shelf life, and the storage and maintenance requirements.

To date the WMD MCM Subcommittee has defined USG requirements and acquisition options for eight medical countermeasures. These HHS acquisition programs address each of the four threat agents determined to be Material Threats to the U.S. population by DHS [*Bacillus anthracis* (anthrax), smallpox virus, botulinum toxins, and radiological/nuclear agents]. Such agents are determined to present a material threat to the U.S. sufficient to affect national security. HHS has used the Special Reserve Fund (SRF) to award two contracts for vaccines against anthrax, one contract for a liquid formulation of a drug to

protect children from radioactive iodine exposure following nuclear events, and one contract for chelating agents for countering the effects of internal exposure to transuranic radioisotopes.

In addition, negotiations are underway for the acquisition of anthrax therapeutics, and countermeasures to address the blood-related deficiencies associated with acute radiation syndrome. With respect to smallpox vaccines, an award will be made for the manufacture and delivery of up to 20 million doses of a next generation attenuated smallpox vaccine, modified vaccinia Ankara (MVA). Additionally, negotiations are underway for procuring 200,000 doses of botulinum antitoxin.

These countermeasures are being added to the Strategic National Stockpile (SNS) that currently includes vaccines, antibiotics to counter infections caused by anthrax and plague, antitoxins, chemical antidotes and radiation emergency medical countermeasures.

### **Emergency Use Authorization**

Project BioShield thus provides an important tool for the acquisition of safe and effective medical countermeasures, licensed or approved by the FDA for addressing CBRN threat agents. BioShield also recognized however that, should CBRN agents threaten the U.S. before these countermeasures are procured, the American people should be provided access to the best available alternatives.

These could include products that are FDA-approved for a different use or those that have not yet obtained FDA-approval, but for which sufficient safety and efficacy data is available to support their emergency use.

The HHS Secretary delegated the authority to issue “Emergency Use Authorizations” (EUAs) to the FDA Commissioner and to date FDA has issued one EUA. The Deputy Secretary of Defense determined in December 2004 that there was a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax. Based on this determination, then-Secretary Thompson declared an emergency justifying the authorization of the emergency use of anthrax vaccine and in January 2005, the FDA authorized the emergency use of the licensed Anthrax Vaccine Adsorbed (AVA) for the prevention of inhalation anthrax for individuals between 18 and 65 years of age who are deemed by the DoD to be at heightened risk of exposure due to attack with anthrax. As conditions of this authorization, each potential AVA recipient was informed of the benefits and risks of this emergency use of AVA and of their option to refuse or accept AVA administration. The authorization for this emergency use of AVA ended one year from the declaration of the emergency in January 2006.

### **Strategic National Stockpile**

Medical countermeasure availability also requires well-planned stockpile and deployment strategies, and all acquisitions made under Project BioShield include

close consultations with the CDC to ensure these medicines will be rapidly available if needed. CDC operates HHS's Strategic National Stockpile (SNS), which contains large quantities of medicine and medical supplies to protect the American public if there is a public health emergency severe enough to cause local supplies to be inadequate. Once Federal and local authorities agree that the SNS is needed, medicines and medical supplies can be delivered to any State in the U.S. within 12 hours. Consequently, each State is now required to develop plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible in the event of a deployment.

### **Challenges to Implementation**

The experience implementing BioShield over the past 21 months has highlighted a number of issues that make acquisitions under Project BioShield challenging and unique.

For example, while liability issues have not prevented the completion of any countermeasure acquisitions to date, liability protection remains a major source of concern to industry, and a recurring theme in the Project BioShield acquisition process. Therefore, we are pleased that Congress last year passed the "Public Readiness and Emergency Preparedness (PREP) Act" as part of the 2006 Defense Appropriations Act (P.L. 109-148). This legislation included liability protections for manufacturers of security and pandemic countermeasures. We believe this will further create industry interest and progress in this area.

Project BioShield acquisitions have also not drawn the attention of large pharmaceutical or biotechnology firms. The potential payoff for a breakthrough in medical countermeasures against CBRN threats is modest when compared with other drugs. For example, the global market for just one cholesterol-lowering agent exceeds the global market for *all* vaccines together, not just those that comprise a security countermeasure. Additionally, it is estimated that the cost of developing and bringing to market a new drug is between \$800 million and \$1.7 billion.

Smaller companies have been attracted to participate in Project BioShield, which results in an expansion of pharmaceutical manufacturing capacity and expertise. A cost to building this capacity among smaller, less experienced companies, however, requires more intensive technical assistance. Unlike the larger, more experienced pharmaceutical firms, these smaller companies require increased levels of federal government assistance and oversight to meet the requirements of Project BioShield procurement contracts and mitigate the risk of failure. HHS has demonstrated a successful track record of enhancing the infrastructure of smaller, less established biotechnology firms, as evidenced by the HHS acquisition programs completed before Project BioShield. Continued successes will require a sustained commitment of federal resources to ensure proper contract oversight and administration, and to ensure that such less-established contractors meet their regulatory and production milestones as may be contractually required.

Notwithstanding limited Secretarial authority to make payments up to 10 percent of the contract cost, the Project BioShield Act of 2004 provides “that no payment shall be made until delivery has been made of a portion, acceptable to the Secretary, of the total number of units contracted for.” This requirement constitutes a significant risk for small biotechnology firms, in particular, that may not have the necessary financial resources available to support final advanced product development prior to receipt of payment.

Finally, for a countermeasure to be eligible for Project BioShield, solid clinical experience and/or research data must support “a reasonable conclusion that the countermeasure will qualify for [FDA] approval or licensure within eight years after the date of a determination.” Only then is the countermeasure eligible for funding from the \$5.6 billion Special Reserve Fund. Late stage research and development funds that can support advanced product development of potential BioShield candidates before they are BioShield eligible are therefore critical to ensuring a robust pipeline. To address this, HHS has proposed \$160 M for advanced development in the FY07 budget to support promising candidates while shifting risk away from Project BioShield acquisition programs.

### **Future Plans**

We recognize that more can and must be done to aggressively and efficiently implement Project BioShield. Secretary Leavitt has announced his intention to establish a dedicated strategic planning function in HHS that more efficiently

integrates biodefense requirements, across the full range of threat agents, with the execution of advanced development and procurement of medical countermeasures. HHS will assign and empower the Office of Public Health Emergency Preparedness (OPHEP) as the responsible office to develop and implement a strategic plan for this purpose, and will ensure that HHS component programs and functions are properly aligned, and that their respective strengths are leveraged, to support OPHEP's efforts. We will also work closely with other departments and agencies to streamline and make more effective the current BioShield interagency governance process. We will make this process more transparent and work to educate the public and industry about our priorities and opportunities. As part of this, HHS will convene an outreach meeting with these external stakeholders later this year.

As we move forward, we would also like to thank Members of Congress for their interest in improving the BioShield program, and we look forward to continuing to work with you.

## **Conclusions**

During the first 21 months of Project BioShield, HHS has used the provisions of this legislation to initiate major acquisition programs for medical countermeasures to biological and radiological/nuclear threats, to expedite the award of grants and contracts for research to identify and develop medical countermeasures to protect the U.S. population from chemical, biological,

radiological, and nuclear threat agents, and to provide access to the best available medical countermeasures in emergency situations.

Thank you once again for inviting me to testify on our efforts and update you on the Department's plans for the future.

I would be happy to take any questions.