

Project BioShield

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AUGUST 2006 – JULY 2007



United States Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority



Project BioShield Annual Report to Congress

August 2006 – July 2007

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1.0 Executive Summary

The Project BioShield Act of 2004 (Public Law [P.L.] 108-276; Project BioShield), enacted on July 21, 2004, provides the U.S. Department of Health and Human Services (HHS) with authorities to expedite research, development, acquisition, and availability of priority medical countermeasures for public health emergencies caused by terrorist attacks. The \$5.6 billion that became the BioShield Special Reserve Fund (SRF) for the acquisition of medical countermeasures was appropriated in the fall of 2003 (P.L. 108-90; amended in P.L. 108-106). The Project BioShield Act delineates the procedures for using the SRF to procure and stockpile emergency medical countermeasures.

The Pandemic and All-Hazards Preparedness Act (PAHPA; P.L. 109-417), enacted December 19, 2006, amended the Public Health Service Act to provide HHS with additional authorities to facilitate advanced development of medical countermeasures, including the authority to provide milestone payments on Project BioShield contracts. PAHPA clarified the scope of Project BioShield to include countermeasures for biological agents (including organisms that cause an infectious disease) that cause a public health emergency that affects national security. PAHPA established the position of the Assistant Secretary for Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA) to facilitate a broad-based approach to emergency medical countermeasure-related activities. PAHPA also authorized funds for advanced development of medical countermeasures not yet ready for acquisition using the SRF.

Project BioShield stipulates that uses of particular authorities granted to HHS in the law be reported to Congress annually. This document is the annual report of the uses of those authorities for the period from August 2006 through July 2007 (the current reporting period; also including August 1-3, 2007). This report puts that information into the context of the overall HHS public

health preparedness activities addressing both (a) emergencies initiated by human actions, whether intentionally by adversaries or accidentally, and (b) naturally occurring emergencies. The first annual report, the *Project BioShield Annual Report to Congress: July 2004 through July 2006 (2006 BioShield Annual Report)* covered the previous reporting periods.

The required information on the uses of the authorities is summarized in section 6.1 of the report. During the current reporting period, HHS used only one of the Project BioShield authorities subject to required annual reporting—the authority to expedite peer review procedures for research proposals. HHS used this authority to award research grants involving radionuclide decorporation agents and in a Request for Applications (RFA) for research involving medical countermeasures to restore gastrointestinal function after radiation exposure.

The acquisition activities under Project BioShield during the current reporting period were carried out using the regular procedures stipulated in the Federal Acquisition Regulation (FAR), as well as some of the expanded authorities authorized in PAHPA. During this period, no Emergency Use Authorizations (EUAs) were issued by the Commissioner of the U.S. Food and Drug Administration (FDA), because no determination of an emergency warranting such an authorization was made. Similarly, the National Institutes of Health (NIH) did not have cause to use the expedited procurement authority related to increased micropurchase threshold, the authority for personal service contracts, or the streamlined personnel authority.

During the current reporting period, HHS engaged in substantial BioShield-enabled acquisition activities¹ (a) to award a contract for acquisition of Modified Vaccinia Ankara (MVA) smallpox vaccine, using the newly added PAHPA authority to award non-refundable milestone payments, along with the original BioShield

¹ The activities listed here are enabled by Project BioShield, but did not employ the specific authorities of which use is required to

be reported in accordance with the reporting criteria from section 5(a)(1)(A) of the Project BioShield Act.



authority for advance payments refundable to the U.S. Government if the contract terms are not met for final delivery to the Strategic National Stockpile (SNS); (b) to initiate a sole-source acquisition of additional Anthrax Vaccine Adsorbed (AVA); and (c) to pursue acquisition both of recombinant protective antigen (rPA) vaccine for anthrax, and of therapeutics to mitigate or treat neutropenia associated with acute radiation syndrome (ARS).

While proceeding with Project BioShield research, development, and acquisition activities, HHS reorganized the BioShield oversight structure as part of a broader reorganization to advance efforts in research, development, acquisition, deployment, and eventual utilization of emergency medical countermeasures. HHS formed the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) immediately prior to the current reporting period, as described in the *2006 BioShield Annual Report*. In addition, HHS reorganized its offices based on PAHPA, establishing the office of the ASPR and, under the ASPR, the BARDA office. HHS has

established a strategic approach to the medical countermeasure mission, expressed in (a) the *HHS PHEMCE Strategy for Chemical, Biological, Radiological and Nuclear (CBRN) Threats*² (*HHS PHEMCE Strategy*), (b) the *HHS PHEMCE Implementation Plan for CBRN Threats*³ (*HHS PHEMCE Implementation Plan*), and (c) the *Draft BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement*⁴ (*Draft BARDA Strategic Plan*), all of which were released during the current reporting period.

These plans and the ongoing efforts to advance research, development, acquisition, deployment, and preparation for utilization of emergency medical countermeasures are substantial accomplishments associated with Project BioShield during the current reporting period. To ensure these efforts are maximally effective, HHS has fostered involvement by private and public stakeholders in the emergency preparedness process, working to make the process transparent while safeguarding national security.

² *Federal Register*, 20 Mar 2007, Vol. 72, No. 53, pp. 13109-13114

³ *Federal Register*, 23 Apr 2007, Vol. 72, No. 77, pp. 20117-20128;

correction: *Federal Register*, 2 May 2007, Vol. 72, No. 84, p. 24313

⁴ <http://www.hhs.gov/aspr/barda/documents/draftbardaplan.pdf>



2.0 Introduction

U.S. President George W. Bush signs the Project BioShield Act of 2004 on 21 July 2004 in Washington, DC.

2.1 Historical Background

The Project BioShield Act (Public Law [P.L.] 108-276; Project BioShield) was enacted in 2004, as a national effort to prepare for major intentional threats to public health, particularly those posed by terrorists. This effort to increase emergency preparedness complemented others taken following the terrorist attacks on September 11, 2001, and the anthrax attacks in the subsequent months. At the time of these attacks, the primary federal governmental department responsible for public health, the U.S. Department of Health and Human Services (HHS), had five agencies participating in issues related to bioterrorism. Research and development-related issues were handled by the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ). Preparedness-related issues were handled by the Centers for Disease Control and Prevention (CDC) and the Office of Emergency Preparedness (OEP). The Federal Response Plan in place at the time designated HHS

to take the lead role in the medical and public health aspects of responses to emergencies, including major natural or accidental disasters and terrorist attacks. Shortly after the attacks, in November 2001, the Secretary of HHS at the time, Tommy Thompson, appointed Dr. D. A. Henderson as a Special Assistant for Bioterrorism to coordinate efforts against bioterrorism throughout HHS, as head of the newly created Office of Public Health Preparedness (OPHP).⁵ In the years since, HHS has continued to enhance its capability to coordinate and manage public health emergency preparedness.

Figure 1 is a timeline of major events associated with public health preparedness from September 11, 2001, through the current reporting period. The previous report to Congress on Project BioShield, the *Project BioShield Annual Report to Congress: July 2004 through July 2006* (2006 *BioShield Annual Report*) covered the period from the enactment of the Project BioShield Act through July 2006.

⁵ *Federal Register*, 15 Jan 2002, Vol. 67, No. 10, p. 1980

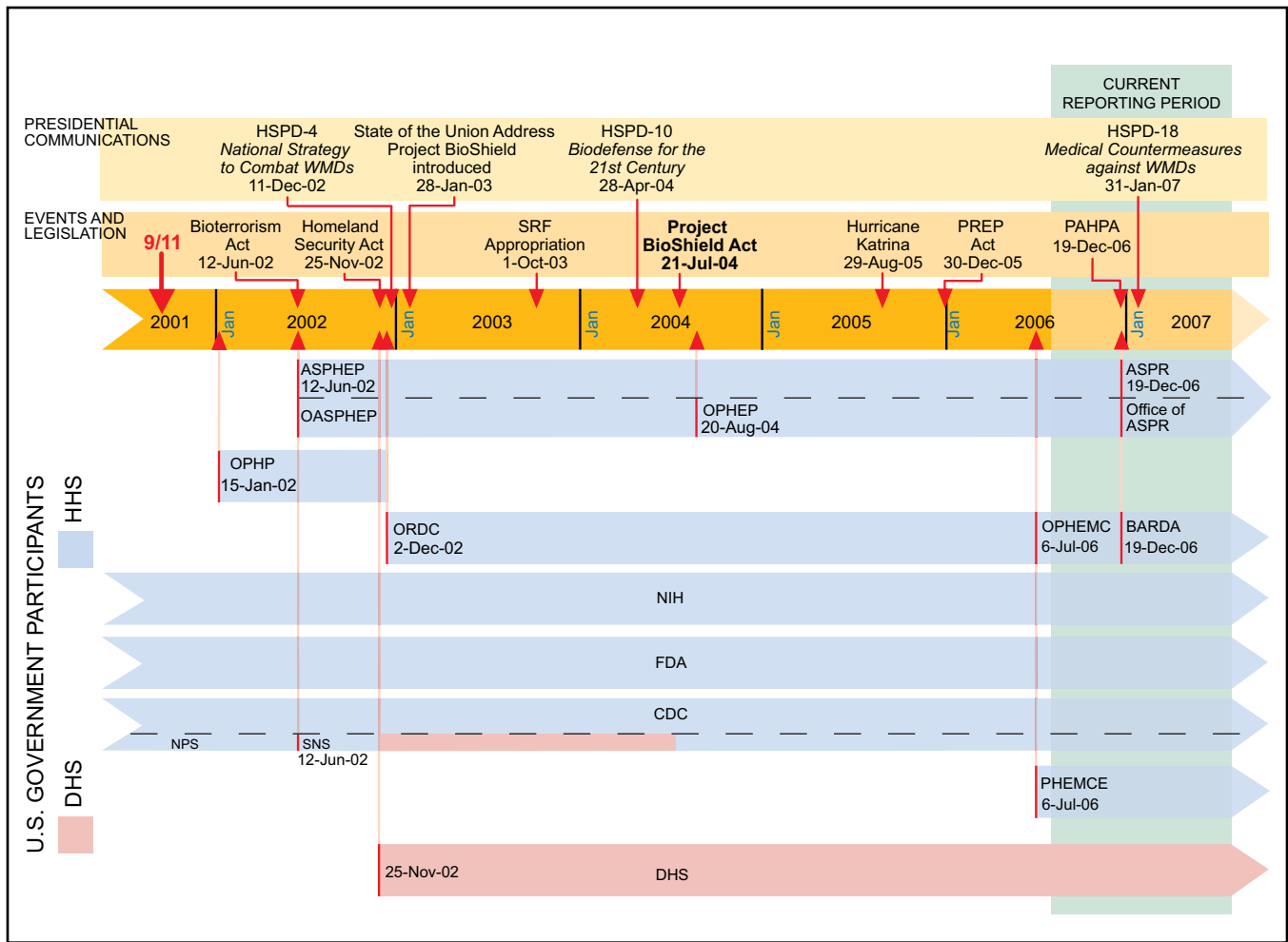


Figure 1. Public health emergency preparedness historical timeline.⁶

The year following the 9/11 attacks, on June 12, 2002, President Bush signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188). Among its key provisions for coordination of public health efforts for emergency response, the law established the Strategic National Stockpile (SNS) to maintain medical countermeasures (as an extension of the previously existing National Pharmaceutical Stockpile [NPS]), and established the position of the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP) to consolidate, in a single office, communication and coordination within the federal government and with state, local, and tribal entities handling public health emergency preparedness. In conjunction with this reorganization, OPHP was subsumed by the Office of the ASPHEP (OASPHEP).⁷

In November 2002 President Bush signed into law the Homeland Security Act (P.L. 107-296), establishing the Department of Homeland Security (DHS) as a cabinet-level department. The SNS was placed under the jurisdiction of DHS, but HHS retained primary responsibility for public health emergency preparedness.

In December 2002 HHS established the Office of Research and Development Coordination (ORDC) as one of several operating divisions under the OASPHEP⁸ (later known as the Office of Public Health Emergency Preparedness, or OPHEP⁹), to coordinate research and development activities for medical countermeasures to pathogenic organisms most likely to be used in bioterrorist attacks against the United States. ORDC was tasked with “working with all scientific agencies of HHS, including NIH, CDC, and FDA, as well as other

⁶ See Appendix C for meanings of acronyms. Dates on the timeline for establishment of positions, offices, and organizations are based on the following conventions: (1) for positions established in legislation and for their respective immediate offices, the dates are the date of enactment of the legislation; (2) for other offices and organizations, the dates are the dates of publication in the *Federal Register* of notice of the offices. The color scheme in this timeline consistent with those in Figures 5 and 7-14, includes these conventions: blue represents

the U.S. Department of Health and Human Services, red represents the U.S. Department of Homeland Security, and yellow represents Presidential authority.

⁷ *Federal Register*, 26 Jul 2002, Vol. 67, No. 144, pp. 48903-48905

⁸ *Federal Register*, 2 Dec 2002, Vol. 67, No. 231, pp. 71568-71570

⁹ *Federal Register*, 20 Aug 2004, Vol. 69, No. 161, pp. 51679-51680

governmental, private, and non-profit scientific entities.” ORDC later became the Office of Public Health Emergency Medical Countermeasures (OPHEMC), and subsequently its functions were subsumed into the Biomedical Advanced Research and Development Authority (BARDA).

In the year and a half after the establishment of ORDC, the President and Congress worked together to institute Project BioShield. President Bush elaborated the approach to combating weapons of mass destruction and principles for the nation’s biodefense in two Homeland Security Presidential Directives (HSPDs): HSPD-4,¹⁰ *National Strategy to Combat Weapons of Mass Destruction* (December 11, 2002¹¹); and HSPD-10, *Biodefense for the 21st Century* (April 28, 2004). President Bush first announced the idea for Project BioShield in his 2003 State of the Union Address.¹² He signed the Project BioShield Act of 2004 (P.L. 108-276) into law on July 21, 2004. Project BioShield aims to foster the research, development, and acquisition of countermeasures to chemical, biological, radiological, and nuclear (CBRN) threats that affect national security. It does so (a) by providing the Secretary of HHS with greater authority and flexibility to facilitate the research and development of biomedical countermeasures; (b) by authorizing the allocation of appropriated funding for the procurement of security countermeasures through a Special Reserve Fund; and (c) by authorizing the emergency use of unapproved drugs, devices, and biologics and the emergency use of approved drugs, devices, and biologics for unapproved indications, when the HHS Secretary declares an emergency justifying such use. Project BioShield transferred the SNS back to the jurisdiction of HHS.

The \$5.6 billion funding for the acquisition of biodefense countermeasures, later designated in the Project BioShield Act as the Special Reserve Fund, was appropriated in the Department of Homeland Security Appropriations Act, 2004 (P.L. 108-90; October 1, 2003), and its purpose was generalized in a subsequent amendment (P.L. 108-106, Sec. 1201; November 6, 2003). During the implementation of Project BioShield, liability concerns were recognized as a stumbling block to robust industry participation. On December 30, 2005, President Bush signed into law the Public Readiness and Emergency Preparedness Act (PREP Act; P.L. 109-148, Division C). This law provides targeted liability protec-

tion for manufacturers and others involved in providing medical countermeasures under defined emergency circumstances in which the countermeasures would be used. This protection was first invoked in December 2006 for countermeasures to pandemic influenza, based on a credible risk that an avian influenza strain would evolve a capability to cause a pandemic of human influenza.¹³

In June and July of 2006, HHS restructured OPHEP,¹⁴ reorganizing ORDC as OPHEMC, and established the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) as a more focused interagency effort among OPHEP, NIH, FDA, and CDC to address the medical countermeasure mission. The reorganization and the structure and mission of the PHEMCE are summarized in the *2006 BioShield Annual Report* and updated in section 3 of this report.

In December 2006, President Bush signed the Pandemic and All-Hazards Preparedness Act (PAHPA; P.L. 109-417). PAHPA established the position and the office of the Assistant Secretary for Preparedness and Response (ASPR), as successors to those of the ASPHER, with expanded responsibilities and authorities. The new authorities provided important new tools for HHS to facilitate advanced development of medical countermeasures, to expedite and further the overall mission of public health emergency preparedness. To coordinate and implement the use of these tools, PAHPA established BARDA, which acquired the duties and responsibilities of the former OPHEMC, as well as the new authorities invested by the statute.

President Bush issued HSPD-18, *Medical Countermeasures Against Weapons of Mass Destruction* (WMDs), on January 31, 2007, expressing the principles for research, development, and acquisition of medical countermeasures, and elaborating associated policy and policy actions.

This report describes the progress that HHS has made in Project BioShield-related activities since the establishment of the PHEMCE and in implementation of the new authorities provided in PAHPA. These initiatives have advanced the implementation of Project BioShield, both in continuing its development and acquisition

¹⁰ Also designated as a National Security Presidential Directive (NSPD), NSPD-17.

¹¹ This is the date of the unclassified version; a classified version is dated September 14, 2002.

¹² <http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html>

¹³ *Federal Register*, 1 Feb 2007, Vol. 72, No. 21, p. 4710

¹⁴ *Federal Register*, 6 Jul 2006, Vol. 71, No. 129, pp. 38403-38405

programs and by integrating it into the strategic approach of the broader efforts to protect the population against adverse effects of any catastrophic events affecting public health. Such events include not only deliberate terrorist or other enemy attacks, but also natural and accidental events and emerging natural diseases.

2.2 Summary of BioShield Authorities and Statutory Reporting Requirements

The Project BioShield Act provided HHS with new authorities to facilitate research, development, acquisition, deployment, and utilization of priority medical countermeasures. Project BioShield requires annual reporting to Congress on specified authorities. These reportable authorities are detailed in Appendix A and summarized below. Section 5 of this report summarizes the process for BioShield acquisitions using the authorities and procedures specified in Project BioShield.

PAHPA amended Project BioShield to clarify that qualified countermeasures covered by Project BioShield research authority include drugs, biological products, or devices that the Secretary of HHS determines to be a priority (a) to diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical agent, or radiological or nuclear agent that may cause a public health emergency affecting national security; or (b) to diagnose, mitigate, prevent, or treat harm due to administering another qualified countermeasure.¹⁵

PAHPA stipulates that the BioShield Special Reserve Fund (SRF) may be used to acquire a countermeasure to a naturally occurring infectious disease or other public health threat only if the countermeasure is deemed to be a national security countermeasure. A national security countermeasure is a qualified drug, biological product, or device that the Secretary of HHS determines to be a priority to address a threat identified by the DHS Secretary as materially affecting national security, expressed in a Material Threat Determination (MTD). HHS efforts to research, develop, acquire, and deploy medical countermeasures for pandemic influenza are funded through appropriations separate from the SRF.¹⁶

PAHPA also amended the payment provisions of Project BioShield to authorize milestone payments of 5% each for achieving specific milestones in product development, up to 50% of the total contract amount, as deemed necessary for success of the contract. These payments would not be subject to refund to the U.S. Government. The original terms of Project BioShield stipulated payment on an acquisition contract only upon delivery of a countermeasure to the SNS, with an exception allowing the Secretary to authorize up to 10% of the contract amount in advance payments if deemed necessary for contract success. The 10% would be subject to refund to the U.S. Government if the contract were not fulfilled through delivery of product to the SNS. This refundable advance payment can still be utilized under Project BioShield as amended by PAHPA, at the discretion of the Secretary of HHS, either along with or separately from the non-refundable milestone payments. A contract utilizing both authorities has been awarded to Bavarian Nordic for acquisition of a new smallpox vaccine (see section 6.2.3).

As required under section 5 (a) of the Project BioShield Act (see Appendix A), this report details the use of the following authorities:

- ***Research and Development of Qualified Medical Countermeasures.*** Section 2 of the Project BioShield Act authorizes the use of a variety of streamlined procedures in awarding grants, contracts, and cooperative agreements relating to the research and development of qualified countermeasures. These streamlined procedures include expedited procurement authority, limited competition, expedited peer review, and increased simplified acquisition thresholds.
- ***Security Countermeasure Procurements and Special Reserve Fund.*** Section 3 of the Project BioShield Act makes available the SRF of \$5.593 billion over 10 years (fiscal year [FY] 2004 through FY 2013) for the procurement of security countermeasures for the SNS. Of that amount, \$3.4 billion may be obligated during FY 2004 through FY 2008. The Project BioShield Act also authorizes the use of simplified acquisition procedures, modified use of other than full and open competition, and the ability to pay premiums in multiple-award contracts.

¹⁵ Pandemic and All-Hazards Preparedness Act (P.L. 109-417), section 403, Clarification of countermeasures covered by Project BioShield.

¹⁶ U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 (P.L. 110-28); and Labor, Health and Human Services, Education and Related Agencies

Appropriations Act of 2006 (P.L. 109-149); Department of Defense Appropriations Act of 2006 (P.L. 109-148); Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005 (P.L. 109-13).



- ***Emergency Use Authorization for Medical Countermeasures.*** Section 4 of the Project BioShield Act allows the Secretary of HHS to authorize the introduction into interstate commerce of a drug, device, or biological product that has not been approved, cleared, or licensed by the FDA, or that has been approved, cleared, or licensed by FDA for another indication, when an emergency has been declared by the Secretary of HHS justifying such use; the Secretary has delegated to the FDA Commissioner the authority to authorize such interstate commerce.

As required by the Project BioShield Act, the description in this report of the use of each authority includes

- the particular actions taken under each authority, including the identification of the threat agent, emergency, or the medical countermeasure;
- the reasons underlying the use of each authority, including the options considered;
- the number and nature of persons and entities receiving a grant, cooperative agreement, or contract and the number of those persons or entities rejected;
- whether each security countermeasure acquisition approved by the President resulted in a contract

that was entered into within one year of presidential approval (the President has delegated to the Director of the Office of Management and Budget [OMB] the authority to approve acquisitions).

Also as required, this report provides a separate summary of activities relating to the use for research and development of (a) the increased micropurchase threshold, (b) authority for personal services contracts, and (c) streamlined personnel authority for NIH positions.

2.3 Scope of This Report

This report fulfills the requirement to report to Congress annually on specified authorities in the Project BioShield Act. This report covers the period from August 1, 2006, through July 2007 (the current reporting period) and also includes the first three days of August 2007, during which the Enterprise Stakeholders Workshop and BARDA Industry Day were held. While the report has been in preparation, additional BioShield-related activities have occurred. Where pertinent, notations have been included for actions expected after the current reporting period;¹⁷ activity in the next year beyond the current reporting period will be included in next year's report.

In addition to providing the required reports, the Department takes this opportunity to place the uses of its authorities in the context of a broader view of its activities in support of and surrounding public health emergency medical countermeasure preparedness. As noted above, these activities have been integrated with broader preparedness efforts, both by the statutory broadening of the scope of Project BioShield itself and by integrating Project BioShield into an expanded inter-agency organizational structure for public health emergency preparedness.

Many of the major efforts of the Department during the current reporting period have focused on enhancing the organizational and strategic foundation for effective future work, as well as maintaining the progress and activities necessary for development and acquisition of medical countermeasures during the restructuring period. The foundation-building has included both administrative restructuring and the development and publication of strategic and implementation plans.

¹⁷ When an anticipated event has occurred before the end of December 2007, the event is noted in a footnote.



3.0 Management/Organizational Structure and Process

3.1 The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

A critical mission for HHS is the timely and coordinated research, development, regulation, acquisition, stockpiling, maintenance, deployment, and provision for utilization of medical countermeasures for public health emergencies following naturally occurring, deliberately induced, or accidental events. To lead this effort, HHS established the PHEMCE in July 2006. The mission of the PHEMCE is

1. to define and prioritize requirements for public health emergency medical countermeasures;
2. to integrate and coordinate research, early and late stage product development, and procurement activities addressing the requirements;
3. to set deployment and use strategies for medical countermeasures held in the SNS.

The PHEMCE is a coordinated, interagency effort led by the ASPR; it includes three HHS internal agencies, NIH, FDA, and CDC, as well as ex officio participation

of other HHS agencies and Federal interagency partners, particularly DHS, the Department of Defense (DOD), and the the Department of Veterans Affairs (VA). BARDA (previously OPHEMC) manages PHEMCE operations in support of this mission.

Figure 2 represents the overall organizational structure of the PHEMCE. Extensive collaboration among multiple HHS agencies is critical to Project BioShield success, as well as to the success of the broader PHEMCE mission. NIH, CDC, and FDA join the ASPR in leading the PHEMCE for HHS. Each agency has particular expertise that it brings to bear in support of the PHEMCE mission and Project BioShield.

The general functions of the ASPR and BARDA are described in the next section, as are other offices operating under the ASPR. Briefly, the ASPR directs and coordinates HHS efforts on behalf of the Secretary to execute preparedness and response programs to address natural, intentional, or accidental public health emergencies, and coordinates such activities with other Departments and Agencies. Consistent with PAHPA, the ASPR specifically oversees and contributes to execution

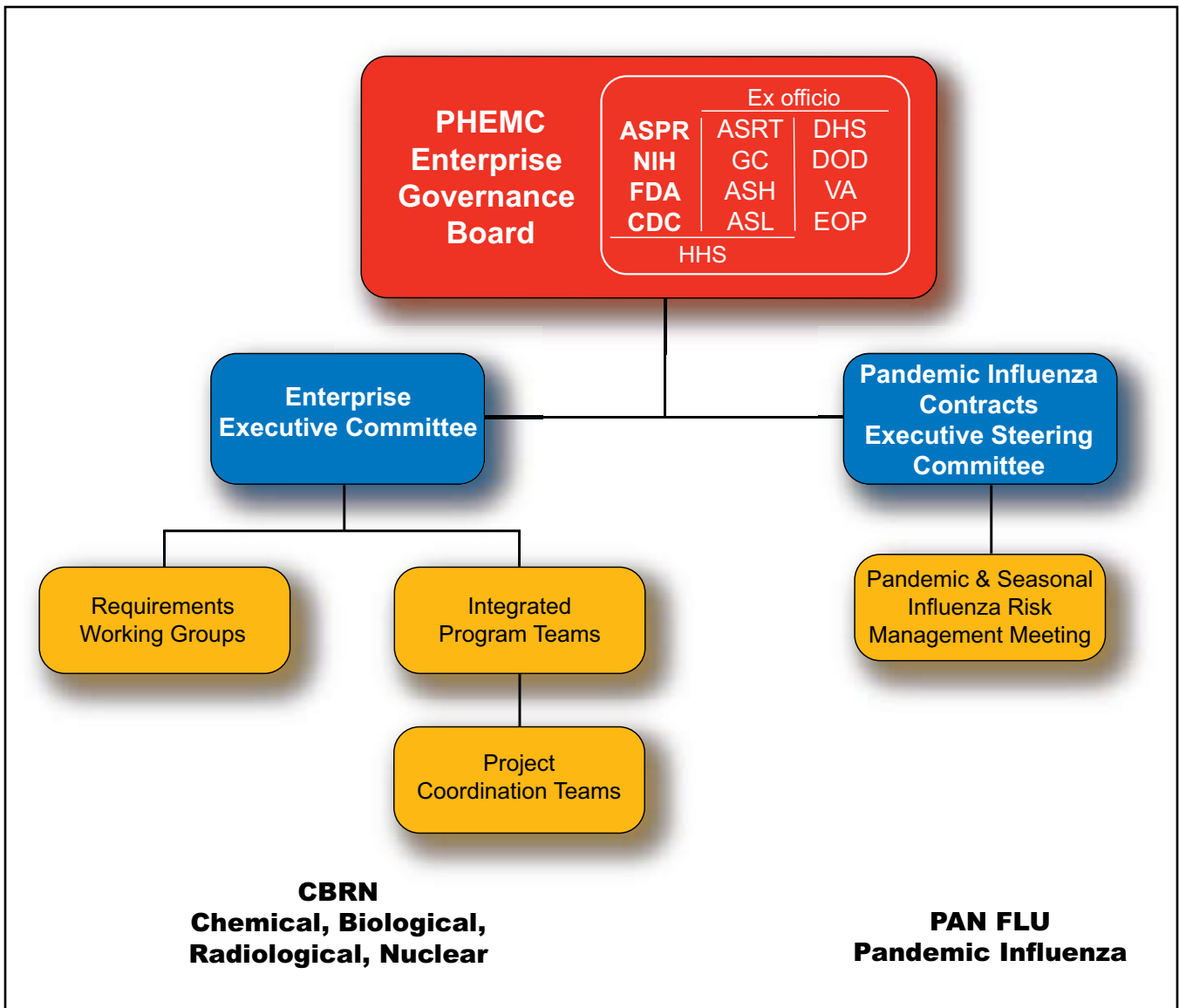


Figure 2. PHEMCE organizational structure. See Appendix C for meanings of acronyms.

of advanced research, development, and procurement of qualified medical countermeasures as well as pandemic or epidemic products. The PHEMCE is the coordinated interagency effort by which the ASPR accomplishes this. BARDA, under the ASPR, manages PHEMCE operations as a vehicle for prioritizing and coordinating the research, development, acquisition, and availability of appropriate medical countermeasures against weapons of mass destruction and for other public health emergencies.

NIH is the lead agency within HHS for conducting and supporting biomedical and behavioral research related to causes, diagnosis, treatment, control, and prevention of human diseases, disorders, and impairments. Within this mission, NIH supports research and development of medical countermeasures to provide a pipeline leading to safe and effective products eligible for Project BioShield acquisition. BARDA works closely with NIH to ensure

a seamless transition from basic research to advanced research and development programs in support of PHEMCE medical countermeasure priorities.

FDA provides regulatory guidance and oversight for medical product development, approval, and post-marketing activities. FDA is charged with ensuring the safety and effectiveness of medical countermeasures, including drugs, biologics (vaccines), and devices, and plays a vital role in product development, post-marketing surveillance, and technical support for countermeasures development, such as guidance to support the development of assays and animal models. The FDA Commissioner, under authority delegated from the Secretary of HHS, may authorize emergency use of medical countermeasures not yet approved for the particular use, when the HHS Secretary declares an emergency justifying the authorization. In the context of the PHEMCE, BARDA and FDA encourage interested persons or contractors to

contact the FDA to obtain guidance regarding the approval, licensure, clearance, or emergency use of medical countermeasures that are or may be included in the SNS.

CDC leads public health surveillance, and its Division of the Strategic National Stockpile (DSNS) operates the Department's SNS—the stockpile that contains substantial quantities of medicines and medical supplies to protect the American public in the event of a public health emergency severe enough that local supplies would not be adequate. CDC also provides critical input for determining the required product characteristics that consider both stockpiling needs and effective deployment and utilization strategies. BARDA, in support of the ASPR and the PHEMCE, works closely with the CDC to establish and annually review the contents of the SNS.

The Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Governance Board (hereafter the Enterprise Governance Board) serves as the primary conduit for communication among Federal entities involved in medical countermeasure development, acquisition, and deployment, and oversees the PHEMC Enterprise. The Enterprise Governance Board succeeded the Weapons of Mass Destruction Medical Countermeasures Subcommittee as the group that oversees requirements and priority-setting regarding emergency medical countermeasures for the civilian population. The structure of that Subcommittee was described in the *2006 BioShield Annual Report*. As illustrated in Figure 2, the Enterprise Governance Board is chaired by the ASPR and includes the heads of NIH, FDA, and CDC within HHS, as well as ex officio, non-voting representatives from other agencies of HHS and from DHS, DOD, the VA, and the Executive Office of the President (EOP). The Enterprise Governance Board is advised by the Enterprise Executive Committee, addressing CBRN threats, and by the Pandemic Influenza Contracts Executive Steering Committee. These two committees are supported by multiple subgroups that include subject matter and policy experts from across the Federal government.

For CBRN threats, Requirements Working Groups establish the medical countermeasure requirements to



address chemical, biological, and radiological/nuclear threats, and blood and tissue needs (particularly for radiological/nuclear events). Integrated Program Teams construct the PHEMCE plans that guide the development and coordination of the research, development, acquisition, storage, and deployment activities needed to fulfill these requirements, in a manner consistent with the policies, strategies, and implementation plans put in place by the Enterprise Governance Board. Project Coordination Teams are responsible for the establishment and daily management of specific research, development, or acquisition contracts, from the issuing of Requests for Applications (RFAs), Broad Agency Announcements (BAAs), or Requests for Proposals (RFPs) through contract award and project fulfillment.

The Pandemic and Seasonal Influenza Risk Management Meeting group and its subgroups fulfill the same functions for the threat posed by influenza. The group addresses risk management issues related to the development, acquisition, deployment, and utilization of medical and public health countermeasures for pandemic and seasonal influenza.

During its first year in operation, the PHEMCE has

- hosted Stakeholders Workshops in September 2006 and July-August 2007;
- published the *HHS PHEMCE Strategy for CBRN Threats*¹⁸ (*HHS PHEMCE Strategy*), which incorporated individual stakeholder feedback gathered through the 2006 Stakeholders Workshop and comments received in response to a corresponding *Federal Register* notice;¹⁹
- published the first *HHS PHEMCE Implementation Plan for CBRN Threats*²⁰ (*HHS PHEMCE Implementation Plan*);
- issued two Sources Sought Notices and awarded one BioShield acquisition contract using the BioShield Special Reserve Fund to pursue the near-term medical countermeasure priority acquisitions detailed in the *HHS PHEMCE Implementation Plan* (see section 6.1, Table 4).

¹⁸ *Federal Register*, 20 Mar 2007, Vol. 72, No. 53, pp. 13109-13114

¹⁹ *Federal Register*, 8 Sep 2006, Vol. 71, No. 174, pp. 53097-53102

²⁰ *Federal Register*, 23 Apr 2007, Vol. 72, No. 77, pp. 20117-20128; correction in *Federal Register*, 2 May 2007, Vol. 72, No. 84, p. 24313

Although the Project BioShield SRF is not used to develop or acquire medical countermeasures for pandemic influenza, pursuit of priority vaccines and drugs to address this threat is an important part of the PHEMCE mission. Using pandemic influenza resources (non-BioShield funding), HHS awarded contracts for programs including (a) the advanced development of pandemic influenza vaccines using adjuvants (to potentially add potency to the current vaccines, thus extending a limited vaccine supply to be available to more people); (b) retrofitting existing domestic vaccine manufacturing facilities to provide additional capacity for manufacturing pandemic influenza vaccines; and (c) the advanced development and domestic industrialization of new influenza antiviral drugs. In addition, pandemic influenza funding has been used for purchases of pandemic influenza vaccines and antiviral drugs. The pandemic influenza program issues update reports on its program periodically, available at <http://www.pandemicflu.gov/plan/federal>, through the link for “U.S. Department of Health & Human Services Activities.”

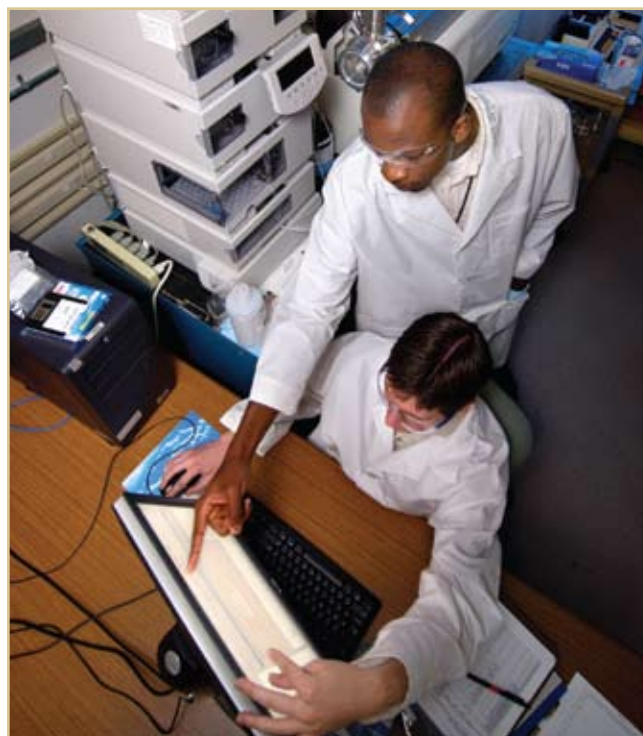
3.2 ASPR and BARDA

PAHPA established the position and office of the ASPR, as a successor to the position and office of the ASPHEP. The ASPR is to “[s]erve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies.” The ASPR’s duties include, among others, overseeing advanced research, development, and procurement of qualified countermeasures and qualified pandemic or epidemic products; coordinating public health emergency response activities with other Federal officials and with state, local, and tribal officials; and providing “leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response.”²¹

The main organizational structure under the Office of the ASPR is illustrated in Figure 3, including the functions within BARDA. The Immediate Office of the ASPR oversees the work of several offices supporting the nation’s public health preparedness and response: the Office of Preparedness and Emergency Operations (OPEO); the Office of Medicine, Science, and Public Health (OMSPH); the Office of Policy and Strategic Planning (OPSP); and BARDA. The functions of these four offices are described in the *2006 BioShield Annual Report*, in the

section regarding the restructuring of OPHEP, with the exception that since that report, under PAHPA, the ASPR has taken over the functions of the ASPHEP, and BARDA has taken over the functions of OPHEMC.

Each of the offices under the Immediate Office of the ASPR has functions relating to public health emergency preparedness and the mission of the PHEMCE. Briefly, OPSP is responsible for policy formulation, analysis, coordination, and evaluation for preparedness, response, and strategic planning. OPEO supports the federal elements of public health emergency response, in particular the National Disaster Medical System, and develops operational plans and analytical products. OPEO coordinates with CDC to determine the deployment and utilization strategies for the SNS contents. OMSPH provides leadership, coordination, and subject matter expertise on medical, scientific, research, and public health aspects of emergency preparedness and response, including coordinating international activities and the ASPR’s overall pandemic influenza efforts. OMSPH oversees the development of medical policies related to providing access to medical products, includ-



ing those needed on an emergency basis. These policies and their implementation include the use of products under Investigational New Drug applications (INDs), Investigational Device Exemptions (IDEs), and/or Emergency Use Authorization (EUA) under the Federal Food, Drug, and Cosmetic Act.

²¹PAHPA (P.L. 109-417; December 19, 2006)

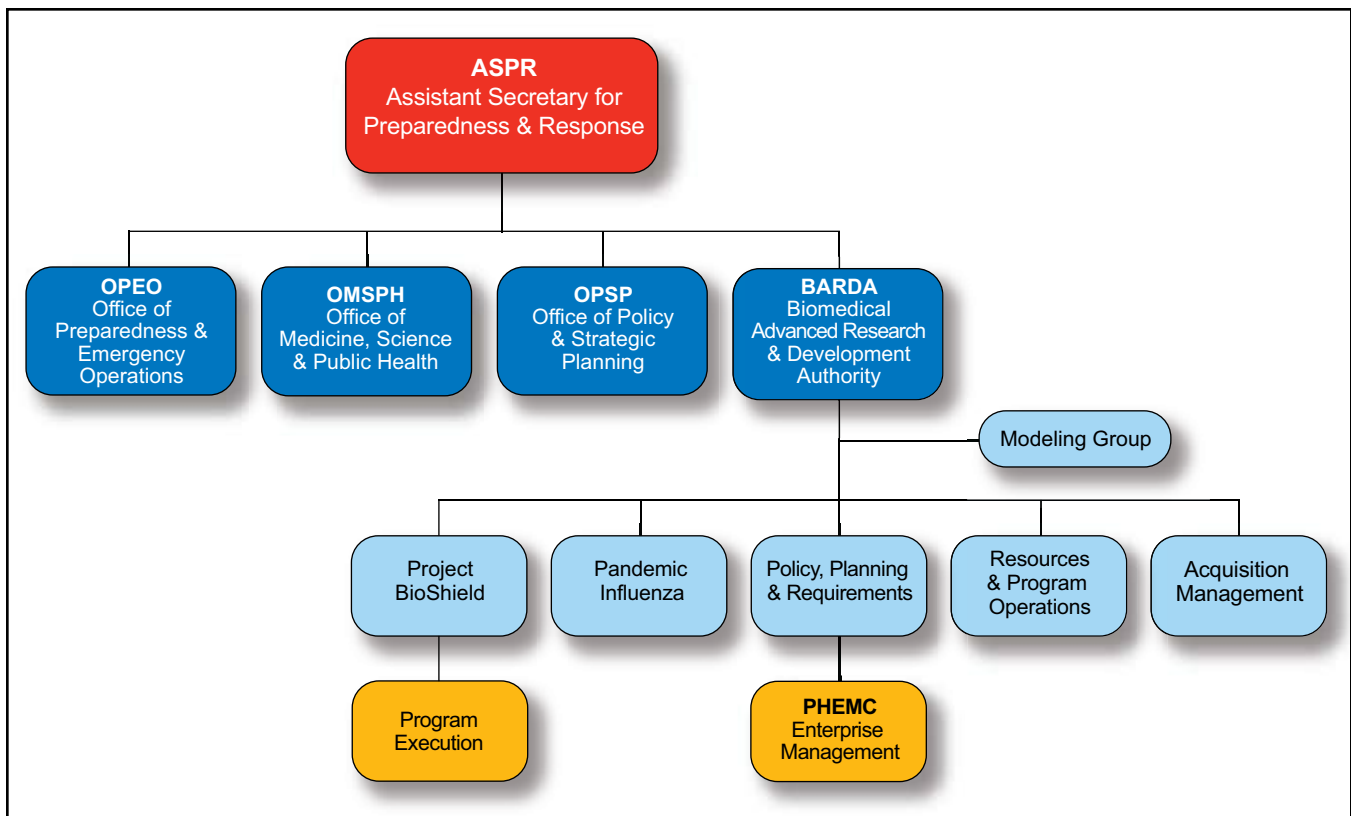


Figure 3. ASPR/BARDA organizational structure.

PAHPA established BARDA as the focal point within HHS for the advanced development and acquisition of medical countermeasures to protect the American civilian population against CBRN and naturally occurring emergency threats to public health. BARDA functions under the authority of the ASPR, and BARDA's Director reports to the ASPR. The BARDA office manages the advanced development of medical countermeasures for CBRN agents; the acquisition of medical countermeasures for CBRN agents under Project BioShield; and the advanced development and procurement of medical countermeasures for pandemic influenza and other emerging infectious diseases that fall outside the auspices of Project BioShield. As illustrated in Figure 3, in addition to offices dedicated to managing these two major projects, BARDA has offices dedicated to (a) Policy, Planning, and Requirements (PP&R), (b) Resources and Program Operations (RPO), (c) Acquisition Management (which includes Contracting and Grants, Regulatory Affairs, and Quality Systems support groups), and (d) Modeling. The advanced research and development authorities granted by PAHPA enable BARDA to address the funding gap²² between early stages of product

development and the acquisition of medical countermeasures for the SNS.

**HHS,
through
BARDA, has built
strong management
controls for Project
BioShield.**

Under the leadership of the ASPR, BARDA manages the PHEMCE (see section 3.1). BARDA organizes and coordinates the operations of the PHEMC Enterprise, its Enterprise Governance Board, its Executive Committee, and the supporting subgroups. To assist the PHEMCE in determining medical countermeasure requirements and effective deployment strategies, BARDA conducts medical and public health consequence modeling of population exposures for potential public health emergencies. BARDA also fosters innovation and promotes strategic initiatives, such as the development of rapid diagnostics, broad-spectrum antimicrobials, and next-generation vaccine manufacturing technologies.

HHS, through BARDA, has built strong management controls for Project BioShield, including an acquisition management system to maximize control, transparency, and accountability in all acquisition decisions and in the evaluation of contractor performance (described in section 5.3). These controls ensure sound stewardship of public dollars through defined processes and decision points.

²²Sometimes referred to as the "valley of death."



4.0 Strategic Planning and Implementation

During Project BioShield's first two years of implementation, its acquisitions were guided by requirements derived from interagency deliberations in 2003 that involved Cabinet-level Departments and the Executive Office of the President. Under this initial strategy, HHS pursued acquisitions for those highest-priority threats for which candidate products were at relatively advanced stages of development, providing opportunities to have a significant impact on preparedness quickly, with limited risk and cost. These products included medical countermeasures for anthrax, smallpox, botulinum toxins, and radiological/nuclear agents — the four categories of threat agents initially determined by the DHS to pose a material threat to national security, with Material Threat Determinations (MTDs) issued for each.

Past acquisitions have resulted in an armamentarium of medical countermeasures in the SNS that provide a substantial preparedness level.

HHS recognizes that these past acquisitions have resulted in an armamentarium of medical countermeasures in the SNS that provide a substantial preparedness level for a number of CBRN threats. HHS also recognizes that, while achieving preparedness is essential, maintaining and advancing preparedness is equally important. A range of activities and rigorous priority-setting are required to develop and acquire the critical medical countermeasures needed to address the thirteen DHS-identified material threats (plus volatile nerve agents), as well as those that will be needed for future threats. The strategies HHS will follow for these activities, and the attendant priorities, are outlined in the *HHS PHEMCE Strategy*, the *HHS PHEMCE Implementation Plan*, and the *Draft BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement (Draft BARDA Strategic Plan)*.

4.1 The HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan for Chemical, Biological, Radiological and Nuclear (CBRN) Threats

The PHEMCE took a holistic, end-to-end approach to consider multiple aspects of the medical countermeasure mission, including research, development, acquisition, storage, maintenance, deployment, and guidance for utilization. Phase 1 of this approach established the *HHS PHEMCE Strategy*. Specifically, the PHEMCE evaluated three possible strategic approaches to medical countermeasure development and acquisition during the priority-setting process. The first option was to focus only on a single, highest-priority threat. In line with this option, all available acquisition dollars would be spent trying to fully address the requirements for this one agent with the aim of eliminating it as a material threat to national security. The second option was to divide the available resources equally among the fourteen identified threats. The third option, and the approach that the PHEMCE ultimately pursued, was to prioritize strategic policy decisions that would most effectively improve overall public health preparedness for known and as-yet unknown threats. The September 2006 BioShield Stakeholders Workshop (described in section 7.2.2.1 of this report) brought together public and private stakeholders from all aspects of the mission to discuss this decision framework and approach for the *HHS PHEMCE Strategy*. The valuable input solicited from stakeholders at the Workshop, combined with the responses received to the medical countermeasures Request for Information (RFI) issued in October 2006 and comments on the draft *HHS PHEMCE Strategy* solicited through the *Federal Register*,²³ was incorporated into the final *HHS PHEMCE Strategy*.²⁴

Published in the *Federal Register* on March 20, 2007,²⁵ the *HHS PHEMCE Strategy* describes a framework of strategic policy goals and objectives for identifying medical countermeasure requirements and establishing priorities for medical countermeasure evaluation, development, and acquisition for CBRN threats. These

strategic policy goals and objectives were subsequently used to establish the *HHS PHEMCE Implementation Plan*.²⁶ Both the *HHS PHEMCE Strategy* and the *HHS PHEMCE Implementation Plan* are consistent with and aligned with two HSPDs concerning biodefense and medical countermeasures, *Biodefense for the 21st Century* (HSPD-10; April 28, 2004)²⁷ and *Medical Countermeasures against Weapons of Mass Destruction* (HSPD-18, January 31, 2007).²⁸

Published in the *Federal Register* on April 23, 2007,²⁹ the *HHS PHEMCE Implementation Plan* addresses medical countermeasure needs for twelve biological threat agents, a class of chemical threats (volatile nerve agents), and radiological and nuclear threats. (The *HHS PHEMCE Implementation Plan* excludes pandemic influenza, which is addressed in the *HHS Pandemic Influenza Plan*.³⁰) The *HHS PHEMCE Implementation Plan* identifies the top-priority medical countermeasure research, development, acquisition, storage, maintenance, deployment, and utilization programs that HHS has determined, in collaboration with interagency partners, to have the greatest potential to improve public health emergency preparedness for these fourteen threats. Table 1 summarizes the top-priority threats and the corresponding projected future top-priority medical countermeasure acquisition programs, along with the current Project BioShield medical countermeasure acquisition programs. The DHS has issued MTDs (explained in section 5.1 and Figure 5) for 13 of the 14 listed threats (all except volatile nerve agents; dates of issue are summarized in Figure 15 in the Conclusion [section 8] of this report) and Population Threat Assessments (PTAs; previously Material Threat Assessments, MTAs) for 13 of them (all except smallpox). PTAs estimate the potential magnitude and severity of the threats to the U.S. population.

Of particular interest for the purposes of this report are the medical countermeasure procurements and acquisitions that will utilize either the funds of the DSNS or the funds remaining in the BioShield SRF. Table 2 displays the proposed near-term (FY 2007-08) and mid-term (FY 2009-13) procurements and acquisitions for the top-priority medical countermeasure programs called out in the *HHS PHEMCE Implementation Plan*, along with the

²³ *Federal Register*, 8 Sep 2006, Vol. 71, No. 174, pp. 53097-53102

²⁴ *Federal Register*, 20 Mar 2007, Vol. 72, No. 53, pp. 13109-13114

²⁵ *Federal Register*, 20 Mar 2007, Vol. 72, No. 53, pp. 13109-13114

²⁶ *Federal Register*, 23 Apr 2007, Vol. 72, No. 77, pp. 20117-20128; correction: *Federal Register*, 2 May 2007, Vol. 72, No. 84, p. 24313

²⁷ <http://www.whitehouse.gov/homeland/20040430.html>

²⁸ <http://www.whitehouse.gov/news/releases/2007/02/20070207-2.html>

²⁹ *Federal Register*, 23 Apr 2007, Vol. 72, No. 77, pp. 20117-20128; correction: *Federal Register*, 2 May 2007, Vol. 72, No. 84, p. 24313

³⁰ <http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>

	THREAT	DISEASE	CURRENT PROJECT BIOSHIELD ACQUISITION PROGRAMS	Projected future top-priority medical countermeasure programs		
				THREAT-SPECIFIC PROGRAMS	BROAD-SPECTRUM ANTIBIOTIC (B) ANTIVIRAL (V)	DIAGNOSTIC(D) BIODOSIMETRY OR BIOSASSAY (B)
Chem	Volatile nerve agents	Nerve agent toxicity		Enterprise CHEMPACKs Volatile nerve agent-single antidote		
Biological	<i>Bacillus anthracis</i> (bacteria), including multi-drug-resistant strains	Anthrax	Anthrax therapeutics (antitoxins) Anthrax vaccine (AVA, rPA)	Anthrax antitoxin(s) Anthrax vaccine(s) (next-gen)	B	D
	Botulinum toxins (from <i>Clostridium botulinum</i> bacteria)	Botulism	Botulinum antitoxin			D
	<i>Burkholderia mallei</i> <i>Burkholderia pseudomallei</i> (bacteria)	Glanders Meliodosis			B	D
	Filoviruses Ebola and Marburg	Hemorrhagic fever		Filovirus medical countermeasures	V	D
	<i>Francisella tularensis</i> (bacteria)	Tularemia			B	D
	Junin virus	Argentine hemorrhagic fever			V	D
	<i>Rickettsia prowazekii</i> (bacteria)	Typhus			B	D
	Variola virus	Smallpox	MVA smallpox vaccine	Smallpox antiviral(s) Smallpox vaccine (next-gen)	V	D
	<i>Yersinia pestis</i> (bacteria)	Bubonic plague			B	D
Rad/ Nuc	Radiological/nuclear agents	ARS, DEARE, various	Pediatric KI DTPA ARS medical countermeasures	Radionuclide-specific agents/ decorporation agents ARS/DEARE medical countermeasures		B

Table 1. Top-priority CBRN threats and medical countermeasure acquisition programs, current (Project BioShield) and projected for the future. Letter abbreviations defined in column headings; see Appendix C for meanings of acronyms.

proposed funding source and level for each. Although this table focuses on the acquisitions, HHS recognizes that numerous efforts both before and after the initial procurements are required to ensure the successful development, maintenance, and utilization of these medical countermeasures.

Improving public health preparedness is an ongoing process as science advances, innovations mature, and the threat scope changes. To achieve this goal, HHS resources beyond the Project BioShield SRF, which expires in FY 2013, will continue to be strategically invested in programs throughout the medical countermeasure development and acquisition pipeline. HHS anticipates that targets for the timeframe beyond FY 2013 will be articulated with increasing clarity and granularity with each biennial revision of the *HHS PHEMCE Implementation Plan*.

4.2 The Draft Biomedical Advanced Research and Development Authority (BARDA) Strategic Plan for Medical Countermeasure Research, Development, and Procurement

BARDA published the *Draft BARDA Strategic Plan*³¹ on July 5, 2007, to guide and facilitate research, development, innovation, and procurement of medical countermeasures. A final *BARDA Strategic Plan* will be released after the appointment of the BARDA Director.

The *Draft BARDA Strategic Plan* describes BARDA's approach and systems to encourage and facilitate the development and acquisition of medical countermeasures, including vaccines, therapeutics, and diagnostics. As depicted in Figure 4, substantial funding sources

³¹ <http://www.hhs.gov/aspr/barda/documents/draftbardaplan.pdf>

	Near-Term FY 2007-2008		Mid-Term FY 2009-2013	
	Funding Source	Funding Level ^a	Funding Source	Funding Level ^{a,b}
BIOLOGICAL THREATS				
Diagnostics			SRF	+
Broad-spectrum antibiotic(s)	DSNS	+	DSNS SRF	+ ++
Anthrax antitoxin(s)			SRF	++
Anthrax vaccine(s)	SRF	++		
Filovirus medical countermeasures			SRF	++
Smallpox antiviral(s)			SRF	+
Smallpox vaccine	SRF	++		
RADIOLOGICAL/NUCLEAR THREATS				
ARS/DEARE medical countermeasures	SRF	++	SRF	++
Biodosimetry, bioassay			SRF*	+
Radionuclide-specific agent(s)			SRF	+
CHEMICAL THREATS				
Enterprise CHEMPACKS			DSNS	++
KEY				
<p>DSNS Anticipated to be funded through the CDC Division of the Strategic National Stockpile budget, pending availability of funds.</p> <p>SRF Anticipated Project BioShield Special Reserve Fund acquisition with remaining available funds.</p> <p>SRF* Although the diagnostic portion of this requirement may be funded through the Project BioShield Special Reserve Fund, appropriate funding to establish the network of biodosimetry and radionuclide bioassay laboratories is yet to be determined.</p> <p>+ Currently estimated to be less than or equal to \$100 million^c</p> <p>++ Currently estimated to be greater than \$100 million^c</p>				
<p>^a Funding is cumulative within the time period indicated.</p> <p>^b Uncertainties in funding support throughout the pipeline in the mid-term preclude making more definitive projections.</p> <p>^c These estimates are not final. Funding levels are subject to change.</p>				

Table 2. Proposed procurements and acquisitions of top-priority medical countermeasures for CBRN threats.

are available for research and early stages of product development and for the later stages leading to and culminating in acquisition of approved or approvable medical countermeasures for the SNS, including Project BioShield acquisitions. Using its advanced research and development authorities (see related discussion of the Pandemic and All-Hazards Preparedness Act in sections 2.2 and 5.6), BARDA, working with the private sector, will strengthen HHS efforts to bridge the funding gap between research and acquisition.

BARDA's path forward is guided by four strategic goals:

- Goal 1. BARDA will align with and coordinate the execution of the medical countermeasure goals articulated in the *HHS Pandemic Influenza Plan*.
- Goal 2. BARDA will align with and coordinate the execution of the medical countermeasure goals articulated in the *HHS PHEMCE Strategy*.

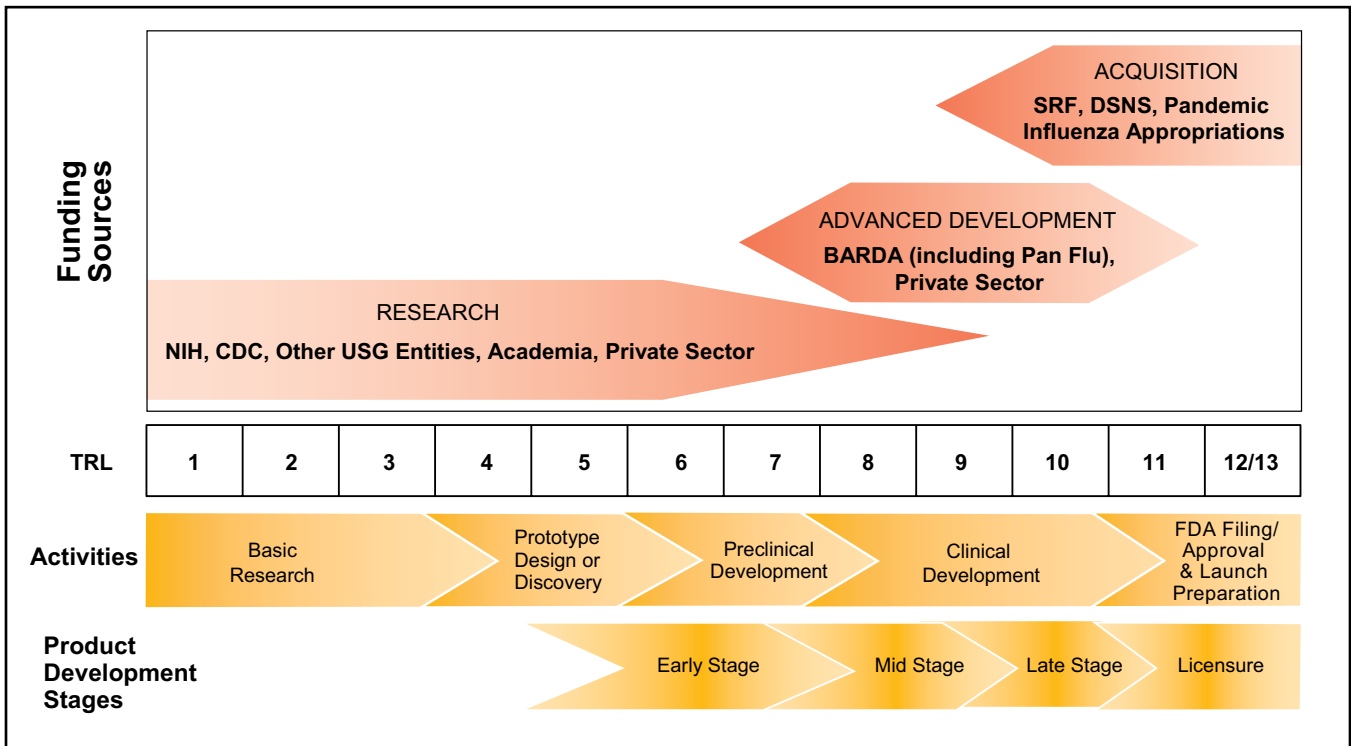
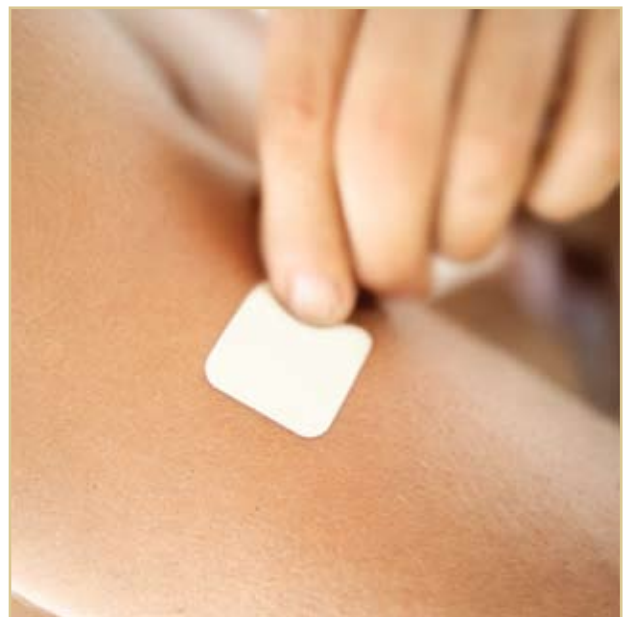


Figure 4. Funding sources for three major stages of medical countermeasure development, associated with 13 Technology Readiness Levels (TRLs),³² and the corresponding activities and product development stages.

- Goal 3. BARDA, in concert with federal partners, will create a road map for execution of the *HHS PHEMCE Implementation Plan*.
- Goal 4. BARDA, in concert with federal partners, will establish programs that promote innovation in medical countermeasure development.

and procurement support is available through the SRF, assets of the DSNS, and appropriations for pandemic influenza medical countermeasures.

As described in the *Draft BARDA Strategic Plan*, BARDA was created to foster advanced research and development and to help coordinate more centrally, in conjunction with the ASPR and the PHEMCE, the U.S. Government’s medical countermeasure development and acquisition process. HHS now has a comprehensive, end-to-end process to facilitate the successful development, procurement, and availability of medical countermeasures to increase public health preparedness for responding to CBRN threats and emerging infectious diseases, including pandemic influenza. NIH basic research and development programs are dedicated to the earliest stages; the newly established BARDA advanced development funding mechanism is designed to address mid-stage and late-stage development; and acquisition



³²TRLs, to serve as an index of the stage of technological development of medical countermeasures, have been under development, as described in the *Draft BARDA Strategic Plan*.



5.0 Project BioShield Process and Funding

The Project BioShield Act charges the HHS Secretary, in collaboration with other federal agencies, to develop and provide medical countermeasures to protect the civilian population from CBRN threats to public health. HHS has implemented Project BioShield to accelerate research, development, purchase, and availability of priority security countermeasures for CBRN threats.

The process leading to Project BioShield funding using the SRF and how this process fits into the larger scope of PHEMCE CBRN medical countermeasure activities are illustrated in Figure 5. The process is outlined for the setting of requirements and for funding during the three major phases of countermeasure development and/or acquisition (depicted also in Figure 4 of section 4 of this report): research, advanced development, and acquisition. Several critical activities support the Project BioShield development and acquisition process, including

- identification of threats;
- determination of potential medical and public health consequences of the threats;
- determination of medical countermeasure requirements in light of the potential consequences;
- prioritization of the requirements to facilitate appropriately balanced investment of the available funds.

5.1 Project BioShield: Requirements for SRF Acquisition

Release of funds from the SRF is subject to interagency and Presidential approval. Specifically, the release of SRF funds requires six formal steps (numbered in Figure 5):

1. The Secretary of Homeland Security, in consultation with the HHS Secretary and other Federal agencies as appropriate, must determine that a material threat exists, which is communicated by issuing an MTD.
2. The HHS Secretary must determine that additional countermeasures are necessary to protect the public health.
3. The HHS Secretary must determine that a particular security countermeasure is appropriate for acquisition for the SNS.

4. The Secretaries of HHS and DHS must jointly recommend use of the BioShield SRF.
5. The Director of the OMB, under authority delegated from the President,³³ must approve use of the SRF.
6. The Secretaries of HHS and DHS must jointly notify Congress of the procurement.

To inform determinations in which the Secretary of HHS is involved, the PHEMCE, acting through the deliberations and actions of the PHEMC Enterprise Governance Board, provides broad-based input. These determinations are based on knowledge of current medical countermeasures and the medical and public health consequences likely to result from each threat; scientific data on prospective medical countermeasures; the quantities to be procured; and the feasibility of meeting FDA requirements for licensure (vaccines and biologics), approval (drugs and some devices, including some diagnostics), or clearances (other devices, including some diagnostics) within eight years. As a result, products must be in advanced development to be eligible for acquisition under Project BioShield using the SRF.

The determination of whether an acquisition is appropriate for funding through the SRF under Project BioShield also involves consideration of whether a product fulfilling the requirement could be available for direct purchase using other funding sources (such as funds of the DSNS; see Figure 5, step labeled “Available for DSNS procurement?”). If a substantial commercial market for a suitable existing product exists, a direct procurement might be feasible without the need to provide added incentives and risk reduction using Project BioShield funding mechanisms. Products without a substantial commercial market require adequate incentives and risk management in an acquisition program for industry to be willing to assume the risk of development and manufacturing.

5.2 Project BioShield Acquisition Process

Once the OMB Director approves use of the Project BioShield SRF for the acquisition of a medical countermeasure, the HHS Secretary, through BARDA, manages the BioShield acquisition and executes contracts with manufacturers. Like other federal programs, Project BioShield acquisitions are subject to competition requirements under the Federal Acquisition Regulation

(FAR). BARDA executes contract awards employing the SRF following a full and open competition, unless the HHS Secretary determines that this requirement would seriously impair the mission of the Project BioShield program, or unless generally applicable exceptions to competition apply. For either type of exception, a Justification for Other than Full and Open Competition (JOFOC) is required.

The Pandemic and All-Hazards Preparedness Act amended the Public Health Service Act to expand advance payments allowed in Project BioShield procurements. Under the new authority, milestone payments may be paid in increments up to 5% of total contract value, up to a total maximum of 50% of the total contract value. These payments are contingent on fulfillment of milestones short of final delivery to the SNS. They need not be repaid to the U.S. Government, even if final delivery to the SNS does not occur. From Project BioShield prior to PAHPA, the Department has the authority to make advance payments up to 10% of the total contract value, if such advance payments are deemed necessary for success of the project. These payments must be refunded to the U.S. Government if contract terms for delivery of the final product to the SNS are not met. This prior authority still stands, and can be used separately or in combination with the milestone payment authority.

Other existing funding terms for Project BioShield procurements continue to apply:

- Project BioShield allows discounted payments for unlicensed/unapproved products. The vendor must seek FDA approval, clearance, or licensure of a product, with additional payments rendered once the product has met full regulatory requirements.
- BioShield procurement contracts are typically awarded for a period not to exceed five years. The only exception is when the Secretary makes a determination at contract award that complexities or difficulties in performance justify an extension to no more than a total of eight years.
- Contracts may be renewable for additional periods, none of which may exceed five years.
- The SRF may be utilized for the shipping, handling, acquisition-related storage, and related costs of the biomedical product.
- Products must meet FDA regulatory requirements. As with all medical products, FDA is responsible

³³The President delegated to OMB the authority to approve the use of the SRF for Project BioShield procurements in a Memorandum to the OMB Director dated October 21, 2004.

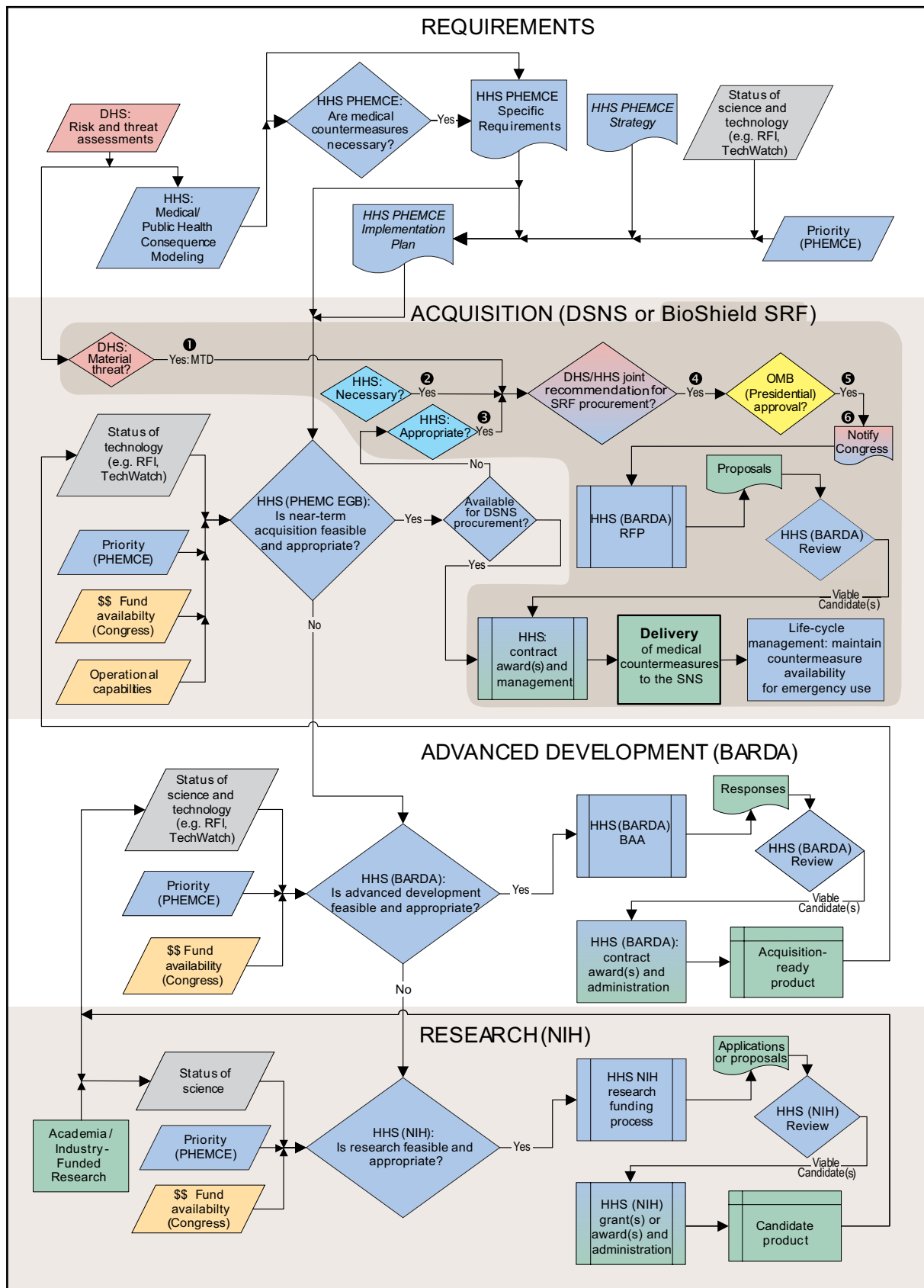


Figure 5.³⁴ PHEMCE medical countermeasure processes: requirements determination, research, advanced development, and acquisition. Steps for acquisitions using the BioShield SRF are highlighted in the ACQUISITION section. Numbers refer to the steps required to release SRF funds (section 5.1).

³⁴ The color scheme in this figure, consistent with those in Figures 1 and 7-14, includes these conventions: blue represents the U.S. Department of Health and Human Services, red represents

the U.S. Department of Homeland Security, yellow represents Presidential authority, and green represents industry and academia.

for regulatory oversight of medical countermeasures; approval for marketing or authorization for emergency use is required before a countermeasure can be used. Specifically, the centers overseeing the various categories of countermeasures are the FDA Center for Biologics Evaluation and Research (CBER), responsible for most categories of biological products, including vaccines; the FDA Center for Drug Evaluation and Research (CDER), which oversees drugs and some biological products; and the FDA Center for Devices and Radiological Health (CDRH), which regulates devices, including diagnostics.

5.3 BARDA Contract Management Activities

BARDA closely oversees acquisition contracts to manage programmatic risks encountered during the acquisition process. Oversight includes the following activities:

- Periodic (usually weekly) conference calls with the contractor
- Periodic (minimum quarterly) program review meetings with the contractor
- Periodic (usually monthly) site monitoring visits by the contracting officer and/or representative(s) (e.g., project officer[s], project manager, technical subject matter experts) to review specific program topics and assess progress against contract milestones
- Technical assistance from BARDA subject matter experts to contractors to resolve technical issues
- Facilitation of relationship between the contractor and other HHS agencies (e.g., FDA, CDC) to clearly define regulatory and logistic requirements for delivery of treatment courses to the SNS
- Development of technical / programmatic risk assessments and presentations to brief HHS executive management and other governmental offices
- Periodic (usually monthly) program review meetings with U.S. Government-only Project Coordinating Teams (see section 3.1 and Figure 2) to ensure alignment with the PHEMCE-wide objectives related to specific contracts
- Periodic (usually quarterly) program review by U.S. Government-only Integrated Program Teams (see section 3.1 and Figure 2) to ensure alignment with PHEMCE-wide objectives related to specific threat agents

These activities provide the information necessary to assess progress against contract milestones and concurrent programmatic risk. This information has subsequently been used to make program decisions regarding ongoing execution of contracts.

5.4 Storage and Life-Cycle Management

After a medical countermeasure is initially procured, its availability must be maintained. Although the SRF pays for acquisition of countermeasures for Project BioShield through delivery, it does not fund the additional costs for the acquisition of necessary ancillary supplies, the storage of the countermeasure, or life-cycle management costs associated with the extension of the expiration dating period, if possible, and replacement of expired product. At this time, the SNS funds and manages the inventory. In the long term, planning for acquisitions must account for the costs associated with storing increasing numbers and types of medical countermeasures, as well as replenishing them upon expiration. CDC, as the entity responsible for management and maintenance of the SNS, is working with the PHEMCE to address these issues.

5.5 BARDA Program Protection Office

In February 2007, BARDA established a Program Protection Office (PPO) to ensure security during the complete life-cycle of acquiring medical countermeasures under the various Project BioShield programs (and pandemic influenza programs). This new office administers and ensures compliance with comprehensive security practices relating to physical security, operations security, personnel security, information security, and transportation security, and conducts security awareness programs at all contractor facilities supporting Project BioShield.

Since its inception, the PPO has adopted standard operating procedures incorporating multi-discipline security requirements at the various stages of the acquisition process. The PPO has completed several security vulnerability assessments in the U.S. and abroad ensuring use of the most cost-effective and efficient security practices in compliance with contractually imposed security provisions. The PPO is also actively involved in coordinating on behalf of BARDA with local, state, federal, and foreign law enforcement agencies to share appropriate information, including ways to minimize potential impact of an emergency situation on contracted acquisition operations.

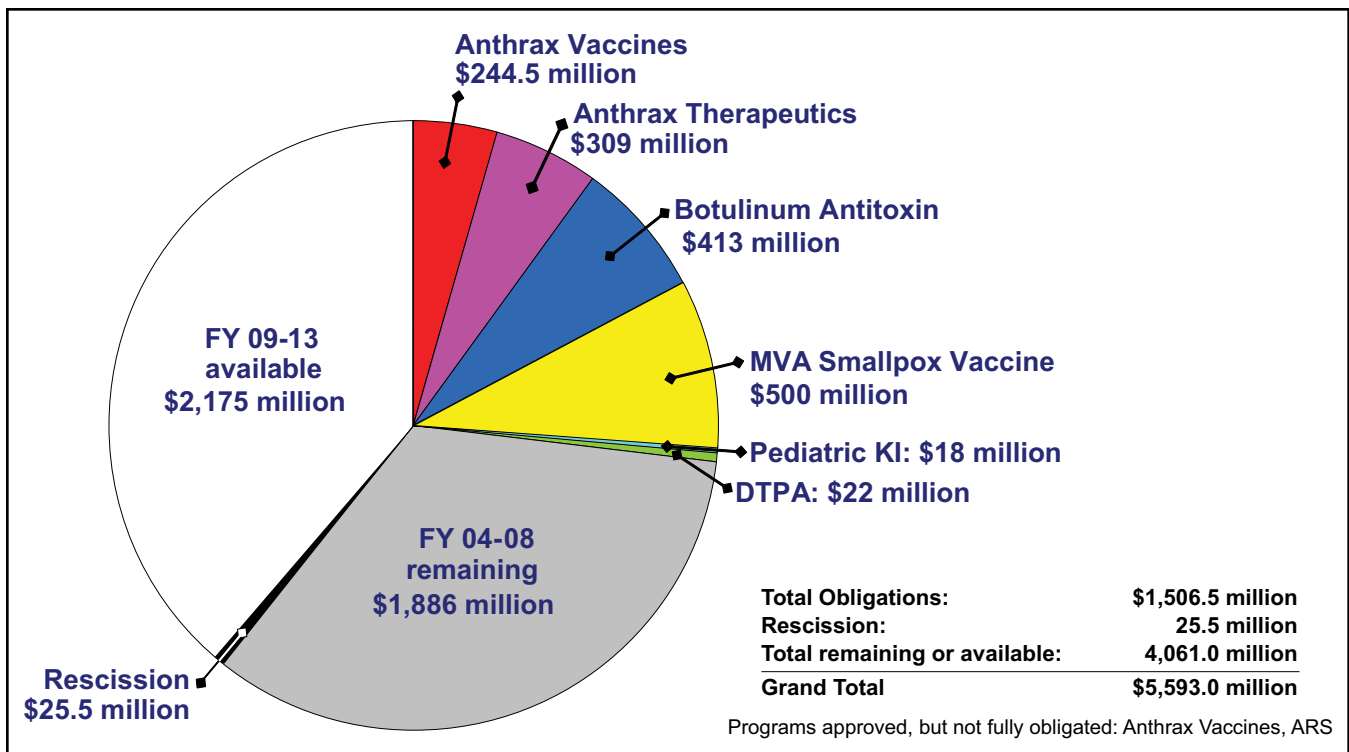


Figure 6. Project BioShield SRF obligations through July 2007. See Appendix C for meanings of acronyms.

5.6 Special Reserve Fund Obligations

The authorities to use the SRF for the acquisition of medical countermeasures for the SNS are in section 3 of the Project BioShield Act (adding section 319F-2 to the Public Health Service Act). The SRF, comprised of the funds provided in the Department of Homeland Security Appropriations Act (P.L. 108-90) on October 1, 2003, made available \$5.593 billion over 10 years (FY 2004 to FY 2013) for the acquisition of security countermeasures for the SNS. Of that amount, \$3.418 billion was available to be obligated during FY 2004 through FY 2008. However, Congress rescinded a portion of the SRF funds available for FY 2004³⁵ and 2005,³⁶ resulting in a total reduction of \$25.5 million. The obligation of \$1.8 billion for the first two years of Project BioShield was reported in the *2006 BioShield Annual Report*. This current report includes additional obligation of \$0.5 billion, and de-obligation of \$0.878 billion from a contract that was terminated. The Project BioShield SRF funds obligated through the current reporting period are

represented in Figure 6, showing the total SRF originally available, the portion of it obligated for each of the major acquisition programs, the portion rescinded, the portion remaining for FY 2004 through FY 2008, and the portion available for FY 2009 through 2013.

5.7 Advanced Development Activities

PAHPA authorized funding to support advanced development activities in HHS. During the reporting period, a combined total of \$103.8 million was appropriated by P.L. 110-5, enacted on February 15, 2007, and P.L. 110-28, enacted on May 25, 2007, for advanced research and development activities in FY 2007. In FY 2008, subject to availability of funds, BARDA anticipates awarding contracts employing PAHPA authorities for the advanced development of anthrax antitoxins, recombinant protective antigen (rPA) anthrax vaccine, smallpox antiviral agents, novel antibiotic formulations, and radiological/nuclear medical countermeasures.³⁷

³⁵ This was part of an across-the-board rescission of 0.59% of funds appropriated for FY 2004, which amounted to \$5.251 million of the total of \$890 million available for FY 2004. The rescission was in the Miscellaneous Appropriations and Offsets Act, 2004, Division H of the Consolidated Appropriations Act, 2004, P.L. 108-199, January 23, 2004, section 168(b), p. 457.

³⁶ This was part of an across-the-board rescission of 0.8% of funds appropriated for FY 2005, which amounted to \$20.224 million of the \$2,528 million additionally available for FY 2005 through FY

2008 (\$3,418 million minus the \$890 million available for FY 2004). The rescission was in the Miscellaneous Appropriations and Offsets Act, 2005, Division J, Title I of the Consolidated Appropriations Act, 2005, P.L. 108-447, December 8, 2004, section 122, p. 540.

³⁷ During the preparation of this report, \$103.921 million was appropriated for advanced research and development of medical countermeasures for FY 2008 in the Consolidated Appropriations Act, 2008, P.L. 110-161, December 26, 2007.



6.0 Overview of BioShield Authorities Used

6.1 Introduction and Summary

Table 3 and the descriptions in the next paragraphs provide a summary of the use during the reporting period of the specific authorities required to be reported, in accordance with the reporting criteria from section 5(a)(1)(A) of the Project BioShield Act. Table 4 summarizes BioShield acquisition activity during the current reporting period, including the time frame of contract awards with respect to presidential approval. Appendix B is an update of the overview that was provided in the *2006 BioShield Annual Report* of Project BioShield acquisition programs for eight products, including new activities in those programs. The remainder of this section contains (a) summaries of the status of development of priority medical countermeasures for CBRN threats, including timelines summarizing previously reported activities, updated with information from the current reporting period; and (b) summaries of the

During the current reporting period, HHS used ... the authority to expedite peer review procedures for research proposals.

roles of the FDA and CDC in Project BioShield during the current reporting period.

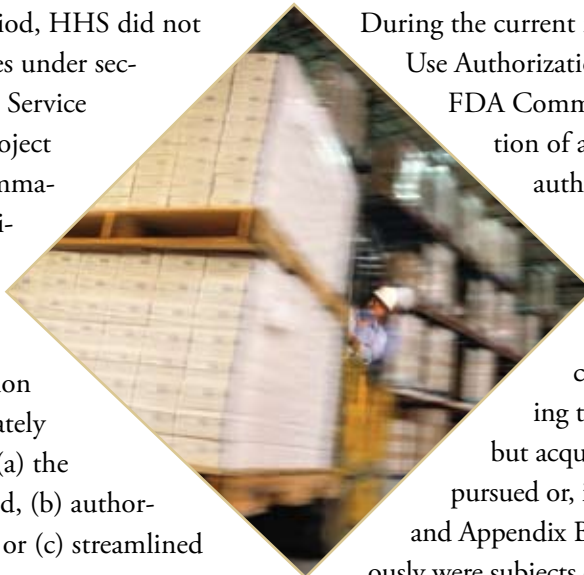
During the current reporting period, HHS used one of the Project BioShield authorities subject to required annual reporting, the authority to expedite peer review procedures for research proposals (Table 3). The National Institute of Allergy and Infectious Diseases (NIAID), a component of NIH, used expedited peer review of applications, a BioShield authority under section 319F-1 of the Public Health Service Act (added by section 2 of the Project BioShield Act), to award five grants to four organizations for research on decorporation agents to treat effects of radiological and nuclear events. NIAID also issued a request for, and received, applications for research on medical countermeasures to restore gastrointestinal function after radiation exposure; NIAID is using the authority for expedited peer review for this initiative.

Summary of Use of Authorities	Medical Countermeasure	Actions	Reason for decision to use authority	Number/nature of recipients of award or contract	Number/nature of those turned down	Contract within one year of Presidential approval?
Research & Development Activities						
Expedited peer review procedure	Radionuclide decorporation agents for radiation/nuclear emergencies	30-Mar-06: NIAID RFA-AI-06-030 Response date: 15-May-06 11 applications received	Although the threat of radiological/nuclear attacks or events continues, few medical countermeasures exist. The regular review process takes too long.	Aug-Sep-06: 5 grants to 4 organizations: 2 national labs 2 universities	6 turned down	NA
Expedited peer review procedure	Medical countermeasures to restore gastrointestinal function after radiation exposure	29-Dec-06: NIAID RFA-AI-07-013 Response date: 19-Apr-07 44 applications received	Same as above	10 grants anticipated, by Oct-07 ³⁸		NA

Table 3. Summary of use of authorities during the current reporting period, Aug 06-Jul 07; activities in gray cells were initiated during the previous reporting period, Jul 04-Jul 06.

During the current reporting period, HHS did not utilize the other special authorities under section 319F-1 of the Public Health Service Act (added by section 2 of the Project BioShield Act) required to be summarized (increased simplified acquisition thresholds; procedures other than full and open competition). NIH did not use any of the authorities under that section required to be summarized separately in a summary report, relating to (a) the increased micropurchase threshold, (b) authority for personal service contracts, or (c) streamlined personnel authority.

HHS did not use any of the special authorities under section 319F-2 of the Public Health Service Act (added by section 3 of the Project BioShield Act) required to be summarized, regarding acquisitions for the SNS (simplified acquisition procedures; procedures other than full and open competition; premium provision in multiple-award contracts). The standard FAR practices were deemed adequate for all acquisition activity during the current reporting period.



During the current reporting period, no Emergency Use Authorizations (EUAs) were issued by the FDA Commissioner because no determination of an emergency warranting such an authorization was made.

Under HHS's Project BioShield authority, no new products were the subject of acquisition contracting efforts initiated during the period covered by this report, but acquisitions initiated previously were pursued or, in some cases, modified (Table 4 and Appendix B). The products that are or previously were subjects of Project BioShield acquisition programs, summarized in this section, are rPA anthrax vaccine, Anthrax Vaccine Adsorbed (AVA), anthrax therapeutics, a liquid pediatric formulation of potassium iodide (KI), Modified Vaccinia Ankara (MVA) smallpox vaccine, botulinum antitoxin (BAT), therapeutics for acute radiation syndrome, and diethylenetriaminepentaacetate (DTPA) for radionuclide removal.

³⁸ In September 2007, during the preparation of this report, NIAID awarded ten grants under RFA-AI-07-013. These grants will support

research and development of medical countermeasures to treat gastrointestinal damage resulting from radiation exposure.

Summary of Acquisition Activities	Medical Countermeasure	Actions	Reason for decision to use authority	Number/ nature of recipients of award or contract	Number/ nature of those turned down	Contract within one year of Presidential approval?
Acquisitions for the Strategic National Stockpile						
Sources Sought Notice	Recombinant Protective Antigen (rPA) anthrax vaccine	14-May-07: Sources Sought Notice SS-DHS-BARDA-07-01; RFP anticipated FY 2008	Anthrax is a high-priority threat. Although the SNS contains AVA vaccine against anthrax and is acquiring additional supplies of it to support near-term preparedness, development of a next-generation anthrax vaccine using the latest vaccine development technologies is among the top priorities of HHS.	TBD	TBD	Approval: 12-Aug-04 No
Contract termination	Recombinant Protective Antigen (rPA) anthrax vaccine	19-Dec-06: Terminated contract of 04-Nov-04 with VaxGen (was for 75 million doses [25 million treatment courses], at a cost of \$878 million).	Contractor did not achieve a major contractual milestone.	NA	NA	NA
RFP cancellation	Therapeutics to mitigate or treat neutropenia associated with Acute Radiation Syndrome (ARS)	07-Mar-07: RFP DHHS-ORDC-DDA-05-13, of 09-Dec-05 cancelled	No offerors had a product that met United States Government requirements and that was mature enough for a BioShield acquisition.	NA	NA	NA
Sources Sought Notice	Therapeutics to mitigate or treat neutropenia associated with Acute Radiation Syndrome (ARS)	30-May-07: Sources Sought DHHS-SOURCES-SOUGHT-ARS- MAY-2007; RFP anticipated FY 2008	ARS is a priority health concern under the high-priority threat of a radiological or nuclear event.	TBD	TBD	Approval: 03-Jan-06 No
Procurement contract	Modified Vaccinia Ankara (MVA) smallpox vaccine	24-Jun-07: Contract awarded to Bavarian Nordic for 20 million doses, at a cost of \$500 million, including (refundable) advance payments under original Project BioShield stipulations, and additional (non-refundable) milestone payments under amendments in PAHPA.	Smallpox is a high-priority threat. Existing vaccines are not recommended for immunocompromised individuals; the MVA vaccine is expected to be safe and effective for such persons.	1 bio-technology company	1 bio-technology company	Approval: 07-Dec-04 No
Intent to negotiate with only one source	Anthrax Vaccine Adsorbed (AVA)	18-Apr-07: RFP-DHHS-OPHEMC-VB-07-02; modified 05-May-07: Notice of intent to acquire; intent to negotiate with only one source. Contract anticipated fall 2007; seeking 10.4 million doses, with an option for 8.35 million additional doses	Anthrax is a high-priority threat. Vaccines are an important medical countermeasure for this threat. Only one source exists for this vaccine, and no other vaccine is currently available. 10 million doses are in the SNS; negotiations are in progress for additional supplies and for replenishment supplies as doses expire. ³⁹	1 bio-technology company	NA (sole-source acquisition)	Approval 21-Jun-07 TBD; contract expected in 2007, within one year ⁴⁰

Table 4. Summary of Project BioShield acquisition activities during the current reporting period Aug 06-Jul 07.

³⁹ During the preparation of this report, on September 25, 2007, the contract was awarded to Emergent Biodefense for 18.75 million doses of AVA, at a cost of \$448 million. The contract includes incentives for obtaining licensure of AVA for post-exposure prophylaxis and

extension of the expiration dating period of the product.

⁴⁰ Contract awarded on 25 September 2007 to Emergent Biodefense Operations, within one year of approval.

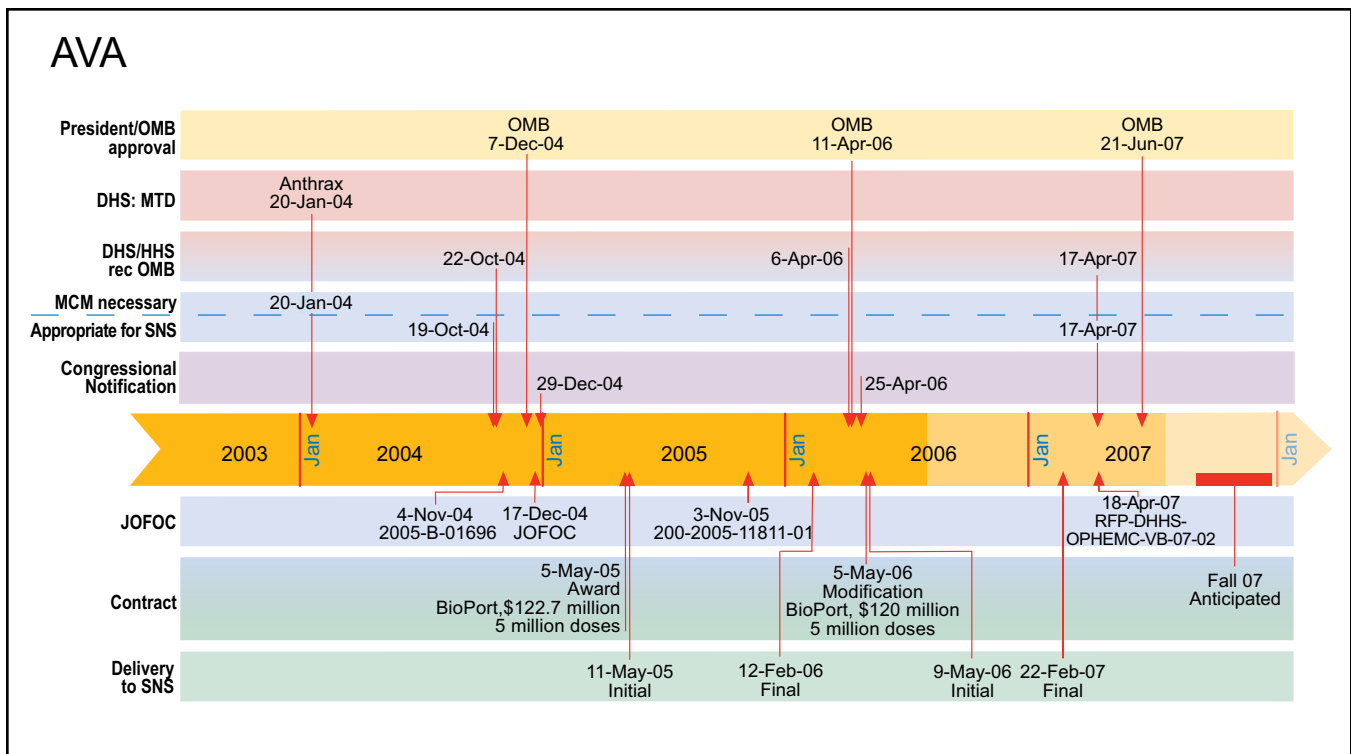


Figure 7. Timeline of AVA acquisition activity under Project BioShield.⁴¹

6.2 Medical Countermeasures for Biological Threats

6.2.1 Medical Countermeasures for Anthrax

Bacillus anthracis, the microorganism causing anthrax, is a leading bioterrorist threat, which was used in late 2001 against U.S. residents. An aerosol anthrax attack could result in hundreds of thousands of casualties. Anthrax spores can persist in the environment and pose a continued risk for infection, particularly for workers who decontaminate an infected area.

The medical countermeasure program for anthrax is multifaceted; different products play essential roles at different stages, from pre-exposure to treatment or mitigation of the disease. Antibiotics currently constitute the first line of defense due to their ability to ameliorate anthrax after unanticipated exposure. Vaccines can be used to stimulate immunity prior to anthrax exposure, and may also be administered post-exposure in combination with antibiotics to potentially reduce the duration of antibiotic use and accelerate the development of immunity. Once an individual is in the later stages of anthrax

infection, therapeutic products are the only effective way to treat the disease, limiting the ability of anthrax toxins to cause morbidity and mortality. The SNS currently contains supplies of all three types of countermeasures.

6.2.1.1 Anthrax Vaccines

Anthrax vaccine programs are underway to increase near-term preparedness by acquisition of currently available anthrax vaccine, while also supporting research and development towards the future acquisition of a second generation vaccine based upon recombinant protective antigen (rPA). BARDA has made important advances during the current reporting period in both anthrax vaccine efforts.

Anthrax Vaccine Adsorbed (AVA; BioThrax[®]) is the only currently licensed anthrax vaccine. Project BioShield acquisitions of AVA through the current reporting period are summarized in Figure 7. As of July 2007, the SNS contained approximately 10 million doses of AVA; Emergent BioSolutions (previously BioPort) made the final delivery of these doses to the SNS based on its modified contract on February 22, 2007. To enhance near-term preparedness, on April 18, 2007, BARDA issued a Notice of Intent to acquire another 10.4 million doses of AVA,

⁴¹ The color scheme in this figure and Figures 8-14, consistent with those in Figures 1 and 5, includes these conventions: blue represents the U.S. Department of Health and Human Services, red represents

the U.S. Department of Homeland Security, yellow represents Presidential authority, and green represents industry and academia.

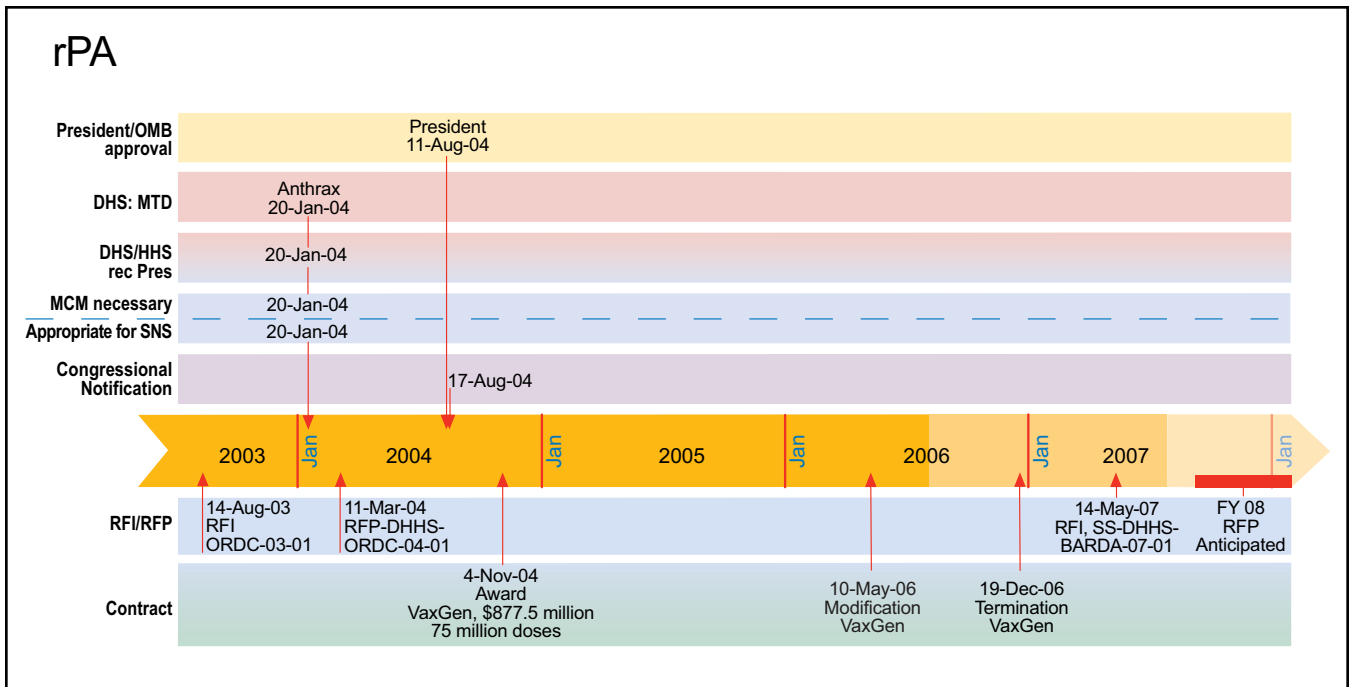


Figure 8. Timeline of rPA vaccine acquisition activity under Project BioShield.

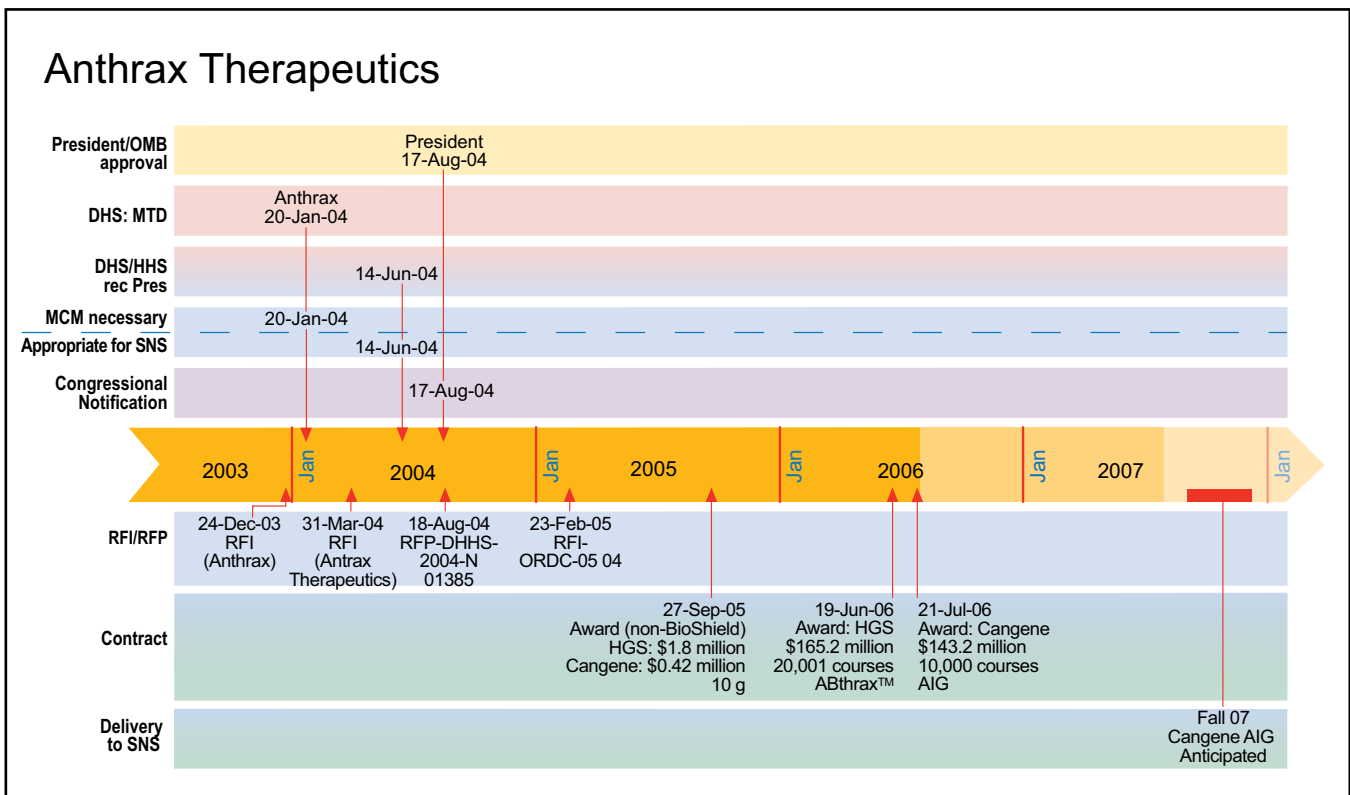


Figure 9. Timeline of anthrax therapeutics acquisition activity under Project BioShield.

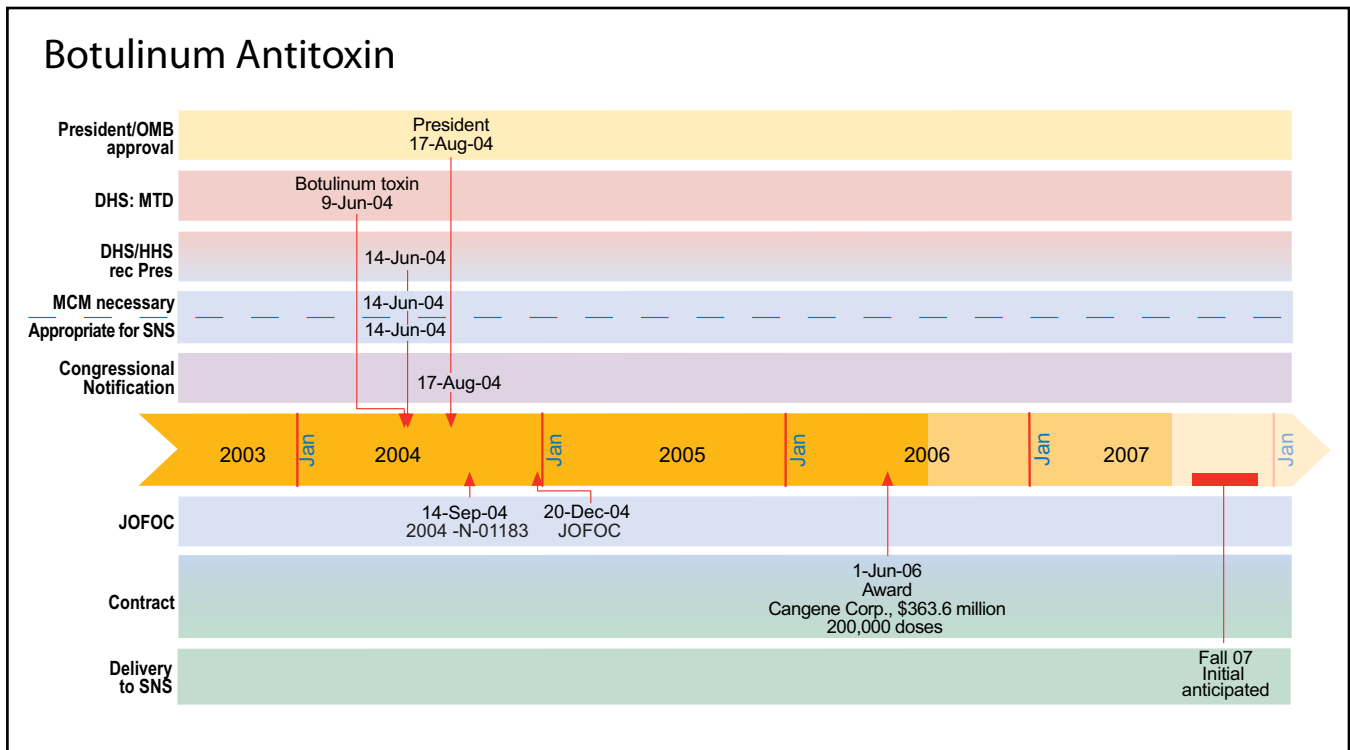


Figure 10. Timeline of botulinum antitoxin acquisition activity under Project BioShield.

with an option for the acquisition of 8.35 million additional doses. BARDA expects to award a sole-source contract to Emergent and complete the acquisition in the fall of 2007.⁴²

Efforts to develop and acquire a second generation anthrax vaccine based on rPA are also ongoing. Figure 8 summarizes these efforts under Project BioShield. HHS terminated a previous contract with VaxGen on December 19, 2006, after the contractor did not achieve a major contractual milestone. To gather information on the overall state of rPA vaccine development programs, BARDA issued a Sources Sought Notice on May 14, 2007. BARDA expects to release an RFP for rPA vaccine during FY 2008.⁴³

6.2.1.2 Anthrax Therapeutics

BARDA continues to make progress toward adding to the stockpile therapeutic antitoxin products for treatment of anthrax-infected patients. The efforts to acquire

these products under Project BioShield are summarized in Figure 9. Two contracts for acquisition of such products are in place, with Human Genome Sciences and Cangene Corporation.

Deliveries to the SNS of Anthrax Immune Globulin (AIG) from Cangene Corporation are expected to begin in fall of 2007.⁴⁴ AIG potentially could be used in an event under an existing Contingency Use IND. Cangene will provide data to support a potential EUA and plans to file a Biologics License Application (BLA) for its AIG product. Work to date on the development of AIG represents significant progress toward these goals.

Product development efforts also continue under the Project BioShield contract for the acquisition of ABthrax™, a therapeutic anthrax antitoxin from Human Genome Sciences. Initial product delivery is anticipated for early 2009.

⁴² During the preparation of this report, on September 25, 2007, the contract was awarded to Emergent Biodefense for 18.75 million doses of AVA, at a cost of \$448 million. The contract includes incentives for obtaining licensure of AVA for post-exposure prophylaxis and extending the expiration dating period of the product. On October 2, 2007, Emergent announced completion of the initial delivery to the SNS on September 28, 2007.

⁴³ During the preparation of this report, on November 26, 2007, BARDA released a draft RFP for rPA vaccine (for comments; not the final solicitation).

⁴⁴ During the preparation of this report, in September 2007, Cangene Corporation announced an initial delivery of AIG to the SNS under the terms of the contract awarded by HHS on July 28, 2006.

6.2.2 Medical Countermeasures for Botulism

Botulinum toxin poses a major biological threat because of its extreme potency and lethality, relative ease of production, and the need for prolonged intensive care of affected persons. Botulism is a muscle-paralyzing disease caused by a toxin made by the bacterium *Clostridium botulinum*.

The PHEMCE has a requirement for 200,000 doses of heptavalent equine botulinum antitoxin. The previous activities toward acquisition of botulinum antitoxin for the SNS were reported in the *2006 BioShield Annual Report*, and are summarized in Figure 10, along with the anticipated initial delivery of antitoxin to the SNS in fall of 2007.⁴⁵ HHS also continues to support research and development for next-generation medical countermeasures for the treatment of botulism.

6.2.3 Medical Countermeasures for Smallpox

Smallpox is an acute, often fatal, infectious disease, caused by *Variola* virus. By 1979, natural incidents of the

disease had been eliminated worldwide by widespread vaccination. Nevertheless, a threat remains that the virus could be used as a biological weapon.

No specific treatments are currently available for smallpox, and the only preventive measure is vaccination. The SNS contains enough vaccine to treat the entire population of the United States. However, the vaccine licensed in the United States can have side effects, and is potentially unsafe for persons with impaired immune systems.

Modified Vaccinia Ankara (MVA) has a limited capacity to reproduce in humans, suggesting that it may be a more suitable vaccine for individuals who are immunocompromised. Early clinical trial data suggest that it is safe and immunogenic in both healthy and immunocompromised people. Nonclinical studies demonstrate it is protective in non-human primates and mice each challenged with the appropriate orthopoxvirus.

The previous activities toward acquisition of an MVA vaccine for the SNS were reported in the *2006 BioShield Annual Report*, and are summarized in Figure 11, along

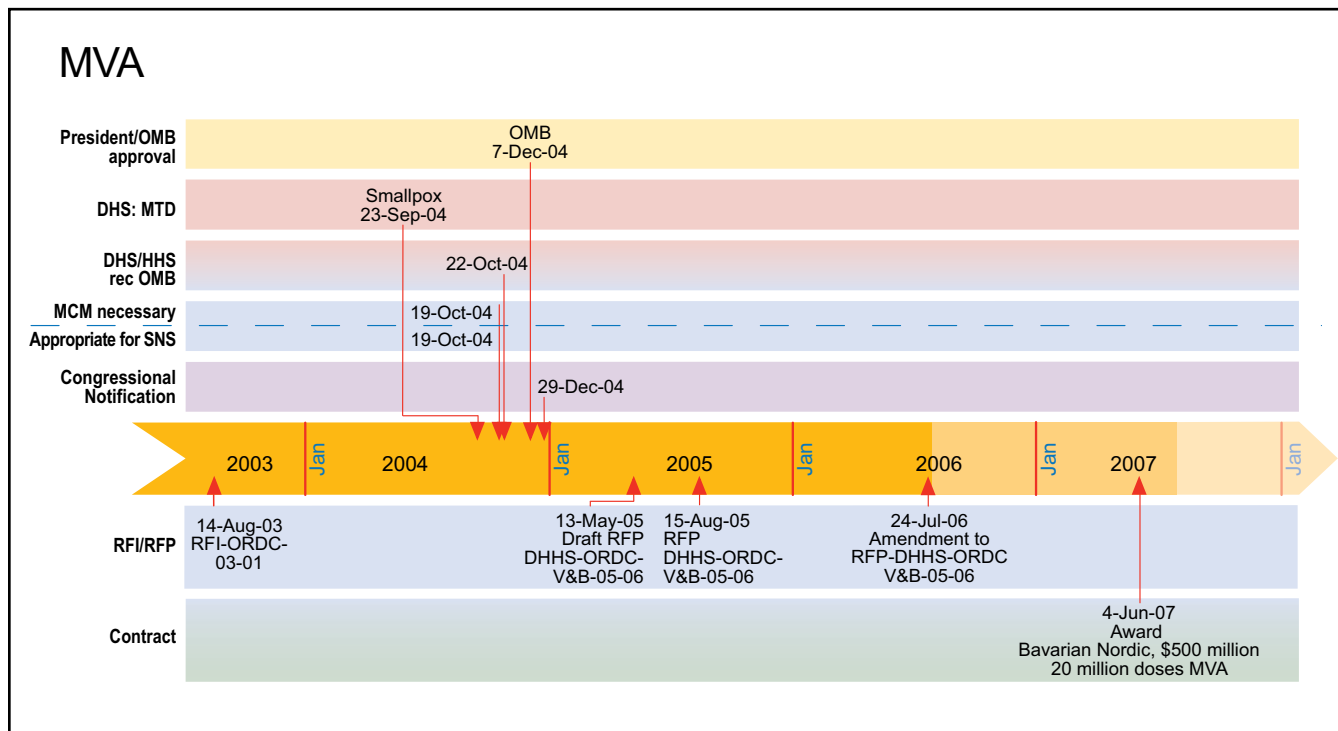


Figure 11. Timeline of MVA acquisition activity under Project BioShield.

⁴⁵ Cangene Corporation made an initial delivery of heptavalent botulinum antitoxin to the SNS during the preparation of this report, in September 2007.

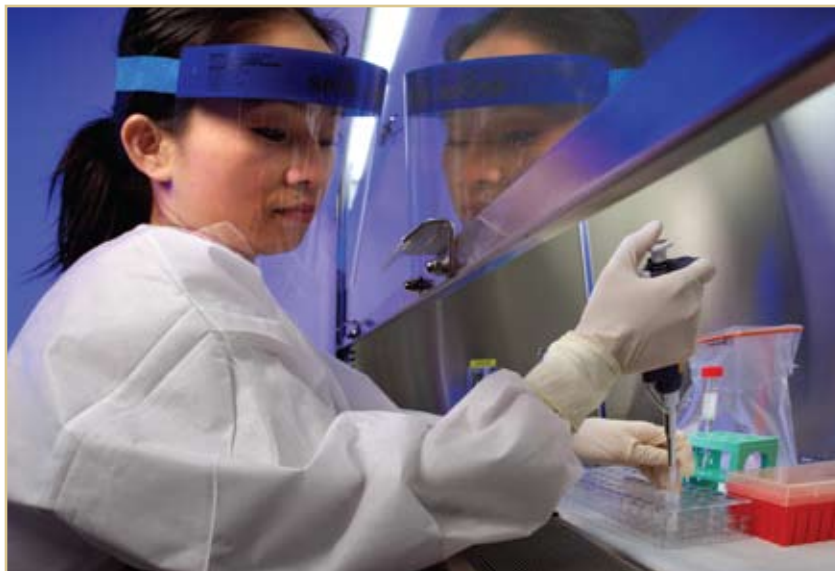
with more recent activities. The previously reported efforts included an RFP posted on August 15, 2005, which closed on October 3, 2005. Two companies responded to the RFP. On July 24, 2006, the RFP was amended to reflect the CDC's post-event vaccination strategy. On June 4,

2007, a contract was awarded to Bavarian-Nordic for 20 million doses of MVA vaccine to treat 10 million people. This contract was the first to use the Project BioShield authorities as amended under PAHPA to allow milestone payments, as well as the original Project BioShield authorities allowing limited payments before delivery if they are deemed necessary to complete the acquisition.⁴⁶ The first milestones eliciting non-refundable payments under the contract are anticipated to be achieved in fall 2007.⁴⁷

6.3 Medical Countermeasures for Radiological and Nuclear Threats

After the Secretary of DHS determined that radiological and nuclear agents are material threats to the U.S. population in September 2004, DHS subsequently analyzed in depth the specific threats caused by both radiological materials and so-called "fissile materials."

The health effects following a radiological/nuclear event can be attributed to whole or partial body radiation exposure and/or to uptake of radioactive particles. Particulate radionuclides can be absorbed into the body by inhalation, ingestion, or wound contamination. Radioactive isotopes in these particles can then be absorbed, transported via the blood, and later incorporated into the bones, liver, thyroid, or lymph nodes. The



radioactive isotopes emit radiation to surrounding tissues, and may cause cell death, organ dysfunction, or cancer. Rapid removal of isotopes from the body (decorporation) can greatly reduce exposure.

Whole-body or significant partial-body exposure

to ionizing radiation can cause radiation sickness, also known as acute radiation syndrome (ARS). ARS is a complex expression of a range of health effects caused by underlying organ injuries. Each tissue has a particular sensitivity to ionizing radiation that varies by organ, and by the rate at which the dose is absorbed. Physiologically important and radiation-sensitive manifestations of ARS include the hematopoietic syndrome, with its associated decreases in various blood cell types and increased risk of infection and bleeding; bone marrow suppression of progenitor cell populations; the gastrointestinal syndrome, associated with severe diarrhea and an increased risk of life-threatening bacteremia (bloodstream infection); skin (or cutaneous) symptoms such as burns and ulcers; lung fibrosis; and cerebrovascular syndrome (affecting the brain and blood vessels).

The 2007 *HHS PHEMCE Implementation Plan* listed the following high-priority medical countermeasures required to address radiological and nuclear threats:

- Medical countermeasures to address ARS and the delayed effects of acute radiation exposure (DEARE) (principally exhibited in organs such as the lung or kidneys in the weeks to months following an acute radiation exposure event)
- Radionuclide-specific medical countermeasures
- Biodosimetry/bioassay capabilities

⁴⁶ In October 2007, during the preparation of this report, HHS approved the payment of an initial 10% advance payment to Bavarian Nordic, which was included in the contract under the original Project BioShield authority for advance payments.

⁴⁷ In November 2007, during the preparation of this report, HHS approved the first non-refundable advance payment for achievement of a milestone to Bavarian Nordic, and made the payment in December 2007.

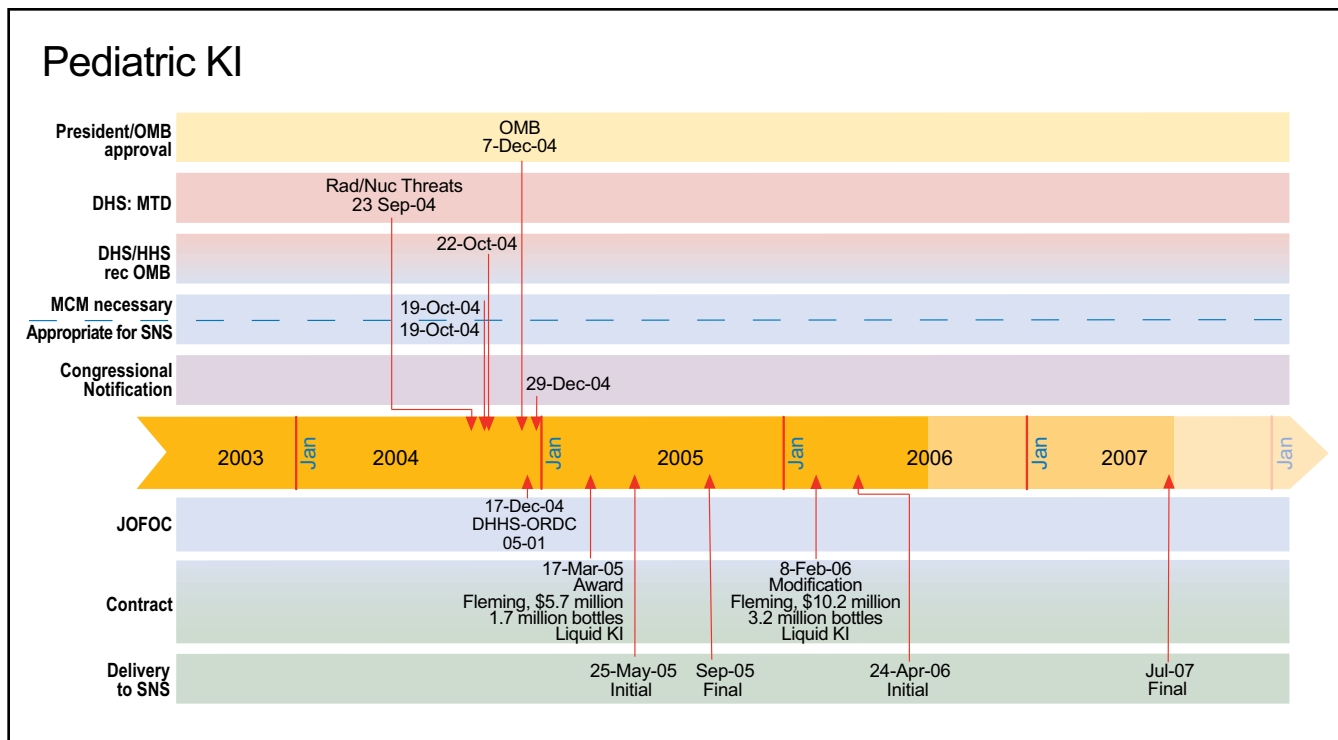


Figure 12. Timeline of liquid KI acquisition activity under Project BioShield.

6.3.1 Research

During the current reporting period, NIAID used the expedited peer review process under Project BioShield authorities to conduct two peer-review meetings. The NIAID Division of Allergy, Immunology and Transplantation used this Project BioShield authority to award grants for research toward developing radionuclide decorporation agents for radiation/nuclear emergencies. In addition, grant applications for research leading to medical countermeasures to restore gastrointestinal function after radiation exposure received expedited review.

Specifically, NIAID exercised this authority granted under Project BioShield to expedite research and development of critical medical countermeasures against accidental or deliberate radiation exposure through the following two projects:

- Radionuclide Decorporation Agents for Radiation/ Nuclear Emergencies
- Medical Countermeasures to Restore Gastrointestinal Function after Radiation Exposure

Despite the threat of radiological and nuclear attacks, few medical countermeasures for this threat exist. The programs for which the expedited peer review authority was used are components of the *NIH Strategic Plan and Research Agenda for Medical Countermeasures against*

Radiological and Nuclear Threats,⁴⁸ a comprehensive program of basic and translational research, with a strong emphasis on product development.

NIAID initially considered the use of normal NIH review and award processes; however, given the timelines involved (18 months from conception of initiative to award), this option was not selected. Because the Project BioShield mechanism expedites the award process timeframe (to approximately nine months), NIAID elected to utilize Project BioShield authorities for these high-priority programs.

6.3.1.1 Radionuclide Decorporation Agents for Radiation/Nuclear Emergencies

NIAID released an RFA for research on radionuclide decorporation agents, on March 30, 2006, and the receipt date for applications was May 15, 2006. NIAID received 11 applications and awarded five grants in August and September 2006, to the following institutions:

- Lawrence Berkeley National Laboratories, Berkeley, CA
- Pacific Northwest National Laboratories, Richland, WA (2 awards)
- University of Florida, Gainesville, FL
- University of Utah, Salt Lake City, UT

⁴⁸ http://www3.niaid.nih.gov/about/overview/planningPriorities/RadNuc_StrategicPlan.pdf

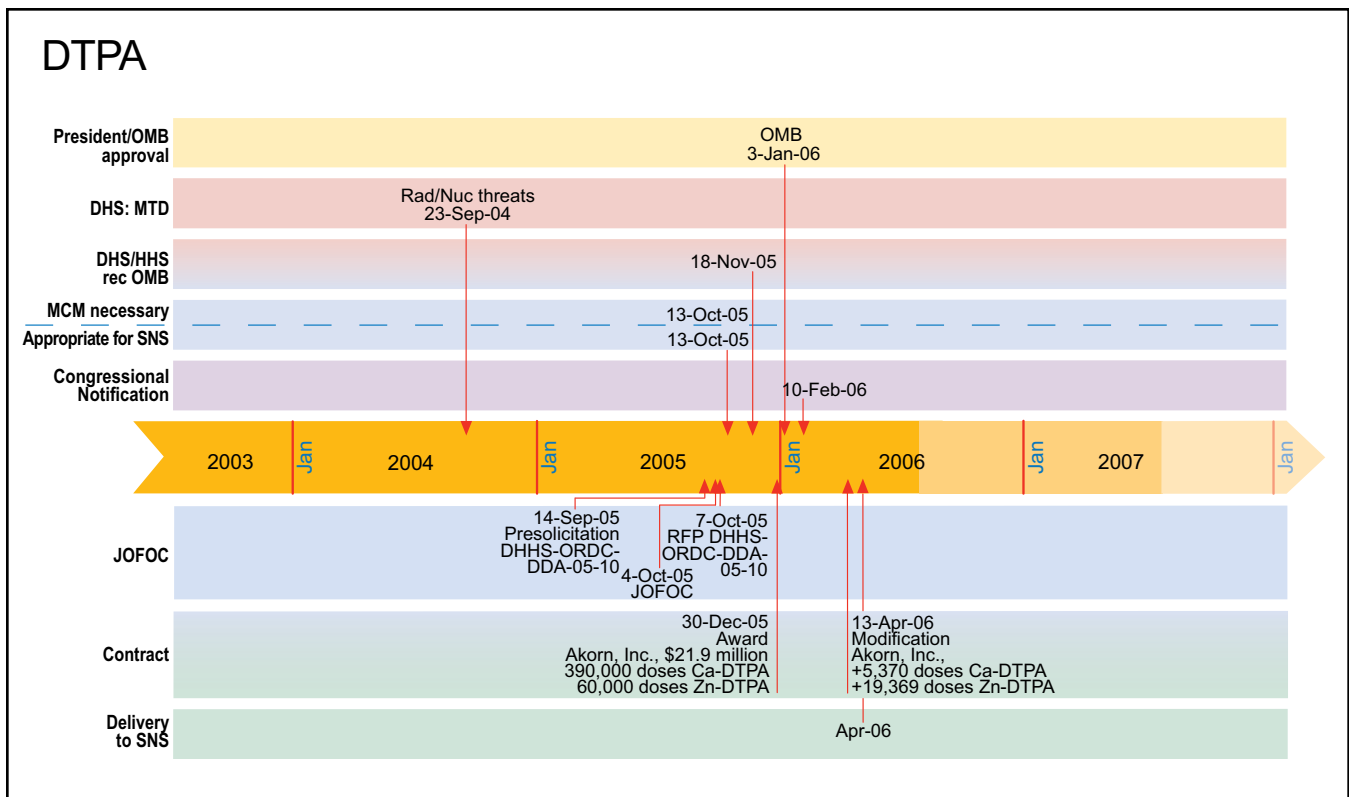


Figure 13. Timeline of DTPA acquisition activity under Project BioShield.

6.3.1.2 Medical Countermeasures to Restore Gastrointestinal Function after Radiation Exposure

NIAID released an RFA for research on countermeasures to restore gastrointestinal function, on December 29, 2006, and the receipt date for applications was April 19, 2007. NIAID received 44 applications.⁴⁹

6.3.2 Advanced Development and Acquisition

Three programs have been in place for acquiring countermeasures to radiological and nuclear threats: for pediatric formulations of KI, for DTPA, and for countermeasures for ARS.

6.3.2.1 Potassium Iodide (KI)

A nuclear detonation or reactor accident could disperse radioactive isotopes, including radioactive iodine (radioiodine) into the environment. Radioiodine poses a threat because any form of absorbed iodine is concentrated in the thyroid gland. Exposure of the thyroid gland to radioiodine can lead to either thyroid cancer or the

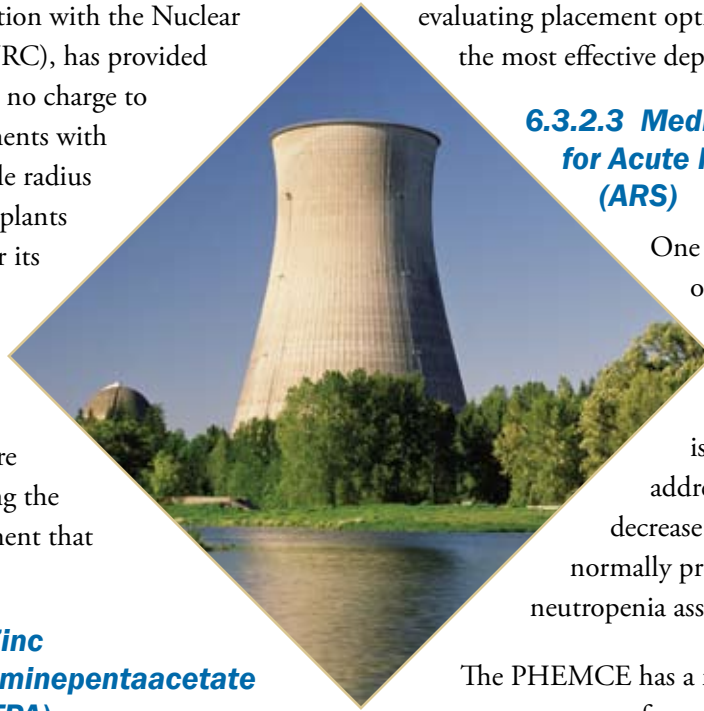
destruction of the thyroid gland. Because the thyroid gland is most active in young children, they are at greatest risk of developing adverse effects following exposure to radioiodine. One strategy to prevent incorporation of radioiodine into the thyroid gland is to saturate the gland with KI. KI is a radionuclide-specific medical countermeasure that acts as a blocking agent to counter thyroid uptake of radioiodine. The FDA has approved KI in tablet form as a nonprescription drug, and supplies of KI tablets are held in the SNS. However, the American Academy of Pediatrics recommended delivery of KI to children in a liquid preparation because children under 10 years of age may find tablets difficult to swallow and/or bad-tasting.⁵⁰

The activities supporting acquisition of liquid KI for pediatric use are summarized in Figure 12, including those reported in the *2006 BioShield Annual Report*. During the current reporting period, in July 2007, Fleming and Company Pharmaceuticals Inc. made the final delivery to the SNS on a modified contract, bringing the total delivered amount to 4.9 million bottles, at a total cost of \$15.9 million.

⁴⁹ In September 2007, during the preparation of this report, NIAID awarded ten grants under RFA-AI-07-013. These grants will support research and development of medical countermeasures to treat gastro-

intestinal damage resulting from radiation exposure.
⁵⁰ http://www.gnyha.org/eprc/general/nbc/nuclear_radiological/Radiation_Speaking_Points.pdf

HHS, working in collaboration with the Nuclear Regulatory Commission (NRC), has provided the pediatric formulation at no charge to all states and tribal governments with populations within a 10-mile radius surrounding nuclear power plants that have approved plans for its distribution and that have requested this material. This far-forward deployment allows the product to be closer to the sites where it might be needed, affording the possibility of prompt treatment that should facilitate efficacy.



evaluating placement options for this asset to ensure the most effective deployment in an emergency.

6.3.2.3 Medical Countermeasures for Acute Radiation Syndrome (ARS)

One of the most pressing needs of survivors exposed to levels of radiation likely to be experienced in a radiological/nuclear event is mitigation or treatment addressing the subsequent decrease in the blood cells that normally protect against infection (the neutropenia associated with ARS).

6.3.2.2 Calcium and Zinc Diethylenetriaminepentaacetate (Ca- and Zn-DTPA)

FDA has approved two radionuclide-specific drugs, calcium diethylenetriaminepentaacetate (Ca-DTPA) and zinc diethylenetriaminepentaacetate (Zn-DTPA), for treating internal contamination from plutonium, americium, or curium. These two forms of DTPA enhance the body's ability to expel these radioactive particles.

The acquisition of DTPA under Project BioShield is summarized in Figure 13; all activities were reported in the *2006 BioShield Annual Report*. HHS is currently

The PHEMCE has a requirement for 200,000 treatment courses of a medical countermeasure to mitigate and/or treat the neutropenia associated with ARS. The activities that support meeting this requirement are summarized in Figure 14, including activities reported in the *2006 BioShield Annual Report*. An RFP to meet an interim requirement for up to 100,000 treatment courses that mitigate and/or treat the neutropenia associated with ARS, alone or in combination with other co-morbidities, was issued on December 9, 2005. The RFP closed on February 23, 2006. In March 2007, HHS cancelled the RFP upon determining, after extensive

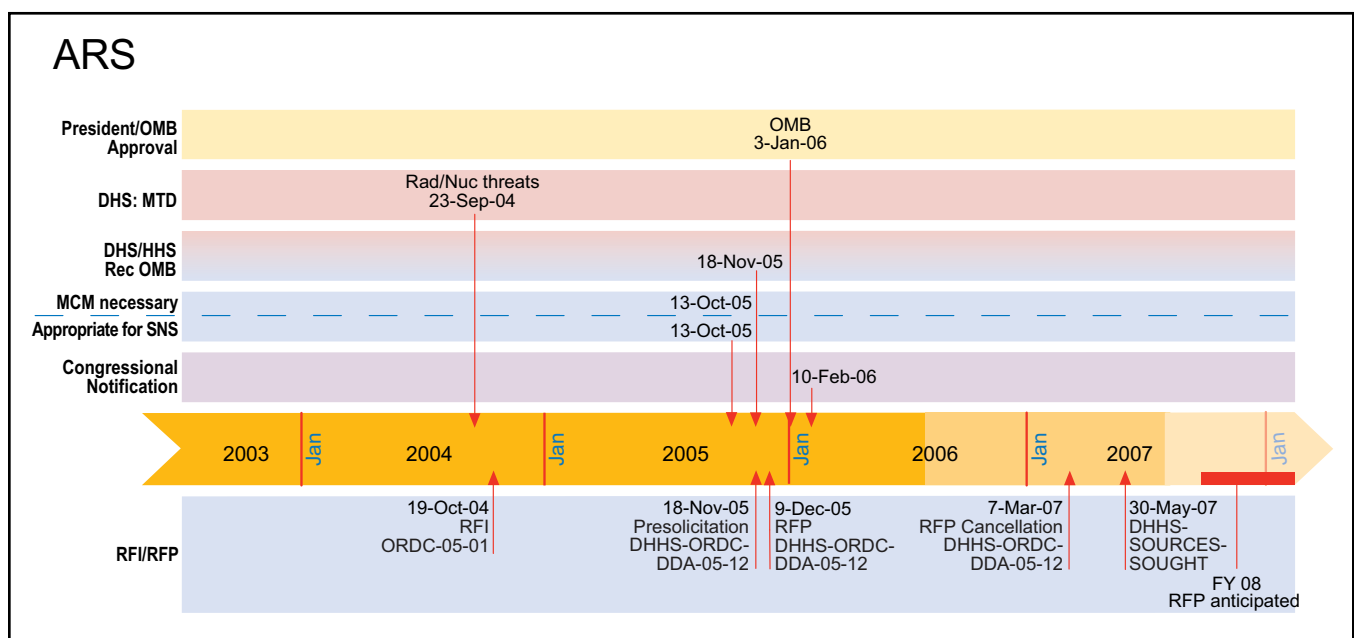


Figure 14. Timeline of acquisition activity under Project BioShield for a medical countermeasure to treat neutropenia associated with ARS.

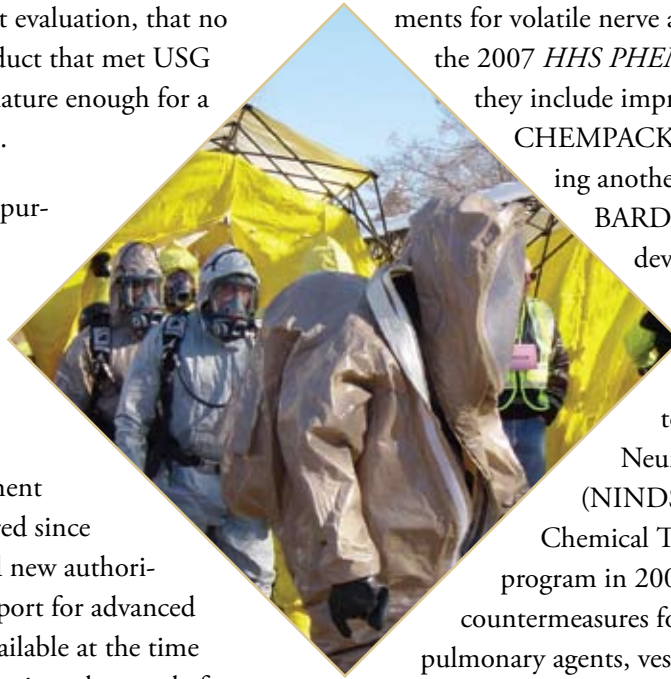
scientific and technical expert evaluation, that no competing offeror had a product that met USG requirements and that was mature enough for a Project BioShield acquisition.

HHS remains committed to purchasing products to respond to radiological and nuclear threats, and will continue to pursue acquisition of appropriate ARS medical countermeasures. HHS is monitoring further development in the science that has occurred since the previous RFP closed, and new authorities under PAHPA allow support for advanced development that was not available at the time of the original RFP, which was issued a year before PAHPA was enacted. On May 30, 2007, HHS issued a Sources Sought Notice for therapeutics to treat the neutropenia component of ARS for the SNS. This Sources Sought document allowed HHS to learn about the latest advances in ARS medical countermeasure research and development. BARDA received responses by the closing date of June 29, 2007, and anticipates releasing an RFP in FY 2008.

6.4 Medical Countermeasures for Chemical Threats

To date, Project BioShield authorities have not been used to acquire medical countermeasures for chemical threats, and DHS has issued no material threat determinations for chemical threat agents. PTAs have been completed by DHS for volatile nerve agents, low-volatility nerve agents, pulmonary agents, vesicants, and blood agents. Based on the PTAs, the HHS PHEMCE has recently established requirements for medical countermeasures for volatile nerve agents and is evaluating possible requirements for the other four chemical threat categories.

The CHEMPACK program, initiated in 2003, currently provides nerve agent antidotes for pre-positioning by state, local, and/or tribal officials throughout the U.S. CDC's DSNS supports this program financially and administratively. The medical countermeasure require-



ments for volatile nerve agents were incorporated into the 2007 *HHS PHEMCE Implementation Plan*; they include improvements to the current CHEMPACK program. Toward fulfilling another of those requirements, BARDA supported the advanced development of midazolam as a countermeasure for nerve agent-induced seizures by providing \$6.32 million to the National Institute of Neurological Diseases and Stroke (NINDS), Countermeasures Against Chemical Threats (CounterACT) grants program in 2007. If requirements for medical countermeasures for low-volatility nerve agents, pulmonary agents, vesicants, and blood agents are established, they will be addressed in the next version of the *HHS PHEMCE Implementation Plan*.

6.5 Report on Exercises of Authority: Food and Drug Administration (FDA)

In a public health emergency, potentially useful products may be available that have not yet attained FDA approval for the particular use contemplated. Section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 360bbb-3), as amended by section 4 of the Project BioShield Act of 2004, permits the FDA Commissioner to authorize the use of an unapproved medical product or to authorize an unapproved use of an approved medical product, during an emergency declared by the HHS Secretary justifying the authorization. Such a declaration, an Emergency Use Authorization (EUA), may be based on a determination (a) by the Secretary of Homeland Security of a domestic emergency or a significant potential for a domestic emergency involving a heightened risk of attack with a specified CBRN agent; (b) by the Secretary of Defense of a military emergency or a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with a specified CBRN agent; or (c) by the HHS Secretary of a public health emergency that affects or has a significant potential to affect national security and that involves a specified CBRN agent or a specified disease or condition that may be attributable to such agent or agents.⁵¹

⁵¹ Pursuant to section 903 of the FFDCA and existing delegations of authority, codified at 21 CFR part 5, the Secretary has delegated his authority to issue an EUA under section 564 to the FDA Commissioner.

6.5.1 FDA Issuance of Emergency Use Authorizations (EUAs)

The FDA Commissioner has issued one EUA to date, on January 27, 2005, for emergency use of AVA, following the declaration of a public health emergency by the Secretary of HHS on January 14, 2005, regarding anthrax. The EUA was described in detail in the *2006 BioShield Annual Report* and is referenced on the timeline in Figure 14 in the Conclusion (section 8) of this report. The EUA terminated on January 14, 2006. No EUAs were issued during the current reporting period.

6.5.2 FDA Final Guidance on EUA

On July 26, 2007, FDA published final guidance on the Emergency Use Authorization of medical products. The guidance explains FDA policies for authorizing the emergency use of medical products.

6.6 CDC Involvement in Project BioShield

CDC manages the SNS, a stockpile of medicines and medical supplies for the protection of the American public as needed after a significant disaster. Under Project BioShield, CDC stores and maintains the acquired countermeasures in accordance with regulatory requirements. Moreover, CDC will ensure that

- the inventory is optimized to meet the priorities identified in the *HHS PHEMCE Implementation Plan*;
- storage, deployment, and utilization plans are in place to support efficient delivery of medical countermeasures;
- surveillance and investigation data during an event are timely to effect countermeasure deployment;
- effective collaboration occurs with state and local public health officials to dispense countermeasures quickly during an emergency.

Another facet of CDC involvement under Project BioShield is participation in the interagency process as part of the PHEMC Enterprise Governance Board. The Enterprise Governance Board addresses the full life cycle of medical countermeasures, including logistical and operational aspects of countermeasure storage that

relate to CDC's realm of direct responsibility managing and maintaining the SNS. See section 5.4, Storage and Life-Cycle Management, for a description of activities involved in meeting this challenge and the necessity for funding to support it.

The SNS contains or is in the process of receiving a number of Project BioShield acquisitions as part of its wider inventory, including the following:

Countermeasures for Radiological/Nuclear Threats

- Calcium DTPA
- Zinc DTPA
- Liquid Potassium Iodide

Countermeasures for Biological Threats

- Anthrax Vaccine Adsorbed
- Anthrax Immune Globulin (initial delivery anticipated in fall 2007)⁵²
- Heptavalent Botulinum Antitoxin (initial delivery anticipated in fall 2007)⁵³



⁵² Cangene Corporation made an initial delivery of AIG during the preparation of this report, in August 2007.

⁵³ Cangene Corporation made an initial delivery of heptavalent botulinum antitoxin during the preparation of this report, in September 2007.



7.0 BARDA and PHEMCE Activities Supporting or Relating to Project BioShield

7.1 Technology Watch (TechWatch)

In support of the PHEMCE goals and Project BioShield, BARDA tracks public and private sector medical countermeasure development and acquisition activities through an endeavor known as Technology Watch, or TechWatch. TechWatch is an ongoing process that involves BARDA staff actively seeking out all open-source information on candidate medical countermeasure products, from scientific literature, conferences, and industry presentations.

7.1.1 Direct Communication

BARDA provides stakeholders the opportunity directly to communicate information on candidate products by scheduling presentations to BARDA, and by responding to Requests for Information and Sources Sought Notices issued by BARDA. The new stakeholders' Internet portal, MedicalCountermeasures.gov, described in section 7.2.3 of this report, is being configured to enable stakeholders to request opportunities to meet directly with HHS staff regarding their technological accomplishments, products, and programs.

Maintaining open communication and an atmosphere that encourages stakeholder engagement is essential for BARDA to meet the nation's medical countermeasure needs. BARDA and the rest of the PHEMCE remain committed to reaching out and engaging interested parties seeking to develop and manufacture medical countermeasures that meet HHS requirements. Such outreach enables effective collaboration with public and private sector persons in the domestic and international product development communities, including those in academia, industry, and federal, state, and local government agencies. These efforts serve as an opportunity to maximize the transparency of HHS priorities, to solicit feedback, and to discuss implementation of future medical countermeasure advanced development and acquisition programs.

7.1.2 Data Call

In June 2006 the Office of Science and Technology Policy and the Homeland Security Council issued the Weapons of Mass Destruction Medical Countermeasures Research and Development Data Call (2006 Data Call) to gain an updated understanding of the status of



federal research, development, and acquisition programs for medical countermeasures for chemical, biological, radiological, and nuclear threats. Such data calls are done when deemed potentially useful. The ongoing monitoring by TechWatch activities builds upon the base of data obtained in the 2006 Data Call.

The 2006 Data Call compiled information on a wide range of research and development programs throughout the U.S. Government. This robust data set allowed for a comprehensive accounting of current priorities in medical countermeasure development; an examination of the support for research and development against different threat agents; the identification of specific gaps in medical countermeasure research and development efforts; and the construction of recommendations for best allocating the limited available resources in the future.

7.1.3 BARDA Industry Day

The ASPR hosted the 2007 BARDA Industry Day on August 3, 2007. This inaugural event provided an open forum for biotechnology and pharmaceutical companies and for academia to showcase technological advances in emergency medical countermeasures for major intentional, accidental, and naturally occurring threats to the nation's public health. PAHPA requires the Secretary to sponsor opportunities annually for industry partners to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies.

BARDA issued a call for abstracts, of which 58 met the criteria for acceptance and were scheduled for presentation. Company representatives demonstrated the progress of their activities in advanced research and

development of medical countermeasures, including both pharmaceutical and non-pharmaceutical products, that have potential to contribute to fulfilling the goals of Project BioShield, the *HHS Pandemic Influenza Plan*, the *HHS PHEMCE Strategy*, the *HHS PHEMCE Implementation Plan*, and the *Draft BARDA Strategic Plan*.

More than 300 participants attended concurrent presentation sessions focused on vaccines, therapeutics, medical diagnostic products, and non-pharmaceutical countermeasures. Key public health emergency medical countermeasure stakeholder constituencies were represented at the event, including biotechnology and pharmaceutical industries; international agencies; academia; federal, state, and local governments; and the media.

The information gained during this event will help inform HHS TechWatch activities, and the opportunity to present such information is anticipated to become an important part of the 2008 Stakeholders Workshop.

7.2 Stakeholder Outreach Activities

7.2.1 National Biodefense Science Board

On June 20, 2007, Secretary Leavitt announced⁵⁴ the establishment of the PAHPA-mandated National Biodefense Science Board, an external advisory council to provide recommendations on scientific, technical, and other matters of special interest to HHS regarding activities to prevent, prepare for, and respond to the adverse health effects of public health emergencies resulting from chemical, biological, radiological, or nuclear events,

⁵⁴ *Federal Register*, 20 Jun 2007, Vol. 72, No. 118, p. 34015, with correction in *Federal Register*, 27 Jun 2007, Vol. 72, No. 123, p. 35246.

whether naturally occurring, accidental or deliberate. Thirteen of the Nation's preeminent scientific, public health, and medical experts from outside the Federal government will serve as voting members of the Board. They will be joined by non-voting, ex officio Federal officials representing a broad range of relevant agencies.

The ASPR is responsible for staffing and managing the Board. Tasks include contributing to an agenda of activities to fulfill the Board's function and providing associated technical support and background material. The agenda will be determined collaboratively by Board members and the Department. The ASPR sees the Board's activities as an excellent opportunity to interact with external stakeholders. The first Board meeting was scheduled for December 17-18, 2007, with members to be announced immediately before the meeting.⁵⁵

7.2.2 Stakeholders Workshops

The HHS Public Health Emergency Medical Countermeasures (PHEMC) Enterprise Stakeholders Workshop is an annual event, now in its second year, that brings together the PHEMCE members⁵⁶ with the diverse community of stakeholders to discuss critical issues surrounding the nation's preparedness for major intentional, accidental, and naturally occurring threats to public health.

7.2.2.1 The 2006 BioShield Stakeholders Workshop

The first Stakeholders Workshop was held September 25-26, 2006, with goals to improve transparency of Project BioShield activities and educate BioShield Stakeholders.⁵⁷ This inaugural event, known as the BioShield Stakeholders Workshop, provided the more than 400 attendees (and the participants via webcast) with insight into the interagency governance process, including information on the Project BioShield Act of 2004, the PHEMCE, and other key topics related to medical countermeasures. External stakeholders from industry, from academia and science, and from medicine and public health also presented information during panel sessions.

The BioShield Stakeholders Workshop gave individual stakeholders an opportunity to provide input into the *HHS PHEMCE Strategy*, then in draft form, and into

other topics of interest to PHEMCE external stakeholders during facilitated working group sessions. The *HHS PHEMCE Strategy* was published in the *Federal Register* in advance of the workshop as a draft for comment on September 8, 2006. The final version of the *HHS PHEMCE Strategy*, published in the *Federal Register* on March 20, 2007, reflected critical input received from external stakeholder panels and breakout work sessions during the Workshop, as well as comments received in response to the *Federal Register* publication.

More detailed information from the 2006 BioShield Stakeholders Workshop, including the videocast of the plenary sessions, presentation slides, and final Workshop Report, can be accessed at <http://www.hhs.gov/aspr/barda/phemce/workshop/2006>.

Stakeholder Group	% of Attendees
Pharmaceutical/Biotech Industry	46%
Federal Government	36%
Academia	16%
Healthcare Provider/First Responder	13%
State/Local/Tribal Governments	10%
General Public, Other	8%
Media	3%

Table 5. Medical countermeasure stakeholder groups attending the 2007 HHS PHEMC Enterprise Stakeholders Workshop

7.2.2.2 The 2007 HHS PHEMC Enterprise Stakeholders Workshop

The 2007 Stakeholders Workshop garnered considerable attention from the medical countermeasure stakeholder community, with more than 400 attendees in-person, along with more than 1000 who watched the Workshop webcast during or in the week following the event. As shown in Table 5, all segments of the medical countermeasure stakeholder community participated. HHS was particularly pleased by the active participation this year from the healthcare provider and first responder community, as well as the over three-fold increase in representatives from state, local, and tribal governments.

⁵⁵ The meeting took place during the preparation of this report. Information on the NBSB, including a membership roster and information on the meeting, is available at <http://www.hhs.gov/aspr/omsp/nbsb>.

⁵⁶ For a description of the PHEMCE and its members please see section 3.1 of this report.

⁵⁷ As expressed in testimony of Secretary Michael O. Leavitt on HHS Bioterrorism and Public Health Emergency Preparedness before the Senate Committee on Health, Education, Labor and Pensions, United States Senate, March 16, 2006, available at <http://www.hhs.gov/asl/testify/t060316.html>.



The 2007 Workshop expanded its focus to include not only medical countermeasures for intentional CBRN threats, but also critical aspects of pandemic influenza preparedness. Over the course of the three-day Workshop, 64 presentations from the Federal government and other key stakeholder communities offered insights regarding the accomplishments, challenges, and future prospects for research, advanced development, procurement, and effective utilization of medical countermeasures for high-priority threats, whether intentional, accidental, or natural.

Attendees also provided individual feedback during facilitated working group sessions on a number of topics:

- BARDA Implementation
- Federal Partnership with State, Local, and Tribal Authorities in Preparedness and Response
- Incentivizing Private Industry to Support CBRN Medical Countermeasures Preparedness
- Medical Countermeasure Concept of Operations
- Technological Innovations to Improve Medical Countermeasure Response to Meet the Challenge of Novel and Emerging Threats

More detailed information on the 2007 HHS PHEMC Enterprise Stakeholders Workshop, including the videocast of the plenary sessions and presentation slides, can be accessed at <http://www.hhs.gov/aspr/barda/phemce/workshop/2007/2007workshop.html>.

Planning has begun for the 2008 Stakeholder Workshop and information will be posted at <http://www.hhs.gov/aspr/barda/> as it becomes available.

7.2.3 MedicalCountermeasures.gov

During the 2006 BioShield Stakeholders Workshop, HHS Secretary Michael O. Leavitt announced that HHS would develop a Stakeholders Portal that “will be a web-based system through which those in industry and the research and development community can reach the people they need in the federal government, whether they’re looking at a basic level of research or focused on end-stage development.” HHS launched the first module of the site MedicalCountermeasures.gov on August 2, 2007, at the 2007 PHEMCE Stakeholders Workshop (see section 7.2.2.2 of this report). The site is a collaborative effort led by BARDA, and includes CDC, FDA, and NIH; other federal agencies may join in the future. The two primary goals of MedicalCountermeasures.gov are (1) to provide external stakeholders with a central resource for information related to the research and development of medical countermeasures to naturally occurring, intentional, and accidental threats; and (2) to improve communication between HHS and its external stakeholders through improved scheduling and management of meetings directly with these stakeholders.

Through MedicalCountermeasures.gov, external stakeholders can access information on upcoming and past conferences; procurement and grant opportunities; strategies and reports; general regulatory information; and federally sponsored resource programs. In line with HHS’s commitment to continuously improve communication with external stakeholders, most aspects of the site are designed to address stakeholder requests directly.

During roundtable discussions at the 2006 BioShield Stakeholders Workshop, stakeholders stressed the importance of access to the appropriate personnel within government. In response, in the coming year HHS plans to launch a meeting management portion



of the site, to provide a structured meeting management process within HHS, with guidance for product developers to navigate the system. Product developers will submit some basic information about their products to MedicalCountermeasures.gov, and the system will route the information to the most appropriate personnel in HHS. This system will help external stakeholders find the people they need within HHS and enable stakeholders to engage in more targeted, effective communication with HHS.

7.2.4 BARDA Dialogues

As part of BARDA's continuing efforts to improve the way that it communicates with its external stakeholders, BARDA participated during the current reporting period in a series of roundtable discussions with important stakeholder groups. These were hosted by McKenna, Long, and Aldridge; the Center for BioSecurity at the University of Pittsburgh; and the Biotechnology Industry Organization. During these dialogues, ASPR and BARDA staff discussed a wide range of issues with interested stakeholders, including the *HHS PHEMCE Strategy and Implementation Plan*, implementation of the Pandemic and All-Hazards Preparedness Act, and the future of the Project BioShield program.

During the 2006 BioShield Stakeholders Workshop, external stakeholders encouraged BARDA to engage stakeholders more frequently and to communicate more openly with the private sector. Recognizing the importance of this need, BARDA has sought to emphasize direct communication with key stakeholders involved in the research, development, acquisition, and deployment of medical countermeasures for naturally occurring and manmade threats. BARDA looks forward to expanding its dialogues with all critical stakeholder groups, to inform BARDA's efforts to establish and coordinate a national infrastructure that effectively defines, develops, acquires, maintains, and delivers critical medical countermeasures in event of a natural or manmade disaster.



7.2.5 International Outreach

The U.S. Government has been a world leader in public health preparedness, including scientific/biomedical development and progress. These efforts, including U.S. domestic efforts related to CBRN threats in the realm of Project BioShield, can be most effective when they engage the diversity and contributions of international partners. Therefore, the long-term HHS strategy for the development of medical countermeasures includes participation in the global efforts to establish and maintain public health emergency preparedness. The U.S. Government works through the Global Health Security Initiative (GHSI) with other major industrialized nations as they implement their public-health emergency preparedness planning.

The GHSI brings together the Secretaries of Health of the United States, Mexico, and Japan; the Ministers of Health of Canada, France, the Federal Republic of Germany, Italy, and the United Kingdom; the European Commissioner for Health; and the Director-General of the World Health Organization. The GHSI has been meeting since 2001, after the Secretary of HHS at that time, Tommy Thompson, suggested in the aftermath of the September 11 terrorist attacks that countries concerned with bioterrorism and global health security share information and coordinate their efforts.⁵⁸ During the reporting period, the annual GHSI Ministerial meeting was held in December 2006 in Tokyo,⁵⁹ and the United States was slated to host the 2007 meeting in fall 2007.⁶⁰ In addition, the U.S. participated in many international meetings, conferences, and ongoing efforts, including continuing to participate in the development of the Global Health Security Action Group (GHSAG) Laboratory Network and hosting an associated smallpox lab workshop in Atlanta in September 2006.⁶¹

⁵⁸ See <http://www.ghsi.ca/english> for further information on the GHSI and its activities.

⁵⁹ See <http://www.ghsi.ca/english/statementtokyoDec2006.asp> for the Ministerial Statement resulting from this meeting.

⁶⁰ During preparation of this report, the United States hosted the annual GHSI Ministerial meeting from 29 October through 2 November 2007, in Washington DC. In these meetings, HHS Secretary Leavitt welcomed his international colleagues for discus-

sions and briefings, including consideration of procurement of medical countermeasures as part of their domestic preparedness agendas, which would expand the market for specialized medical countermeasures. See <http://www.ghsi.ca/english/statementwashington2007.asp> for the Ministerial Statement resulting from the meeting.

⁶¹ Ministerial Statement from the 2007 GHSI meeting: <http://www.ghsi.ca/english/statementwashington2007.asp>



8.0 Conclusion

During the period covered by this report, HHS substantially advanced implementation of Project BioShield objectives, through use of authorities required to be reported annually, through other activities associated with acquisition of emergency medical countermeasures, and through development and release of important strategic and implementation plans. HHS used Project BioShield authorities to expedite peer review procedures for applications for research grants both for radionuclide decorporation agents and for medical countermeasures to restore gastrointestinal function after radiation exposure. During the period covered by this report, no Emergency Use Authorizations were issued because no determination of an emergency warranting such an authorization was made. NIH did not use the expedited procurement authority related to increased micropurchase threshold, the authority for personal service contracts, or the streamlined personnel authority.

During the current reporting period, HHS engaged in specific acquisition activities (a) to pursue acquisition of rPA vaccine for anthrax, and of therapeutics to mitigate

or treat neutropenia associated with ARS; (b) to award a contract for acquisition of MVA smallpox vaccine, using the newly added PAHPA authority to award milestone payments, as well as original BioShield provisions for advance payments; and (c) to initiate a sole-source acquisition of additional AVA anthrax vaccine. In following up previous Project BioShield activities, HHS (a) terminated a contract for acquisition of rPA vaccine against anthrax, after the contractor did not achieve a major contractual milestone, and (b) canceled an RFP for acquisition of therapeutics to mitigate or treat neutropenia associated with ARS, because no offeror had a product that met the U. S. Government's requirements and that was mature enough to be awarded a Project BioShield contract.

More broadly, during the reporting period HHS has advanced research, development, and acquisition activities related to emergency medical countermeasures, while effecting a major reorganization of the HHS structures responsible for these efforts and developing a strategic vision for implementing the medical countermeasure mission. The timeline in Figure 15

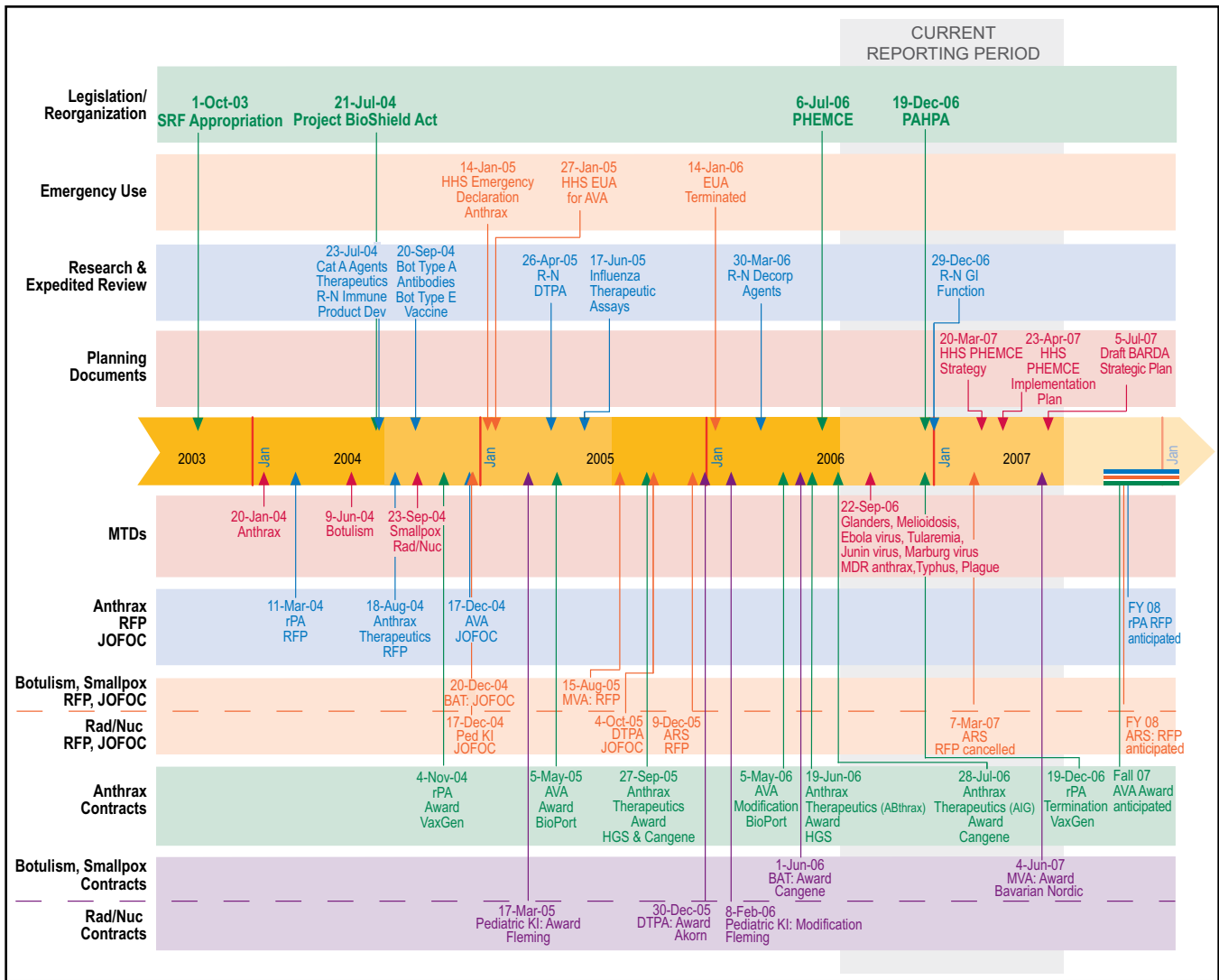


Figure 15. Timeline summarizing major Project BioShield activity.

summarizes major Project BioShield-associated activities through the current reporting period, including the uses of special authorities and major steps in all Project BioShield acquisition programs, starting before enactment of Project BioShield itself. A substantial reorganization was begun just before the period covered in this report, with the creation of the PHEMCE, as reported in the *2006 BioShield Annual Report* and summarized in this report, and continued according to the additional authorities provided by PAHPA after it was signed into law in December 2006. As part of the restructuring stipulated in PAHPA, the new position and office of the ASPR replaced those of the ASPHER, and BARDA succeeded OPHEMC as the central coordinating office for advanced development and acquisition of medical countermeasures.

The recent restructuring efforts have involved substantial growth of the HHS public health emergency preparedness organization to enable accomplishment of the important tasks serving its mission. BARDA has grown from the 29 full-time-equivalent Federal employees working for its predecessor, OPHEMC, at the beginning of August 2006 (not including contract employees) to 81 at the end of July 2007. Throughout this process BARDA has emphasized fostering and institutionalizing transparency and dialogue with all stakeholders, by hosting two Stakeholders Workshops and multiple dialogues with stakeholders around the country; launching an Internet portal for direct communication between HHS and product manufacturers; and soliciting and incorporating substantial stakeholder feedback on the HHS

strategic vision for fulfilling the medical countermeasure mission. The *HHS PHEMCE Strategy*, the *HHS PHEMCE Implementation Plan*, and the *Draft BARDA Strategic Plan* together express the HHS vision for an integrated, systematic approach to the development, acquisition, and availability of the highest-priority vaccines, drugs, therapies, and diagnostic tools for public health and medical emergencies, whether due to intentional acts of adversaries, accidents, or natural events.

Compared with the period covered by the *2006 BioShield Annual Report*, the frequency of some types of Project BioShield activities has been lower during the period covered in this report. This decrease reflects the fact that initial acquisitions and development activities focused on high-priority programs that were already advanced, the “low-hanging fruit.” The substantial attention HHS has given over the past year to establishing a strategic vision for accomplishing the medical countermeasure mission, including efforts under Project BioShield, will ensure that future HHS resources focus on the medical countermeasure programs that have the greatest potential to improve public health emergency preparedness. In parallel with its strategic planning initiatives, HHS has continued to advance its activities under Project BioShield, including (a) a major contract awarded for MVA to treat smallpox in vulnerable segments of the population; (b) steps taken toward additional acquisitions of countermeasures for ARS and



for anthrax; (c) continued management of existing acquisition programs; and (d) ongoing efforts setting the groundwork for future programs.

Project BioShield originally established authorities to facilitate the development, acquisition, and availability of medical countermeasures for use in a public health emergency, including providing for use of the Special Reserve Fund to encourage private sector participation and partnership in this endeavor. In December 2006 PAHPA authorized additional tools with which HHS can provide incentives and share risks with industry. HHS is committed to utilizing fully all the assets available, and has shown substantial progress in implementing both the original and new authorities.

HHS recognizes that successful progress in fulfilling the medical countermeasure mission will require a talented, devoted, and accomplished team, working in coordination with federal, state, local, and tribal partners, with private industry, with academia, and, ultimately, with the general public the endeavor is designed to serve. With the important new tools granted by PAHPA and an enhanced emergency medical countermeasure infrastructure, HHS has been building a solid foundation for engaging all its stakeholders in continuing to achieve preparedness for major public health threats affecting our national security.

9.0 References

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BARDA web site: <http://www.hhs.gov/aspr/barda>

ASPR web site: <http://www.hhs.gov/aspr>

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HSPD-18, *Medical Countermeasures Against Weapons of Mass Destruction*, 7 February, 2007, available at <http://www.whitehouse.gov/news/releases/2007/02/20070207-2.html>

Legislation

Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. 107-188, June 12, 2002, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_aws&docid=f:publ188.107.pdf

Homeland Security Act, P.L. 107-296, November 25, 2002, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ296.107.pdf

Department of Homeland Security Appropriations Act, 2004, P.L. 108-90, October 1, 2003, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ090.pdf (contains the biodefense appropriation that Project BioShield designated as the SRF)

Legislation (continued)

Emergency Supplemental Appropriations Act for Defense and for the Reconstruction of Iraq and Afghanistan, 2004, P.L. 108-106, November 6, 2003, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ106.pdf (contains amendment to the biodefense appropriation that Project BioShield designated as the SRF)

Miscellaneous Appropriations and Offsets Act, 2004, Division H of the Consolidated Appropriations Act, 2004, P.L. 108-199, January 23, 2004, section 168(b), available at http://www.dscs.osd.mil/programs/LPA/2004/getdoc.cgi_dbname=108_cong_public_laws&docid=f:publ199.108.pdf (contains across-the-board rescission that includes the biodefense fund designated as the SRF by Project BioShield)

Project BioShield Act of 2004, P.L. 108-276, July 21, 2004, available through a link at <http://www.hhs.gov/aspr/barda/bioshield> or directly at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ276.108.pdf

Miscellaneous Appropriations and Offsets Act, 2005, Division J, Title I of the Consolidated Appropriations Act, 2005, P.L. 108-447, December 8, 2004, section 122, available at <http://www.loc.gov/law/help/guide/federal/108-477cd.pdf> (contains across-the-board rescission that includes the SRF)

Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005, P.L. 109-13, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ013.109 (includes funding for pandemic influenza)

Department of Defense Appropriations Act of 2006, P.L. 109-148, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ148.109.pdf (includes funding for pandemic influenza)

Public Readiness and Emergency Preparedness Act, Division C of P.L. 109-148, December 30, 2005, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ148.109.pdf

Labor, Health and Human Services, Education and Related Agencies Appropriations Act of 2006, P.L. 109-149, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ149.109.pdf (includes funding for pandemic influenza)

Pandemic and All-Hazards Preparedness Act, P.L. 109-417, December 19, 2006, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ417.109.pdf

Revised Continuing Appropriations Resolution, 2007, P.L. 110-5, February 15, 2007, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:hj20enr.txt.pdf (includes funding available for advanced research and development of medical countermeasures)

U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, P.L. 110-28, May 25, 2007, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ028.110.pdf (includes funding for advanced research and development of medical countermeasures and for preparation and response to pandemic influenza, for FY 2007)

Consolidated Appropriations Act, 2008, P.L. 110-161, December 26, 2007, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h2764enr.txt.pdf (includes funding for advanced research and development of medical countermeasures and for preparation and response to pandemic influenza, for FY 2008)

Other references

“Radiation Disasters and Children” Speaking Points, American Academy of Pediatrics; available at http://www.gnyha.org/eprc/general/nbc/nuclear_radiological/Radiation_Speaking_Points.pdf (recommendation of delivery of KI to children in a liquid preparation due to difficulty children have with tablets)

Testimony of Secretary Michael O. Leavitt on HHS Bioterrorism and Public Health Emergency Preparedness before the Senate Committee on Health, Education, Labor and Pensions, United States Senate, March 16, 2006, available at <http://www.hhs.gov/asl/testify/t060316.html>

Information about the Global Health Security Initiative and its activities, available at <http://www.ghsi.ca/english>

10.0 Appendices

10.1 Appendix A: Statutory Reporting Requirements

The required annual reports to Congress are to address (1) particular exercises of authority and (2) a summary regarding certain activity. These required reports are combined here into this single report.

The Project BioShield Act requires that the Secretary of the Department of Health and Human Services (the Secretary) submit an Annual Report to the following Congressional Committees:

- House Committees
 - Committee on Energy and Commerce
 - Committee on Appropriations
 - Committee on Oversight and Government Reform
 - Select Committee on Homeland Security
- Senate Committees

The Project BioShield Act states “any appropriate committee.” These committees are being provided with the report:

 - Committee on Appropriations
 - Committee for Commerce, Science, and Transportation
 - Committee on Health, Education, Labor, and Pensions
 - Committee on Homeland Security and Governmental Affairs

1. Annual Report on Particular Exercises of Authority:

The Secretary shall submit reports in accordance with subparagraph (B) (see below, “Contents of Reports”) regarding the exercise of authority under the following provisions of law (as specified in section 5(a)(1)(A)(i)–(iii) of the Project BioShield Act):

- (i) With respect to section 319F-1 of the Public Health Service Act (as added by section 2 of this Act, regarding qualified countermeasure research and development activities):
 - (I) Subsection (b)(1) relating to increased simplified acquisition threshold.
 - (II) Subsection (b)(2) relating to procedures other than full and open competition.
 - (III) Subsection (c) relating to expedited peer review procedures.
- (ii) With respect to section 319F-2 of the Public Health Service Act (as added by section 3 of this Act, regarding the Strategic National Stockpile):
 - (I) Subsection (c)(7)(C)(iii) relating to simplified acquisition procedures.
 - (II) Subsection (c)(7)(C)(iv) relating to procedures other than full and open competition.
 - (III) Subsection (c)(7)(C)(v) relating to premium provision in multiple-award contracts.
- (iii) With respect to section 564 of the Federal Food, Drug, and Cosmetic Act (as added by section 4 of this Act, regarding authorization for medical products for use in emergencies):
 - (I) Subsection (a)(1) relating to emergency uses of certain drugs and devices.

- (II) Subsection (b)(1) relating to a declaration of an emergency in consultation with Secretaries of DHS & DOD.

- (III) Subsection (e) relating to conditions on authorization

Contents of Reports (subparagraph B): The Secretary shall annually submit to the designated Congressional Committees a report that summarizes (for each of the exercises of authority listed above):

- (i) the particular actions that were taken under the authorities specified above, including, as applicable, any identification of the threat agent, emergency, or the biomedical countermeasure;
- (ii) the reasons underlying the decision to use these authorities, including as applicable, any options that were considered and rejected;
- (iii) the number and nature of persons/entities that received a grant, agreement, or contract as a result of the use of such authorities and the number and type of persons/entities that were turned down for such grants, agreements or contracts (without disclosing the identity of such persons/entities); and
- (iv) whether a contract was entered into within one year of the President’s approval of any of the procurements (under the conditions as listed in section 3 of the Project BioShield Act).

2. Annual Summary Report to Congress:

The Secretary shall annually submit to the designated Congressional Committees a report that summarizes the activity undertaken pursuant to the following authorities under section 319F-1 of the Public Health Service Act (as added by section 2 of this Act, regarding qualified countermeasure research and development activities):

- (A) Subsection (b) (expedited procurement authority) (3) relating to the increased micropurchase threshold;
- (B) Subsection (d) relating to authority for personal service contracts;
- (C) Subsection (e) relating to streamlined personnel authority.

With respect to subparagraph (B) (above, regarding personal service contracts), the report shall include a provision specifying the dates for the one-year period discussed, the number of persons paid greater than \$100,000 for that period, and the number of persons paid between \$50,000 and \$100,000 for that period.

Note: These actions had to be engaged into for the purpose of performing, administering, or supporting qualified countermeasure research and development activities deemed necessary by the Secretary to respond to pressing qualified countermeasure research and development needs under section 2 of the BioShield Act.

10.2 Appendix B: Update of Acquisitions Reported Previously

Threat Agent/ Acquisition Program	Date Use of SRF Approved by President/OMB	Award Date or Status of Acquisition	Delivery Status to the SNS	Awardee	Quantity	Cost
Anthrax						
Recombinant Protective Antigen (rPA) anthrax vaccine	12-Aug-04 President	Award: 04-Nov-04; contract terminated 19-Dec-06	-	VaxGen, Inc.	75 million doses (25 million treatment courses)	\$878 million
		Sources Sought Notice: 14-May-07; RFP anticipated FY 2008				
Anthrax Vaccine Adsorbed (AVA)	07-Dec-04 OMB	Award: 04-May-05	Completed 12-Feb-06	BioPort Corporation	5 million doses	\$123 million
		Award: 04-May-06	Completed 22-Feb-07	BioPort Corporation	Additional 5 million doses	\$120 million
		Intent to negotiate with only one source: 18-Apr-07; modified 05-May-07; negotiating for additional supply ⁶²	⁶³ ---			
Anthrax therapeutics	12-Aug-04 President	Award: 23-Sep-05 (non-SRF)	Completed	Human Genome Sciences and Cangene Corporation	10 grams	HGS \$1.8 million Cangene \$0.42 million
		Award: 19-Jun-06	-	Human Genome Sciences	20,001 treatment courses	\$165.2 million
		Award: 27-Jul-06	⁶⁴ ---	Cangene Corporation	10,000 treatment courses	\$143.8 million
Radiological/ Nuclear						
Therapeutics to mitigate or treat neutropenia associated with Acute Radiation Syndrome (ARS)	03-Jan-06 OMB	07-Mar-07: RFP of 09-Dec-05 cancelled				
		RFP anticipated FY 2008				

⁶² During the preparation of this report, on September 25, 2007, the contract was awarded to Emergent Biodefense (previously BioPort Corporation) for 18.75 million doses of AVA, at a cost of \$448 million. The contract includes incentives for obtaining licensure of AVA for post-exposure prophylaxis and extension of the expiration dating period of the product.

⁶³ Delivery of AVA under the new contract with Emergent Biodefense (previously BioPort Corporation) commenced during the preparation of this report, on September 28, 2007.

⁶⁴ Delivery of AIG commenced in September 2007, during the preparation of this report.

Threat Agent/ Acquisition Program	Date Use of SRF Approved by President/OMB	Award Date or Status of Acquisition	Delivery Status to the SNS	Awardee	Quantity	Cost
Radiological/ Nuclear (continued)						
Pediatric liquid potassium iodide (KI)	07-Dec-04 OMB	Award: 17-Mar-05	Completed, Sep-05	Fleming & Company Pharmaceuticals	1.7 million bottles	\$5.7 million
		Award: 08-Feb-06	Completed Jul-07 --	Fleming & Company Pharmaceuticals	3.1 million bottles plus retrofitting original purchase with child- proof packaging	plus \$1.5 million
DTPA	03-Jan-06 OMB	Award: 30-Dec-05	Completed, Apr-06	Akorn, Inc.	390,000 doses of Ca-DTPA and 60,000 doses of Zn-DTPA	\$21.9 million
		Modification: 13-Apr-06	Completed, Apr-06	Akorn, Inc.	Contract modification for an additional 5,370 doses of Ca-DTPA and 19,369 doses of Zn-DTPA	\$32,500
Smallpox						
Modified Vaccinia Ankara (MVA) smallpox vaccine	07-Dec-04	Award: 24-Jun-07 ⁶⁵	--	Bavarian Nordic	20 million doses	\$500 million
Botulism						
Botulinum antitoxin (BAT)	17-Aug-04 President	Award: 01-Jun-06	--- ⁶⁶	Cangene Corporation	200,000 doses	\$363 million
Yellow – changed (new or revised) from the 2006 BioShield Annual Report						

⁶⁵ Includes (refundable) advanced payments under original Project BioShield authorities, and additional (non-refundable) milestone payments under amendments in PAHPA.

⁶⁶ Delivery of BAT commenced in September 2007, during the preparation of this report.

10.3 Appendix C: Abbreviations and Glossary

2006 BioShield Annual Report.....	Project BioShield Annual Report to Congress: July 2004 through July 2006
AHRQ.....	Agency for Healthcare Research and Quality
AIG.....	Anthrax Immune Globulin
ARS.....	Acute Radiation Syndrome
ASPHEP.....	Assistant Secretary for Public Health Emergency Preparedness
ASH.....	Assistant Secretary for Health
ASL.....	Assistant Secretary for Legislation
ASPR.....	Assistant Secretary for Preparedness and Response
ASRT.....	Assistant Secretary for Resources and Technology
AVA.....	Anthrax Vaccine Adsorbed
BAA.....	Broad Agency Announcement
BARDA.....	Biomedical Advanced Research and Development Authority
BAT.....	Botulinum Antitoxin
BLA.....	Biologics License Application
CBER.....	Center for Biologics Evaluation and Research; an office of FDA
CBRN.....	chemical, biological, radiological and nuclear
CDC.....	Centers for Disease Control and Prevention
CDER.....	Center for Drug Evaluation and Research; an office of FDA
CDRH.....	Center for Devices and Radiological Health; an office of FDA
CHEMPACK.....	A program providing packages of nerve agent antidotes for prepositioning by state, local, and/or tribal officials throughout the U.S.
CounterACT.....	Countermeasures Against Chemical Threats grants program of the NINDS
current reporting period.....	August 2006 through July 2007, plus August 1-3, 2007
DEARE.....	Delayed Effects of Acute Radiation Exposure
DHHS.....	U.S. Department of Health and Human Services (also HHS)
DHS.....	Department of Homeland Security
DSNS.....	Division of the Strategic National Stockpile – a division of the Centers for Disease Control and Prevention responsible for managing the Strategic National Stockpile
DTPA.....	diethylenetriaminepentaacetate
DOD.....	Department of Defense
<i>Draft BARDA Strategic Plan</i>	<i>Draft BARDA Strategic Plan for Medical Countermeasure Research, Development, and Procurement</i> (http://www.hhs.gov/aspr/barda/documents/draftbardaplan.pdf)
Enterprise Governance Board.....	Public Health Emergency Medical Countermeasures Enterprise Governance Board
EOP.....	Executive Office of the President

EUA.....	Emergency Use Authorization
FAR	Federal Acquisition Regulations
FDA.....	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FY	fiscal year
GC.....	General Counsel
GHSAG	Global Health Security Action Group
GHSI	Global Health Security Initiative
HHS	U.S. Department of Health and Human Services (also DHHS)
<i>HHS PHEMCE Implementation Plan</i>	<i>HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan for Chemical, Biological, Radiological and Nuclear (CBRN) Threats (Federal Register, 23 Apr 2007, Vol. 72, No. 77, pp. 20117-20128; correction: Federal Register, 2 May 2007, Vol. 72, No. 84, p. 24313)</i>
HHS PHEMCE Strategy.....	<i>HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear (CBRN) Threats (Federal Register, 20 Mar 2007, Vol. 72, No. 53, pp. 13109-13114)</i>
HSPD.....	Homeland Security Presidential Directive
IDE.....	Investigational Device Exemption
IND	Investigational New Drug application
JOFOC.....	Justification for other than full and open competition
KI	potassium iodide
MCM.....	medical countermeasure
medical countermeasure.....	used interchangeably with “security countermeasure” as defined in section (3)(c)(1)(B) of the Project BioShield Act of 2004, section 319F-2 of the Public Health Service Act (PHS Act): a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act [FFDCA] (21 U.S.C. 321 (g)(1))), biological product (as that term is defined by section 351(i) of the PHS Act (42 U.S.C. 262(i))), or device (as that term is defined by section 201 (h) of the FFDCA (21 U.S.C. 321 (h))) that the Secretary of HHS determines to be a priority (consistent with sections 302(2) and 304(a) of the Homeland Security Act of 2002) to treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2) (A)(ii), or to treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; the Secretary determines under section 319F-2(c)(2)(B)(ii) of the PHS Act to be a necessary countermeasure; and is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within eight years after the date of a determination under paragraph (5) of section 319F-2(c); or is approved or cleared under chapter V of the FFDCA or licensed under section 351 of the PHS Act; or is authorized for emergency use under section 564 of the FFDCA.

Abbreviations and Glossary (continued)

MTA	Material Threat Assessment; now called PTA, Population Threat Assessment. See PTA.
MTD	Material Threat Determination; refers to an official statement by DHS that a specific CBRN agent has been determined to pose a material threat to the U.S. population sufficient to affect national security.
MVA	Modified Vaccinia Ankara
NA.....	not applicable
NIAID	National Institute of Allergy and Infectious Diseases
NINDS	National Institute of Neurological Diseases and Stroke
NIH	National Institutes of Health
NPS	National Pharmaceutical Stockpile
NRC	Nuclear Regulatory Commission
NSPD.....	National Security Presidential Directive
OASPHEP	Office of the Assistant Secretary for Public Health Emergency Preparedness, later named Office of Public Health Emergency Preparedness (OPHEP), and subsequently the Office of the Assistant Secretary for Preparedness and Response (ASPR)
OEP.....	Office of Emergency Preparedness
OGHA.....	Office of Global Health Affairs
OMB	Office of Management and Budget
OMSPH.....	Office of Medicine, Science, and Public Health
OPEO	Office of Preparedness and Emergency Operations
OPHEMC	Office of Public Health Emergency Medical Countermeasures
OPHEP.....	Office of Public Health Emergency Preparedness
OPHP	Office of Public Health Preparedness
OPSP	Office of Policy and Strategic Planning
ORDC.....	Office of Research and Development Coordination, which later became the Office of Public Health Emergency Medical Countermeasures (OPHEMC), and subsequently the Biomedical Advanced Research and Development Authority (BARDA)
PAHPA.....	Pandemic and All-Hazards Preparedness Act (P. L. 109-417)
PHEMCE.....	Public Health Emergency Medical Countermeasures Enterprise
PHEMC Enterprise.....	Public Health Emergency Medical Countermeasures Enterprise
PHS Act	Public Health Service Act
P. L.....	Public Law
PP&R.....	Policy, Planning, and Requirements; an office within BARDA
PPO.....	Program Protection Office; an office within BARDA

PREP Act	Public Readiness and Emergency Preparedness Act (P. L. 109-148)
Project BioShield	Project BioShield Act of 2004 (P.L. 108-276)
PTA	Population Threat Assessment; previously MTA, an official estimate of the magnitude and severity of the threat that a specific CBRN agent poses to the U.S. population, based on scientific evidence and classified intelligence information of plausible high-consequence scenarios.
qualified medical countermeasure	A medical countermeasure that qualifies for research under the terms of section 2 of the Project BioShield Act, which inserts a new section (319F-1) into the Public Health Service Act
RFA	Request for Applications
RFI	Request for Information
RFP	Request for Proposals
rPA	recombinant protective antigen
RPO	Resources and Program Operations; an office within BARDA
security countermeasure	A countermeasure that qualifies for purchase under the terms of section 3 of the Project BioShield Act, which inserts a new section (319F-2) into the Public Health Service Act.
SNS	Strategic National Stockpile. The federal cache of pharmaceuticals, vaccines, medical supplies, equipment, and other items to augment local supplies of critical medical care targeted to high-priority diseases and conditions (based on the CDC Category A agents). Also refers to the program and support staff managing and operating this cache. Formerly known as the National Pharmaceutical Stockpile (NPS).
SRF	Special Reserve Fund as defined in the Project BioShield Act, using the funds appropriated in P.L. 108-90, the Department of Homeland Security (DHS) Appropriations Act, 2004. P.L. 108-90 appropriated \$5.593 billion for FY 2004 through FY 2013, for the purpose (as amended in P.L. 108-106) of “procuring security countermeasures under section 319F-2(c) of the Public Health Service Act, as authorized under section 510(a) of the Homeland Security Act of 2002.” This is an advance appropriation for the entire 10-year cost of Project BioShield. The appropriation specifies that \$890 million of the total are available to be obligated in FY 2004 and \$3.418 billion of the total (including the amount up to \$890 million for FY 2004) are available for obligation for FY 2004 through FY 2008.
TBD	to be determined
TechWatch	Technology Watch; BARDA’s program to keep up-to-date information on technological developments in medical countermeasures.
TRLs	Technology Readiness Levels; an index of the stage of technological development of medical countermeasures
USG	United States Government
VA	U.S. Department of Veterans Affairs
WMDs	Weapons of Mass Destruction



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