



Project BioShield Annual Report to Congress

August 2007 through December 2008

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CONTENTS

1.0	Executive Summary	2
2.0	Introduction	4
2.1	Background	4
2.2	Summary of BioShield Authorities and Statutory Reporting Requirements	4
2.3	Scope of This Report	6
3.0	Overview of BioShield Authorities Used	7
3.1	Introduction and Summary	7
3.2	Medical Countermeasures for Biological Threats	13
3.2.1	Medical Countermeasures for Anthrax	13
3.2.1.1	Anthrax Vaccines	13
3.2.1.2	Anthrax Therapeutics	13
3.2.1.3	Anthrax Personal Preparedness	14
3.2.2	Medical Countermeasures for Botulism	14
3.2.3	Medical Countermeasures for Smallpox	14
3.3	Medical Countermeasures for Radiological and Nuclear Threats	15
3.3.1	Research	16
3.3.1.1	Medical Countermeasures to Restore Gastrointestinal Function after Radiation Exposure	16
3.3.1.2	Medical Countermeasures to Enhance Platelet Regeneration and Increase Survival Following Radiation Exposure	17
3.3.1.3	Medical Countermeasures to Mitigate and/or Treat Ionizing Radiation-Induced Pulmonary Injury	17
3.3.1.4	Medical Countermeasures to Mitigate and/or Treat Ionizing Radiation-Induced Cutaneous Injury	17
3.3.2	Advanced Development and Acquisition	17
3.3.2.1	Potassium Iodide (KI)	17
3.3.2.2	Calcium and Zinc Diethylenetriaminepentaacetate (Ca- and Zn-DTPA)	18
3.3.2.3	Medical Countermeasures for Acute Radiation Syndrome (ARS)	19
3.4	Medical Countermeasures for Chemical Threats	19
3.5	Report on Exercises of Authority: Food and Drug Administration (FDA)	20
4.0	Conclusion	21
5.0	Footnotes	22
6.0	References	23
7.0	Appendices	26
7.1	Appendix A: Statutory Reporting Requirements	26
7.2	Appendix B: Update of Acquisitions Reported Previously	28
7.3	Appendix C: Abbreviations and Glossary	30

Tables

Table 1. Summary of use of authorities during the current reporting period, Aug 07-Dec 08	9
Table 2. Summary of Project BioShield acquisition-related activities during the current reporting period, Aug 07-Dec 08.	10
Appendix B: Update of Acquisitions Reported Previously	28

1.0 EXECUTIVE SUMMARY



THE PROJECT BIOSHIELD ACT OF 2004 (Public Law [P.L.] 108-276; Project BioShield), enacted on 21 July 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 19 December 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 infectious disease-causing organisms) that cause a public health emergency affecting national security. PAHPA established the position of the Assistant Secretary for Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA, which is within the Office of the ASPR) to facilitate a broad-based approach to emergency medical

countermeasure-related activities, including enhancing the capabilities for support of advanced research and development. PAHPA authorized funds for advanced development of medical countermeasures that are not yet ready for acquisition using the SRF. An important authority for advanced research and development included in PAHPA affecting eventual Project BioShield acquisitions is to “give priority to the advanced research and development of qualified countermeasures...that are likely to be safe and effective with respect to children, pregnant women, elderly, and other at-risk individuals.”

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 2007 through December 2008. The previous annual reports, the *Project BioShield Annual Report to Congress: July 2004 through July 2006 (2006 BioShield Annual Report)* and the *Project BioShield Annual Report to Congress: August 2006 through July 2007 (2007 BioShield Annual Report)* covered the previous reporting periods.

The required information on the uses of the authorities is summarized in section 3 of this report. During the current reporting period, HHS used two of the Project BioShield authorities subject to required annual reporting—the authority to expedite peer review procedures for research proposals and the Emergency Use Authorization (EUA).

HHS used the expedited peer review authority (1) to award research grants involving radionuclide decorporation agents and (2) to issue three Requests for Applications (RFAs) and award the associated grants for research involving medical countermeasures for other aspects of radiation-induced injury. The U.S. Food and Drug Administration (FDA) Commissioner issued an EUA for the emergency use of doxycycline hyclate tablet emergency kits for post-exposure prophylaxis of inhalational anthrax for United States Postal Service (USPS) participants and their household members as part of the Cities Readiness Initiative (CRI).¹

Acquisition activities under Project BioShield during the current reporting period were carried out using regular procedures stipulated in the Federal Acquisition Regulation (FAR), as well as some of the expanded authorities authorized in PAHPA. None of the special BioShield authorities were necessary, as regular procedures were sufficient. 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 activities² (a) to complete a sole-source acquisition of additional Anthrax Vaccine Adsorbed (AVA) initiated during the previous reporting period; (b) to pursue acquisition of recombinant protective antigen (rPA) vaccine for anthrax, by issuing a Sources-Sought Notice and a Request for Proposals (RFP); (c) to pursue acquisition of therapeutics to mitigate or treat neutropenia associated with acute radiation syndrome (ARS), by issuing a Sources-Sought Notice and a Request for Proposals; (d) to determine potential suppliers for emergency responder anthrax antimicrobial kits, by issuing a Sources Sought Notice; and (e) to determine potential suppliers of physical and biological dosimetry techniques and devices that would be useful in initial triage after radiological

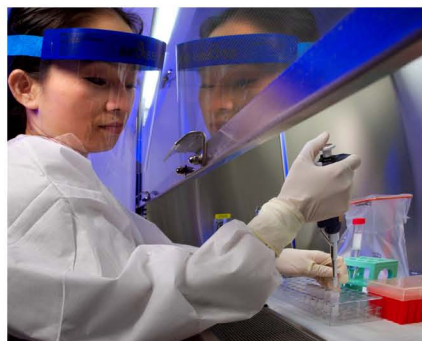
and nuclear incidents, by issuing a Sources Sought Notice. In addition, broad agency announcements (BAAs) were issued during this reporting period to invite proposals for advanced development of the following medical countermeasures: filovirus vaccines, broad-spectrum antimicrobials, platform technologies, vaccine enhancement, and radiation-exposure countermeasures. BARDA also awarded, for the first time, advance payment and milestone payments to a contractor in alignment with the authorities granted under Project BioShield and the new authorities granted under PAHPA (respectively). The contract to Bavarian-Nordic for Modified Vaccinia



Ankara (MVA) smallpox vaccine was awarded during the previous reporting period, as reported in the *2007 BioShield Annual Report*. The payments are in advance of the contractor delivering product to the U.S. Government (USG) and assist the contractor in bridging the “valley of death” (a dearth of financial support between Phase I clinical studies and FDA approval). In awarding these payments the USG is now sharing with its industry stakeholders more of the risk associated with developing medical countermeasures.

These ongoing efforts to advance research, development, and acquisition of emergency medical countermeasures for biological, radiological, and nuclear threats are substantial accomplishments associated with Project BioShield during the current reporting period.

2.0 INTRODUCTION



2.1 Background

THE PROJECT BIOSHIELD ACT (PUBLIC Law [P.L.] 108-276; Project BioShield) was enacted in 2004, as part of a national effort to prepare for major intentional threats to public health, particularly those posed by terrorists. The effort to increase emergency preparedness complemented others taken following the terrorist attacks on September 11, 2001, and the anthrax attacks in the subsequent months. The historical events associated with these efforts were summarized in the *2007 BioShield Annual Report*.

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; 1 October 2003), and its purpose was generalized in a subsequent amendment (P.L. 108-106, Sec. 1201; 6 November 2003).

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 Assistant Secretary for Public Health Emergency Preparedness, 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 the Biomedical Advanced Research and Development Authority (BARDA), which is within the Office of the ASPR and acquired the duties and responsibilities of the former Office of Public Health Emergency Medical Countermeasures, as well as the new authorities invested by the statute.

This report describes the use of the special authorities required to be reported annually by the Project BioShield Act, and associated Project BioShield acquisition-related activities from August 2007 through December 2008.

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. The *2007 BioShield Annual 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 infectious disease-causing organisms) 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.³

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 Department of Homeland Security (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.⁴

PAHPA also amended the payment provisions of Project BioShield to authorize milestone payments of 5 percent each for achieving specific milestones in product development, up to 50 percent of the total contract amount, as deemed

necessary for success of the contract. These payments, made in advance of the contractor delivering product to the U.S. Government (USG), would not be subject to refund to the USG if delivery is not completed. The original terms of Project BioShield stipulated payment on an acquisition contract only upon delivery of a countermeasure to the Strategic National Stockpile (SNS), with an exception allowing the Secretary to authorize up to ten percent of the contract amount in advance payments if deemed necessary for contract success. This original type of advance payment would be subject to refund to the USG if the contract were not fulfilled through delivery of product to the SNS. A 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. The PAHPA-authorized non-refundable milestone payments assist contractors in bridging the “valley of death” of risky financial investment during the late stages of development of medical countermeasures. A contract utilizing both authorities was awarded in the 2006-2007 reporting period to Bavarian Nordic for acquisition of a new smallpox vaccine (reported in the *2007 BioShield Annual Report* and summarized here in section 3.2.3 and in Appendix B).

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 authorized the appropriation of up to \$5.593 billion over ten years (fiscal year [FY] 2004 through FY 2013) in a Special Reserve Fund (SRF) for the procurement of security countermeasures for the SNS. The Act specified that up to \$3.4 billion could be obligated from FY 2004 through FY 2008, with the balance available from FY 2009 through FY 2013. The Project BioShield Act also authorized the use of simplified acquisition procedures and the modified use of other than full and open competition, and enabled the USG to pay premiums in multiple-award contracts.

- **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 use, when an emergency has been declared by the Secretary of HHS justifying such use; the Secretary has delegated this Emergency Use Authorization authority to the FDA Commissioner.

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).

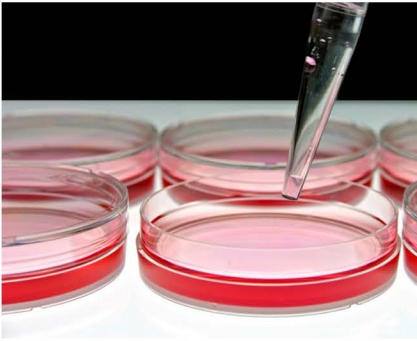
Also as required, this report provides a separate summary of activities relating to the use for research and development of (a) the increased micropurchase threshold, (b) authority for personal services contracts, and (c) streamlined personnel authority for NIH positions.

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 2007, through December 2008 (the current reporting period). 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;⁵ activity in the next year beyond the current reporting period will be included in next year's report.

Besides reporting on the use of authorities required to be reported, this report also covers closely associated Project BioShield acquisition activities, including an update of the corresponding material in the *2007 BioShield Annual Report*, and advanced development activities aimed eventually to make products available that are suitable for Project BioShield acquisition. For contextual and historical information, refer to the BARDA Web site,⁶ to previous *BioShield Annual Reports*,⁷ and to a recent *BARDA Annual Report*,⁸ on the broader organizational, strategic, and planning context of BARDA's efforts through which it works to safeguard public health aspects of national security.

3.0 OVERVIEW OF BIOSHIELD AUTHORITIES USED



3.1 Introduction and Summary

Table 1 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 2 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 Appendix B of the *2007 BioShield Annual Report* of Project BioShield acquisition programs for eight products, including new activities in those programs. The remainder of this section contains brief summaries of the status of development of priority medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) threats.

During the current reporting period, HHS used two of the Project BioShield authorities subject to required annual reporting, the authority of NIH to expedite peer review procedures for research proposals (Table 1 and Section 3.3.1) and the FDA's Emergency Use Authorization (EUA; Section 3.5).

The National Institute of Allergy and Infectious Diseases (NIAID), a component of the 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), (1) to award ten grants to ten organizations for research on medical countermeasures to restore gastrointestinal function after radiation exposure, and (2) to issue Requests for Applications and to award the following associated grants: (a) five grants to five organizations for research on medical countermeasures to enhance platelet regeneration and increase survival after radiation exposure; (b) four grants to four organizations for the development of medical countermeasures to mitigate and/or treat radiation-induced pulmonary syndrome; and (c) four grants to four organizations for the development of medical countermeasures to mitigate and/or treat radiation-induced cutaneous syndrome.

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;⁹ 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.¹⁰

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, the FDA Commissioner issued an Emergency Use Authorization (EUA) on 3 October 2008 for the emergency use of doxycycline hyclate tablet emergency kits for post-exposure prophylaxis of inhalational anthrax for United States Postal Service (USPS) participants and their household members as part of the Cities Readiness Initiative (CRI).¹¹

As noted above, PAHPA established BARDA with expanded authorities for advanced research and development (ARD), along with authorizing a funding mechanism for ARD separate from the SRF used for Project BioShield acquisitions. Although ARD activity is separate from Project BioShield per se, and it is funded through a separate funding mechanism, ARD activity is nevertheless aimed at development of countermeasures that would eventually qualify for acquisition under Project BioShield, and therefore is included as part of the context here for Project BioShield-related activity. Sources Sought Notices intended to determine the state of development and availability of desired types of medical countermeasures are also included as Project BioShield-related activity. In addition, a Centers for Disease Control and Prevention (CDC) contract used for resupply of AVA, which was originally a Project BioShield acquisition, is included as follow-on activity sustaining the supply that Project BioShield initially made possible.

During the reporting period, Sources Sought Notices were issued (a) for development of emergency responder anthrax antimicrobial kits; (b) for determination of ways to make antibiotics for antimicrobial kits palatable for children and to label the kits appropriately; and (c) for physical



and biological dosimetry techniques and devices useful in triage after radiological and nuclear incidents. A Broad Agency Announcement (BAA) was issued to solicit offers and contracts were awarded for advanced development of therapies for hematopoietic syndrome, bone marrow stromal cell loss, and vascular injury resulting from acute exposure to ionizing radiation. In addition, acquisitions initiated previously were pursued (Table 2 and Appendix B). The products that are or previously were subjects of Project BioShield acquisition programs are rPA anthrax vaccine, Anthrax Vaccine Adsorbed (AVA), anthrax therapeutics, Modified Vaccinia Ankara (MVA) smallpox vaccine, botulism antitoxin (BAT), therapeutics for acute radiation syndrome (ARS), a liquid pediatric formulation of potassium iodide (KI) to block thyroid uptake of radioactive iodine, and diethylenetriaminepentaacetate (DTPA) for radionuclide removal. Besides the activity indicated in Table 2 and Appendix B, ARD funding was used to fund five contracts for anthrax therapeutics, two for anthrax vaccine, one for broad-spectrum antibiotics, two for smallpox therapeutics, and one for a Good Laboratory Practices (GLP) radionuclide facility; and to fund three grants for orally available DTPA, four for treatment of radiation-induced cutaneous injury, four for treatment of radiation-induced pulmonary injury, and 19 for use of midazolam as a countermeasure for chemical agents.¹²

Table 1. Summary of use of authorities during the current reporting period, Aug 07-Dec 08.

Gray shading indicates activities initiated during the previous reporting period, Aug 06-Jul 07.

Summary of Use of Authorities	Threat Agent/ Emergency/ Medical Countermeasure	Actions	Reason for decision to use authority	Number/nature of recipients of award or contract	Number/nature of those turned down
RESEARCH AND DEVELOPMENT ACTIVITIES					
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	Although the threat of radiological/nuclear attacks or incidents continues, few medical countermeasures exist. The regular review process takes too long.	10 grants awarded Sep-07: 1 non-profit organization, 8 universities, and 1 biotech company	34 turned down: 5 non-profit organizations, 22 universities, and 7 biotech companies
Expedited peer review procedure	Medical countermeasures to enhance platelet regeneration and increase survival following radiation exposure	27-Sep-07: NIAID RFA-AI-07-036 Response date: 9-Jan-08 26 applications received	Same as above	5 grants awarded Jul – Sep-08: 1 non-profit organization, 2 universities, and 2 biotech companies	21 turned down: 5 non-profit organizations, 11 universities, and 5 biotech companies
Expedited peer review procedure	Medical countermeasures to mitigate and/or treat ionizing radiation-induced pulmonary injury	18-Dec-07: NIAID RFA-AI-07-040 Response date: 11-Mar-08 34 applications received	Same as above	4 grants awarded Sep-08: 1 non-profit organization, 2 universities, and 1 biotech company	30 turned down: 4 non-profit organizations, 21 universities, and 5 biotech companies
Expedited peer review procedure	Medical countermeasures to mitigate and/or treat ionizing radiation-induced cutaneous injury	27-Dec-07: NIAID RFA-AI-07-037 Response date: 11-Mar-08 31 applications received	Same as above	4 grants awarded Sep-08: 4 universities	27 turned down: 3 non-profit organizations, 16 universities, and 8 biotech companies
AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES					
Emergency Use Authorization	Threat agent: inhalational anthrax Biomedical countermeasure: doxycycline hyclate tablet emergency kits	03-Oct-08: Authorization for emergency use of doxycycline hyclate tablet emergency kits for post-exposure prophylaxis of inhalational anthrax for United States Postal Service (USPS) participants and their household members as part of the Cities Readiness Initiative (CRI)	Determination by the Secretary of DHS that there is a significant potential for a domestic emergency, involving a heightened risk of attack with <i>Bacillus anthracis</i> . On the basis of such determination, Secretary of HHS Michael O. Leavitt (the Secretary) declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a).	NA	NA

Table 2. Summary of Project BioShield acquisition-related activities during the current reporting period, Aug 07-Dec 08.

Summary of Acquisition-Related Activity	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 (OMB) approval?
Anthrax						
Contract award (SRF)	Anthrax Vaccine Adsorbed (AVA)	25-Sep-07: Contract award for \$447.7 million, for 18.75 million doses. The contract includes incentives for obtaining licensure of AVA for post-exposure prophylaxis and incentives for extension of the expiration dating period of the product.	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.	Biotechnology company: Emergent BioSolutions		Approval 21-Jun-07; contract 25-Sep-07, within one year
Contract award (CDC)	Anthrax Vaccine Adsorbed (AVA)	30-Sep-08: RFP-DHHS-BARDA-08-26 Contract award for \$404.7 million, for up to 14.5 million doses.	[See above cell.]	Biotechnology company: Emergent BioSolutions		NA
Sources Sought Notice	rPA vaccine	08-Feb-08: HHS-BARDA-08-01-SB Response date: 21-Feb-08 (seeking responses from small businesses)	Anthrax is a high-priority threat. Although the SNS contains AVA vaccine against anthrax and has been acquiring additional supplies of it to support near-term preparedness, acquisition of a next-generation anthrax vaccine using the latest vaccine development technologies is among the top priorities of HHS.	NA		NA
RFP (SRF)	rPA vaccine	28-Feb-08: RFP-BARDA-08-15 Response date: 31-Jul-08	[See above cell.]	TBD Multiple awards possible, subject to the availability of funds		Approval: 12-Aug-04; not within one year ^A
Sources Sought Notice	Emergency Responder Anthrax Antimicrobial Kits	07-Mar-08: SS-HHS-BARDA-08-99 Response date: 21-Mar-08	Anthrax is a high-priority threat. In case of a threat, emergency responders will need to be protected to serve the community.	NA		NA

Table 2. Summary of Project BioShield acquisition-related activities during the current reporting period, Aug 07-Dec 08 (continued).

Summary of Acquisition-Related Activity	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 (OMB) approval?
Anthrax (continued)						
RFP (ARD)	For antimicrobial MedKits, food palatability studies to mask the bitter taste of doxycycline and ciprofloxacin, and studies evaluating home preparation instructions.	25-Jan-08: RFP-BARDA-08-12 Response date: 08-Feb-08	Following the 2001 anthrax mail attacks, concerns were raised about the availability of pediatric formulations of ciprofloxacin and doxycycline should another anthrax attack occur. Therefore, the development of emergency home preparation instructions for pediatric use of these antibiotic drugs began. Drugs mixed with food/drink were rated for palatability. However, absolute palatability was not measured. As a result of these initial studies, there is also interest in determining how home preparation instructions could be a viable component of a home MedKit for personal stockpiling purposes.	NA		NA
Radiological/Nuclear Threats						
Sources Sought Notice	Physical and Biological Dosimetry Techniques and Devices Useful in Initial Triage After Radiologic and Nuclear Events	20-May-08: RFI-BARDA-08-21A Response date: 07-Jul-08 ^B	HHS regards radiological and nuclear agents as a significant threat to national security. Biodosimetry capability will be essential for medical management of those acutely exposed to radiation and is integral to triage and management processes. Medical decision tools and processes that will be used for medical triage must allow for rapid, rational initiation of necessary medical intervention, including medical countermeasures, in the midst of a large-scale emergency.	NA	NA	NA
RFP (SRF)	Advanced Therapeutics for Treating Neutropenia Resulting from Acute Exposure to Ionizing Radiation	17-Mar-08: HHS-BARDA-08-10 Response date: 23-May-08 ^C	ARS resulting from acute exposure to ionizing radiation, of which neutropenia is a primary health-endangering component feature, is a priority health concern under the high-priority threat of a radiological or nuclear incident.	TBD ^D	TBD ^E	Approval: 03-Jan-06; not within one year ^F

Table 2. Summary of Project BioShield acquisition-related activities during the current reporting period, Aug 07-Dec 08 (continued).

Summary of Acquisition-Related Activity	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 (OMB) approval?
Radiological/Nuclear Threats (continued)						
BAA (ARD)	Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss and Vascular Injury Resulting From Acute Exposure to Ionizing Radiation	06-Mar-08; BAA-BARDA-08-08 Response date: 17-Apr-08 7 awards made on 16-Sep-08	ARS resulting from acute exposure to ionizing radiation, of which hematopoietic syndrome, bone marrow stromal cell loss, and vascular injury are health-endangering component features, is a priority health concern under the high-priority threat of a radiological or nuclear incident. This announcement is for advanced development using non-SRF funding, but is intended to lead eventually to a BioShield acquisition.	7 total: 1 non-profit research organization; 3 universities; 3 small business biotech companies ^g	6 total: 1 university; 1 non-profit organization; 3 small business biotech companies; 1 foreign offeror	NA

Footnotes for Table 2

^A A contract associated with this approval was originally awarded within one year (4-Nov-04), but the contract was subsequently terminated (19-Dec-06), as reported in the *2007 BioShield Annual Report* (p. 36).

^B A presolicitation notice was released on 16-Jan-09 for advanced research and development for this purpose, BAA-BARDA-09-36, "Point of care or high-throughput biological assays for determining absorbed ionizing radiation dose (biodosimetry) after radiologic and nuclear events," followed by an announcement (BAA) on 27-Feb-09.

^C This solicitation was canceled on 16-Jan-09 because none of the offers received in response met the Government's requirements. A subsequent presolicitation notice for advanced development of medical countermeasures for the same purpose was issued on 16-Jan-09: HHS-BARDA-09-33, followed by a Draft RFP on 20-Feb-09, and an RFP on 13-Mar-09: BARDA-09-100-SOL-00005. ARD funding is anticipated to be used for the contract(s) resulting from this solicitation.

^D See previous footnote regarding cancellation of this RFP.

^E See previous footnote regarding cancellation of the RFP.

^F An initial RFP of 09-Dec-05 was canceled on 07-Mar-07, because no competing offeror had a product that met U.S. Government requirements and that was mature enough for a Project BioShield acquisition, as reported in the *2007 BioShield Annual Report* (pp. 41-42).

^G Details are available through "Award" links at https://www.fbo.gov/index?s=opportunity&mode=form&id=a8f8740158d15c32d4f9f4a8defdfcb2&tab=core&_cview=1.

3.2 Medical Countermeasures for Biological Threats

3.2.1 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.

3.2.1.1 Anthrax Vaccines

Anthrax vaccine programs have been underway to increase near-term preparedness by acquisition of currently available anthrax vaccine, while also supporting work toward 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. Emergent BioSolutions (previously BioPort) made



the final delivery of ten million initially contracted doses to the SNS in February 2007. To enhance near-term preparedness, on 25 September 2007 BARDA awarded a sole-source contract to Emergent for 18.75 million new doses of AVA, at a cost of \$448 million. The contract includes incentives for obtaining licensure of AVA for post-exposure prophylaxis and for extension of the expiration dating period of the product. On 2 October 2007 Emergent announced completion of the initial delivery to the SNS, on 28 September 2007.

Efforts to acquire a second generation anthrax vaccine based on rPA are also ongoing. On 26 November 2007, BARDA released a draft RFP for rPA vaccine for comments. On 08 February 2008 HHS released a Sources Sought Notice seeking responses from small businesses, with a response date of 21 February 2008. HHS released the final RFP on 28 February 2008, with a response date of 31 July 2008. One or more awards are anticipated to result from this solicitation, depending on availability of funds.

3.2.1.2 Anthrax Therapeutics

BARDA continues to make progress toward adding to the stockpile therapeutic antitoxin products for treatment of anthrax-infected patients. Two contracts for acquisition of such products have been in place, with Human Genome Sciences and Cangene Corporation.

In September 2007, Cangene Corporation announced an initial delivery to the SNS of Anthrax Immune Globulin (AIG) under the terms of the



contract awarded by HHS on 28 July 2006. AIG potentially could be used in an incident under an existing CDC-held Investigational New Drug (IND) protocol. It has been administered in two cases in which men who made drums from animal hides developed anthrax infections.¹³ Cangene will provide data to support an EUA and plans to file a Biologics License Application (BLA) for its AIG product.

Product development efforts also continue under the Project BioShield contract for the acquisition of Raxibacumab™ (formerly “Abthrax™”), a therapeutic anthrax antitoxin from Human Genome Sciences. Initial product delivery is anticipated for 2009.¹⁴

3.2.1.3 Anthrax Personal Preparedness

BARDA issued a Sources Sought Notice¹⁵ for Emergency Responder Anthrax Antimicrobial Kits on 7 March 2008, which would contain antibiotic medication to protect first responders to an anthrax incident.

3.2.2 Medical Countermeasures for Botulism

Botulism is a muscle-paralyzing disease caused by a toxin made by the bacterium *Clostridium botulinum*. 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.

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) has a requirement for supplies of heptavalent botulism

antitoxin (h-BAT). The previous activities toward acquisition of h-BAT for the SNS were reported in the previous *BioShield Annual Reports*. Cangene Corporation completed all of the FDA-mandated product requirements to support the submission of pre-EUA documentation, and made an initial delivery of h-BAT to the SNS in September 2007. HHS/NIAID also continues to support research and development for next-generation medical countermeasures for the treatment of botulism.

The h-BAT from the SNS was administered in early 2008 to an infant with type F botulism under a CDC-held IND protocol, with positive results.¹⁶

3.2.3 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 for the entire population of the United States. However, the vaccine licensed in the United States is potentially unsafe for persons with impaired immune systems.

Modified Vaccinia Ankara (MVA) is unable to reproduce in human cells, suggesting that it may be a more suitable vaccine for immunocompromised individuals; it therefore addresses a stipulation in PAHPA that “at-risk” populations be afforded

a priority for medical countermeasure advanced research and development. Clinical data demonstrate that the vaccine is well tolerated, 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 activities toward acquisition of an MVA vaccine for the SNS were reported in the previous *BioShield Annual Reports*. A contract awarded to Bavarian-Nordic in June 2007 for 20 million doses of MVA vaccine to treat ten million people 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 advance payments before delivery if they are deemed necessary to complete the acquisition. In awarding these payments the USG is now sharing with its industry stakeholders the risk associated with developing medical countermeasures. In October 2007 HHS approved the payment of an initial ten percent advance payment to Bavarian Nordic. In November and December 2007 HHS approved non-refundable milestone payments, each of five percent of the total contract award, to Bavarian Nordic for achieving significant programmatic milestones stipulated by the U.S. Government.



3.3 Medical Countermeasures for Radiological and Nuclear Threats

After the Secretary of DHS determined in September 2004 that radiological and nuclear agents are material threats to the U.S. population, 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 incident can be attributed to whole- or partial-body radiation exposure and/or to uptake of radioactive particles. Particulate radionuclides can be brought 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, increased risk of infection, bleeding, and bone marrow suppression of progenitor cell populations; the gastrointestinal syndrome, associated with severe diarrhea and an increased risk of life-threatening bacteremia (bloodstream infection); cutaneous (skin) symptoms such as burns, ulcers, and a reduced rate of wound healing; pulmonary (lung) complications, including fibrosis and pneumonitis; and cerebrovascular syndrome, affecting the brain and blood vessels, which



initially causes mental confusion and impaired movement and balance, and then leads to death within one to two days.

The 2007 *HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan for Chemical, Biological, Radiological and Nuclear (CBRN) Threats (HHS PHEMCE Implementation Plan)* listed the following medical countermeasures required to address radiological and nuclear threats as high priorities for development and acquisition:

- 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 incident)
- Radionuclide-specific medical countermeasures
- Biodosimetry/bioassay capabilities

3.3.1 Research

During the current reporting period, the NIAID Division of Allergy, Immunology, and Transplantation used the expedited peer review process under Project BioShield to award grants for research toward developing medical countermeasures to restore gastrointestinal function after radiation exposure. In addition, NIAID used the expedited peer review authority to conduct peer-review meetings and subsequently to grant awards for three other research areas. 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 three programs:

- Medical Countermeasures to Enhance Platelet Regeneration and Increase Survival Following Radiation Exposure: Project BioShield
- BARDA/NIAID Medical Countermeasures to Mitigate and/or Treat Ionizing Radiation-Inducing Pulmonary Injury: Project BioShield
- BARDA/NIAID Medical Countermeasures to Mitigate and/or Treat Ionizing Radiation-Induced Cutaneous Injury: Project BioShield

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*,¹⁷ 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.

3.3.1.1 Medical Countermeasures to Restore Gastrointestinal Function after Radiation Exposure

NIAID released RFA-AI-07-013 for research on radionuclide decorporation agents, on 29 December 2006, and the receipt date for applications was 19 April 2007. NIAID received 44 applications and awarded ten grants in September 2007, to the following types of institutions:

- One grant to a non-profit research organization
- Eight grants to eight universities
- One grant to a biotechnology company

3.3.1.2 Medical Countermeasures to Enhance Platelet Regeneration and Increase Survival Following Radiation Exposure

NIAID issued RFA-AI-07-036 for research on countermeasures to enhance platelet recovery after radiation exposure on 27 September 2007 and received 26 applications by the 9 January 2008 receipt date for applications. Five grants were awarded between July and September 2008.

- One grant to a non-profit research organization
- Two grants to two universities
- Two grants to two biotechnology companies

3.3.1.3 Medical Countermeasures to Mitigate and/or Treat Ionizing Radiation-Induced Pulmonary Injury

NIAID and BARDA jointly issued RFA-AI-07-040 for research on countermeasures to mitigate and/or treat radiation-induced pulmonary injury on 18 December 2007 and received 34 applications by the 11 March 2008 receipt date for applications. Four grants were awarded in September 2008.

- One grant to a non-profit research organization
- Two grants to two universities
- One grant to a biotechnology company

3.3.1.4 Medical Countermeasures to Mitigate and/or Treat Ionizing Radiation-Induced Cutaneous Injury

NIAID and BARDA jointly issued RFA-AI-07-037 for research on countermeasures to mitigate and/or treat radiation-induced cutaneous injury on 27 December 2007 and received 31 applications by the 11 March 2008 receipt date for applications. Four grants were awarded in September 2008.

- Four grants to four universities



3.3.2 Advanced Development and Acquisition

Three programs have been in place for acquiring countermeasures to radiological and nuclear threats: for pediatric formulations of potassium iodide (KI), for diethylenetriaminepentaacetate (DTPA), and for countermeasures for acute radiation syndrome (ARS).

3.3.2.1 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. For many years, the Nuclear Regulatory Commission (NRC) has provided KI tablets at no cost to any State with population in ten mile Emergency Planning Zones (EPZs) around nuclear power plants. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) required the President to make KI available



to populations within 20 miles of nuclear power plants. This responsibility was delegated to the Secretary of HHS, and supplies of KI tablets have been held in the SNS. However, the American Academy of Pediatrics recommended delivery of KI to children in a liquid preparation because children under ten years of age may find tablets difficult to swallow and/or bad-tasting.¹⁸

Liquid KI for children under age ten, funded by the SRF, under contracts awarded in March 2005 and February 2006, has been delivered to the SNS. Activities supporting this acquisition are reported in the previous *BioShield Annual Reports*. Retrofitting with child-proof packaging of initially delivered bottles of liquid KI was completed in December 2007.

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 ten-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. However, States have not participated heavily in this program, citing storage costs and limited shelf life as the primary reason for not accepting free shipments of liquid KI.

On 22 January 2008 Dr. John Marburger, Director of the Office of Science and Technology Policy (working under delegation from the President), invoked a waiver in the Public Health Security

and Bioterrorism Preparedness and Response Act (P.L. 107-188 §127(f) waiver). Dr. Marburger “determined that a more effective preventive measure [existed] for the extended zone covered by the Act [P.L. 107-188], namely avoidance of exposure altogether through evacuation of the potentially affected population.” As a result of this decision, HHS no longer has a mandate to provide KI beyond the ten-mile EPZ program already covered by the NRC.

Due to the removal of the requirement for HHS to provide KI, and to the importance of forward deployment of it, HHS has been arranging for the both the tablets and the liquid KI in the SNS to be forward-deployed in areas that could potentially use it in the initial hours after an incident, by organizations equipped to facilitate the deployment.¹⁹

3.3.2.2 Calcium and Zinc Diethylenetriamine-pentaacetate (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.

Activities associated with the acquisition of DTPA under Project BioShield were reported in the *2006 BioShield Annual Report*. HHS is in the process of forward-deploying some quantities of this asset near potential locations of use to ensure the most effective deployment for initial early use in an emergency.

3.3.2.3 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 incident is mitigation or treatment addressing the subsequent decrease in the blood cells that normally protect against infection – the neutropenia associated with ARS.

The PHEMCE has a requirement for a medical countermeasure to mitigate and/or treat the neutropenia associated with ARS. Previous activities



that supported meeting this requirement are reported in the previous *BioShield Annual Reports*. An RFP for acquisition under Project BioShield of therapeutics to treat the neutropenia component of ARS for the SNS was released on 17 March 2008, with a response date of 23 May 2008.²⁰ In addition, a BAA was issued on 6 March 2008, with a response date of 17 April, for advanced development of therapies for hematopoietic syndrome, bone marrow stromal cell loss and vascular injury resulting from acute exposure to ionizing radiation. Seven contracts for advanced development using ARD funding authorized under PAHPA were awarded on 16 September 2008; see Table 2 for details.²¹ These contracts are to support development of candidate countermeasures to a point at which they would be eligible for a Project BioShield acquisition using the SRF.

3.4 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. Population threat assessments (PTAs) have been completed by DHS for volatile nerve agents, low-volatility nerve agents, pulmonary agents, vesicants, and blood agents.²² Based on the PTAs, the HHS PHEMCE has established requirements for medical countermeasures for volatile nerve agents and low-volatility nerve agents and is evaluating possible requirements for the other 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. The Division of the Strategic National Stockpile (DSNS), overseen by the CDC's Coordinating Office for Terrorism Preparedness and Emergency Response, supports this program financially and administratively. The medical countermeasure requirements 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 additional advanced research and development funds of \$700,000 for FY 2008 and \$500,000 for FY 2009 to the National Institute of Neurological Diseases and Stroke (NINDS), Countermeasures Against Chemical Threats (CounterACT) grants program (\$6.32 million was provided for FY 2007); the support of midazolam funded a total of 19 grants. The new requirements for medical countermeasures for low-volatility nerve agents will be addressed in the next version of the *HHS PHEMCE Implementation Plan*.

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

In an 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 emergency use of an unapproved drug, device, or biological product or an unapproved use of an approved drug, device, or biological product, during the effective period of a declaration of emergency

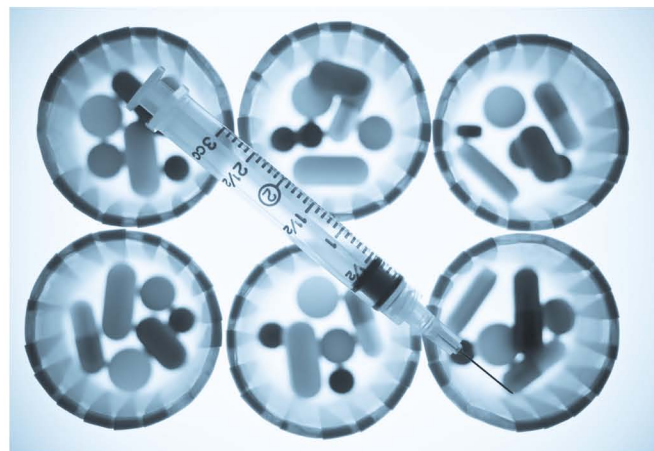


issued by the HHS Secretary. Under section 564(b) of the FFDCA, a declaration of emergency justifying issuance of an Emergency Use Authorization (EUA) must be based on a determination (a) by the Secretary of Homeland Security of a domestic emergency, or a significant potential for a domestic emergency, 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 under section 319 of the Public Health Service Act 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.²³ In July 2007 FDA published guidance on FDA policies for authorizing the emergency use of medical products under section 564 of the FFDCA.²⁴ FDA intends to update this guidance to reflect FDA's recent EUA and "pre-EUA" experiences.

As part of pre-emergency activities, FDA continues to review and provide feedback on an increasing number of "pre-EUA" submissions. For example, FDA has reviewed and processed several "pre-EUA" submissions for the use of antimicrobial products for first responders and affected populations as part of critical emergency preparedness activities for the 2008 Political Conventions and the 2009 Presidential Inauguration. Some of these efforts resulted in the issuance of an EUA on 3 October 2008 for the emergency use of doxycycline hyclate tablet emergency kits for the post-exposure prophylaxis of inhalational anthrax for United States Postal Service (USPS) participants and their household members as part of the Cities Readiness Initiative (CRI).²⁵

Prior to the current reporting period, the FDA Commissioner issued one EUA, on 27 January 2005, for emergency use of AVA, following the declaration of a public health emergency by the Secretary of HHS on 14 January 2005 regarding anthrax. This EUA, which terminated on 14 January 2006, was described in the *2006 BioShield Annual Report*.



4.0 CONCLUSION



DURING THE PERIOD COVERED BY THIS report, HHS has continued to advance implementation of Project BioShield objectives, through use of authorities required to be reported annually and through other activities associated with or leading to acquisition of emergency medical countermeasures. HHS used Project BioShield authorities to expedite peer review procedures for applications for research grants for medical countermeasures to treat effects of radiation exposure, and to issue an EUA for the emergency use of doxycycline hyclate tablet emergency kits for post-exposure prophylaxis of inhalational anthrax for USPS participants and their household members. 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, development, or information-gathering activities (a) to pursue acquisition of rPA vaccine for anthrax; (b) to pursue acquisition of therapeutics to mitigate or treat neutropenia associated with ARS; (c) to make a sole-source acquisition of additional AVA anthrax vaccine; (d) to develop therapies for hematopoietic syndrome, bone marrow stromal cell loss, and vascular injury resulting from exposure to ionizing radiation; (e) to seek sources for

physical and biological dosimetry techniques and devices useful in initial triage after radiological and nuclear incidents; and (f) to seek sources for emergency responder anthrax antimicrobial kits. Advanced development contracts were awarded for anthrax therapeutics, anthrax vaccine, broad-spectrum antibiotics, smallpox therapeutics, and a GLP radionuclide facility; and grants were funded for orally available DTPA, treatment of radiation-induced cutaneous injury, treatment of radiation-induced pulmonary injury, and use of midazolam as a countermeasure for chemical agents.

HHS has continued to advance its activities under Project BioShield, including (a) continued management of existing acquisition programs; and (b) 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, including both the original and the newer authorities.

5.0 FOOTNOTES

¹ See Federal Register, 21-Oct-08, Vol. 73, No. 204, pp. 62507-62514; http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=62507&dbname=2008_register. This EUA was subsequently revised on 25 February 2009.

² 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.

³ Pandemic and All-Hazards Preparedness Act (P.L. 109-417), section 403, Clarification of countermeasures covered by Project BioShield.

⁴ U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007 (P.L. 110-28); 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).

⁵ When an anticipated event has occurred before the end of March 2009, the event is noted in a footnote.

⁶ <https://www.medicalcountermeasures.gov/BARDA/BARDA.aspx>

⁷ Available through links at <https://www.medicalcountermeasures.gov/BARDA/bioshield/annualreport/annualreport.aspx>

⁸ Available through a link at <https://www.medicalcountermeasures.gov/BARDA/BARDA.aspx>

⁹ Increased simplified acquisition thresholds were used during the reporting period covered in the *2006 BioShield Annual Report*: (a) for medical countermeasures for botulinum neurotoxin: two biotechnology companies (XOMA Limited and Dynport Vaccine Co. LLC); and to develop improved DTPA for radionuclide chelation: one academic institution (University of Kentucky), one biotechnology company (Nanotherapeutics, Inc.), and one nonprofit organization (SRI International).

¹⁰ Three uses of the streamlined personnel authority by NIH were previously reported, in the *2006 BioShield Annual Report* (pp. 43-44). In addition, (a) during the same reporting period (July 2004 through July 2006), three additional uses were made of this authority, for hiring three senior scientific officers: (i) a Chemical, Biological, Radiological, Nuclear Scientific Advisor in the Office of the Director (salary greater than \$100,000); (ii) a Chief for the Influenza, SARS, and other Viral Respiratory Diseases Section, in the Respiratory Diseases Branch, Division of Microbiology and Infectious Diseases (DMID; salary greater than \$100,000); and (iii) Associate Director for Clinical Research, in DMID (salary greater than \$100,000); and (b) during the subsequent reporting period (August 2006 through July 2007), the authority was used to hire an Associate Director for International Research Affairs in the Office of the Director (salary greater than \$100,000).

¹¹ See Federal Register, 21-Oct-08, Vol. 73, No. 204, pp. 62507-62514; http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=62507&dbname=2008_register. This EUA was subsequently revised on 25 February 2009.

¹² The following activity has also occurred after the end of the reporting period: On 10-Feb-09, a presolicitation (RFP-BARDA-09-35) was released for a BioShield (SRF) acquisition of a smallpox antiviral agent, and on 11-Mar-09, the corresponding solicitation was released. On 17-Feb-09 a presolicitation (BAA-BARDA-09-34) was issued, and on 04-Mar-09 a solicitation, in the form of a "rolling" BAA, in which brief white paper proposals will be accepted on any topic of interest to BARDA for advanced research and development, to be followed by a more extensive proposal if the brief one is judged favorable for further consideration.

¹³ In one case in the U.S., in February 2006, the patient improved after AIG administration and survived (for descriptions of this case, see Walsh et al., 2007, *Clinical Infectious Diseases*; 44:968–971 [<http://www.journals.uchicago.edu/doi/full/10.1086/512372?prevSearch=%28james+walsh%29+AND+%5Bjournal%3A+cid%5D&searchHistoryKey=&cookieSet=1>] and "Inhalation Anthrax Associated with Dried Animal Hides — Pennsylvania and New York City, 2006," in *Morbidity and Mortality Weekly Report (MMWR)*, 17 Mar 06, 55(10): 280-282 [www.cdc.gov/mmwr/preview/mmwrhtml/mm5510a4.htm]). In the other case, in London in October 2008, AIG was administered after substantial progression of the infection, but the patient eventually died (see "Investigations and control measures following a case of inhalational anthrax in East London in a drum maker and drummer, October 2008," in *Eurosurveillance*, 18 Dec 08, 13 (51): 11-13 [www.eurosurveillance.org/images/dynamic/EE/V13N51/V13N51.pdf]).

¹⁴ Delivery of Raxibacumab to the SNS commenced in January 2009.

¹⁵ https://www.fbo.gov/index?s=opportunity&mode=form&id=c76ae3ff222468476cae1bd0a1cfff0c&tab=core&_cview=0

¹⁶ For a news article about this case, see "Springs baby one of youngest to contract botulism," *Colorado Springs Gazette*, 23 Feb 08; <http://www.gazette.com/articles/botulism-33470-food-health.html>.

¹⁷ http://www3.niaid.nih.gov/about/overview/planningPriorities/RadNuc_StrategicPlan.pdf

¹⁸ http://www.gnyha.org/eprc/general/nbc/nuclear_radiological/Radiation_Speaking_Points.pdf

¹⁹ The tablets have been provided to the NRC for inclusion in its program providing KI in the areas around nuclear power plants.

²⁰ This solicitation was canceled on 16-Jan-09 because none of the offers received in response met the Government's requirements. A subsequent presolicitation notice for advanced development of medical countermeasures for the same purpose was issued on 16-Jan-09: HHS-BARDA-09-33, followed by a Draft RFP on 20-Feb-09, and an RFP on 13-Mar-09: BARDA-09-100-SOL-00005. ARD funding is anticipated to be used for the contract(s) resulting from this solicitation.

²¹ Additional details can be found by accessing the "Award" links at https://www.fbo.gov/index?s=opportunity&mode=form&id=a8f8740158d15c32d4f9f4a8defdfcb2&tab=core&_cview=1.

²² In February 2009 the PTA for GABA antagonists was completed.

²³ Pursuant to section 903 of the FFDCA and existing delegations of authority, codified at 21 CFR part 5, the Secretary has delegated the authority to issue an EUA under section 564 to the FDA Commissioner.

²⁴ <http://www.fda.gov/oc/guidance/emergencyuse.html>

²⁵ See Federal Register, 21-Oct-08, Vol. 73, No. 204, pp. 62507-62514; [http://frwebgate.access.gpo.gov/cgi-bin/getpage.cgi?position=all&page=62507&dbname=2008_register]. This EUA was subsequently revised on 25 February 2009.

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BARDA Web site: <https://www.medicalcountermeasures.gov/BARDA/BARDA.aspx>

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

HHS PHEMCE Web portal: <http://www.MedicalCountermeasures.gov>

NIH Web site: <http://www.nih.gov/>

National Institute of Allergy and Infectious Diseases (NIAID) Web site: <http://www3.niaid.nih.gov/>

Division of Microbiology and Infectious Diseases (DMID) Web site: <http://www3.niaid.nih.gov/about/organization/dmid/>

Division of Allergy, Immunology, and Transplantation (DAIT) Web site: <http://www3.niaid.nih.gov/about/organization/dait/>

FDA Web site: <http://www.fda.gov/>

PROJECT BIOSHIELD ANNUAL REPORTS TO CONGRESS

All available through links at <https://www.medicalcountermeasures.gov/BARDA/bioshield/annualreport/annualreport.aspx>

Project BioShield Annual Report to Congress: July 2004 through July 2006

Available at <https://www.medicalcountermeasures.gov/BARDA/documents/bioshieldannualreport.pdf>

Project BioShield Annual Report to Congress: August 2006 through July 2007

Available at <https://www.medicalcountermeasures.gov/BARDA/documents/bioshieldannualreport2006.pdf>

OTHER BARDA, NIH, AND FDA PUBLICATIONS

BARDA Strategic Plan and BARDA Annual Report

BARDA Publications available through links at <https://www.medicalcountermeasures.gov/BARDA/BARDA.aspx>

NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats

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

FDA Guidance on Emergency Use Authorization of Medical Products; July 2007

<http://www.fda.gov/oc/guidance/emergencyuse.html>

LEGISLATION

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

Department of Homeland Security Appropriations Act, 2004, P.L. 108-90, 1 October 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)

Emergency Supplemental Appropriations Act for Defense and for the Reconstruction of Iraq and Afghanistan, 2004, P.L. 108-106, 6 November 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)

Project BioShield Act of 2004, P.L. 108-276, 21 July 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

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 (contains pandemic influenza funding)

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 (contains pandemic influenza funding)

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 (contains pandemic influenza funding)

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

U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007, P.L. 110-28, 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 for and response to pandemic influenza, for FY 2007)

SOLICITATIONS, ANNOUNCEMENTS, AND NOTICES

Biodefense

BAA and Award Notices: Biodefense Vaccine Enhancement: BAA-NIH-BARDA-NIAID-DMID-AI2007007: https://www.fbo.gov/index?s=opportunity&mode=form&id=9f8f98fb480427f946ed989702d643b2&tab=core&_cview=1

BAA and Award Notices: Development of Therapeutic Agents for Select Biodefense Pathogens: BAA-NIH-NIAID-DMID-08-20: https://www.fbo.gov/?s=opportunity&mode=form&id=9f5ae4c87de43db16623210cf66dc031&tab=core&_cview=1

BAA: Application of Platform Technologies for the Development of Therapeutics for Biodefense: BAA-DMID-NIAID-BARDA-NIHAI20080022: https://www.fbo.gov/index?s=opportunity&mode=form&id=907864a7fc0d24e9bae3d3f9f04718b5&tab=core&_cview=1

MedKits

Presolicitation and RFP: Acquisition of palatability studies for masking the respective tastes of ciprofloxacin and doxycycline when prepared for oral suspension at home during a public health emergency; and of evaluation studies of home preparation instructions for said oral suspensions: RFP-BARDA-08-12: https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=20f41700228499d4bedb4df5fe1696ec&_cview=1

Anthrax

Sources Sought Notice: Emergency Responder Anthrax Antimicrobial Kits: SS-HHS-BARDA-08-99: https://www.fbo.gov/index?s=opportunity&mode=form&id=c76ae3ff222468476cae1bd0a1ccff0c&tab=core&_cview=0

Sources Sought Notice: Recombinant protective antigen (rPA) anthrax vaccine for the Strategic National Stockpile: HHS-BARDA-08-01-SB: https://www.fbo.gov/?s=opportunity&mode=form&id=9fe69ef628ae8e9472f2504d7e7f4a04&tab=core&_cview=0

RFP: Recombinant Protective Antigen (rPA) anthrax vaccine for the strategic national stockpile: RFP-BARDA-08-15: https://www.fbo.gov/index?s=opportunity&mode=form&id=76e4ea7485dced12e3cf65c31b10018b&tab=core&_cview=1

Contract Award: Anthrax Vaccine Adsorbed for the Strategic National Stockpile (SNS): RFP-DHHS-BARDA-08-26: https://www.fbo.gov/?s=opportunity&mode=form&id=b2537d14797d4691a225426aa8edf1e6&tab=core&_cview=1

Smallpox

Special Notice: NDA-Enabling Development for ST-246: A Smallpox Antiviral Drug: HHSN266200600014C: https://www.fbo.gov/?print_preview=1&s=opportunity&mode=form&id=760de9c4320039b938b4bfb40406daae&tab=core&tabmode=list

Filovirus

BAA and Award Notices: Advanced Development of Multivalent Filovirus (Ebola and Marburg) Hemorrhagic Fever Vaccines: BAA-NIH-BARDA-NIAID-DMID-AI2007003: https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=97d4aa16a50f3d70a9357c9e7f4c11d3&_cview=1

Radiological-Nuclear Threats

Sources Sought Notice: Physical and Biological Dosimetry Techniques and Devices Useful in Initial Triage after Radiologic and Nuclear Events: RFI-BARDA-08-21A: https://www.fbo.gov/?s=opportunity&mode=form&id=997f67c8155b32dfa03e01951dfa77cc&tab=core&_cview=0

BAA and Award Notices: Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss and Vascular Injury Resulting From Acute Exposure to Ionizing Radiation: BAA-BARDA-08-08: https://www.fbo.gov/index?s=opportunity&mode=form&id=a8f8740158d15c32d4f9f4a8defdfcb2&tab=core&_cview=1

Sources Sought Notice: Physical and Biological Dosimetry Techniques and Devices Useful in Initial Triage after Radiologic and Nuclear Events: RFI-BARDA-08-21A: https://www.fbo.gov/?s=opportunity&mode=form&id=3e7743eb353597091efeb4194cb685b4&tab=core&_cview=1

RFP: Advanced Therapeutics for Treating Neutropenia Resulting from Acute Exposure to Ionizing Radiation: HHS-BARDA-08-10: https://www.fbo.gov/index?s=opportunity&mode=form&id=2f88e0c22409ef7751f93e73e00a974d&tab=core&_cview=1

RFA: Medical Countermeasures to Restore Gastrointestinal Function after Radiation Exposure: Project Bioshield (RC1): RFA-AI-07-013: <http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-07-013.html>

RFA: Medical Countermeasures to Enhance Platelet Regeneration and Increase Survival Following Radiation Exposure (RC1): RFA-AI-07-036: <http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-07-036.html>

RFA: BARDA/NIAID Medical Countermeasures to Mitigate and/or Treat Ionizing Radiation-Induced Cutaneous Injury: Project Bioshield (RC1): RFA-AI-07-037: <http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-07-037.html>

RFA: BARDA/NIAID Medical Countermeasures to Mitigate and/or Treat Ionizing Radiation-Induced Pulmonary Injury: Project Bioshield (RC1): RFA-AI-07-040: <http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-07-040.html>

Sources Sought Notices: Development of Improved DTPA for Radionuclide Chelation: DTPA-01 and DTPA-02: https://www.fbo.gov/index?s=opportunity&mode=form&id=c16d5c71d0e7bb3cc165caa38dd2e997&tab=core&_cview=0 and https://www.fbo.gov/index?s=opportunity&mode=form&id=692298100c7d49b798f5b505208457cd&tab=core&_cview=0

Sources Sought Notice: GLP Radionuclide/Radiation Animal Models and Resources Development: RFP-NIH-NIAID-DAIT-BARDA-08-09: https://www.fbo.gov/index?s=opportunity&mode=form&id=49808484a236d7074ef849ae51a5a97f&tab=core&_cview=1

RFP: GLP Radionuclide/Radiation Animal Models and Resources Development: RFP-NIH-NIAID-DAIT-BARDA-08-20 [postponed indefinitely]: https://www.fbo.gov/index?s=opportunity&mode=form&id=587e865d6fcaeb90ce242f5ee06f8c0b&tab=core&_cview=1

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)

Walsh et al., 2007, *Clinical Infectious Diseases*; 44:968–971; <http://www.journals.uchicago.edu/doi/full/10.1086/512372?prevSearch=%28james+wash%29+AND+%5Bjournal%3A+cid%5D&searchHistoryKey=&cookieSet=1> (2006 case of anthrax in which AIG was administered)

“Inhalation Anthrax Associated with Dried Animal Hides—Pennsylvania and New York City, 2006,” in *Morbidity and Mortality Weekly Report (MMWR)*, 17 Mar 06, 55(10):280-282; www.cdc.gov/mmwr/preview/mmwrhtml/mm5510a4.htm (2006 case of anthrax in which AIG was administered)

“Investigations and control measures following a case of inhalational anthrax in East London in a drum maker and drummer, October 2008,” in *Eurosurveillance*, 18 Dec 08, 13 (51): 11-13; www.eurosurveillance.org/images/dynamic/EE/V13N51/V13N51.pdf (2008 case of anthrax in which AIG was administered)

“Springs baby one of youngest to contract botulism,” *Colorado Springs Gazette*, 23 Feb 08; <http://www.gazette.com/articles/botulism-33470-food-health.html> (case of infant botulism in which h-BAT was administered)

7.0 APPENDICES

7.1 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 (or any successors)
- Senate Committees

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

- Committee on Appropriations
- 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.

7.2 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	28-Feb-08: RFP- BARDA-08-15 Response date: 29-May-08	TBD	TBD	25 million doses (8.33 million treatment courses)	TBD
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	5 million doses	\$120 million
		Intent to negotiate with only one source: 18-Apr-07; Modified 05-May-07	Commenced 28-Sep-07	Emergent BioSolutions (previously BioPort Corporation)	18.75 million additional doses	\$447.7 million
		Award: 25-Sep-07. The contract includes incentives for obtaining licensure of AVA for post- exposure prophylaxis and incentives for extension of the expiration dating period of the product.				
		CDC contract award: 30-Sep-08				
Anthrax therapeutics	12-Aug-04 President	Award: 19-Jun-06	___ ^B	Human Genome Sciences	20,001 treatment courses of Raxibacumab (previously "ABthrax")	\$165.2 million
		Award: 27-Jul-06	Commenced Sep-07	Cangene Corporation	10,000 treatment courses of AIG	\$143.8 million
Radiological/ Nuclear Threats						
Therapeutics to mitigate or treat neutropenia associated with Acute Radiation Syndrome (ARS)	03-Jan-06 OMB	17-Mar-08: HHS-BARDA-08-10; Response date: 23-May-08 ^C	___ ^D	___ ^E	100,000 treatment courses, with option for another 100,000	___ ^F

^A Delivery on this contract is due to commence in September 2009.^B Delivery commenced in January 2009.^C This solicitation was canceled on 16-Jan-09 because none of the offers received in response met the Government's requirements. A subsequent presolicitation notice for advanced development of medical countermeasures for the same purpose was issued on 16-Jan-09: HHS-BARDA-09-33, followed by a Draft RFP on 20-Feb-09, and an RFP on 13-Mar-09: BARDA-09-100-SOL-00005. ARD funding will be used for this contract.^D See previous footnote.^E See previous footnote.^F See previous footnote.

7.2 Appendix B: Update of Acquisitions Reported Previously (continued)

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 Threats (continued)						
Pediatric liquid potassium iodide	07-Dec-04 OMB	Award: 17-Mar-05	Completed, Sep-05	Fleming & Company Pharmaceu- ticals	1.7 million bottles	\$5.7 million
		Award: 08-Feb-06	Completed Jul- 07	Fleming & Company Pharmaceu- ticals	3.1 million bottles plus retrofitting original purchase with child-proof packaging	\$10.3 million plus \$1.5 million
	Completed Dec-07 (retrofitting)					
NA	NA	Explorations have begun to forward- deploy liquid KI in participating states, outside the jurisdiction of the SNS				
DTPA	03-Jan-06 OMB	Award: 30-Dec-05	Completed, Apr-06	Akorn, Inc.	390,000 doses Ca-DTPA, 60,000 doses Zn-DTPA	\$21.9 million
		Modification: 13-Apr-06	Completed, Apr-06	Akorn, Inc.	Contract modification (+ 5,370 Ca- DTPA, 19,369 Zn-DTPA)	\$32,500
Smallpox⁶						
Modified Vaccinia Ankara (MVA) smallpox vaccine	07-Dec-04 OMB	Award: 24-Jun-07 ^H	— ^I	Bavarian Nordic	20 million doses	\$500 million
Botulism						
Botulinum antitoxin	17-Aug-04 President	Award: 01-Jun-06	Commenced Sep-07	Cangene Corporation	200,000 doses	\$363 million
Yellow – changed (new or revised) from the 2007 BioShield Annual Report						

⁶ On 10-Feb-09, a presolicitation (RFP-BARDA-09-35) was released for a BioShield acquisition of a smallpox antiviral agent, and on 11-Mar-09, the corresponding solicitation was released.

^H Includes a refundable advanced payment under original Project BioShield authorities, and additional non-refundable milestone payments under amendments in PAHPA.

^I Delivery is due to commence in 2009.

7.3 Appendix C: Abbreviations and Glossary

<i>2006 BioShield Annual Report</i>	<i>Project BioShield Annual Report to Congress: July 2004 through July 2006</i>
<i>2007 BioShield Annual Report</i>	<i>Project BioShield Annual Report to Congress: August 2006 through July 2007</i>
AIG	Anthrax Immune Globulin
ARD	advanced research and development
ARS	Acute Radiation Syndrome
ASPR	Assistant Secretary for Preparedness and Response
AVA	Anthrax Vaccine Adsorbed
BAA	Broad Agency Announcement
BARDA	Biomedical Advanced Research and Development Authority
BAT	botulism antitoxin
BLA	Biologics License Application
CBRN	chemical, biological, radiological, and nuclear
CDC	Centers for Disease Control and Prevention
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
CRI	Cities Readiness Initiative
current reporting period	August 2007 through December 2008
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 Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention, responsible for managing the Strategic National Stockpile
DTPA	diethylenetriaminepentaacetate
DOD	Department of Defense
EPZ	Emergency Planning Zone; area within 10 miles of a nuclear power plant
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
h-BAT	heptavalent botulism antitoxin
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>
IND	Investigational New Drug
KI	potassium iodide
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.
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 of the NIH
NINDS	National Institute of Neurological Diseases and Stroke of the NIH
NIH	National Institutes of Health
NRC	Nuclear Regulatory Commission

OMB	Office of Management and Budget
PAHPA	Pandemic and All-Hazards Preparedness Act (P. L. 109-417)
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHS Act	Public Health Service Act
P. L.	Public Law
Project BioShield	Project BioShield Act of 2004 (P.L.108-276)
PTA	Population Threat Assessment; previously MTA, Material Threat Assessment; 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
RFP	Request for Proposals
rPA	recombinant protective antigen
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 FY2004 through FY2008.
TBD	to be determined
U.S.	United States
U.S.C.	United States Code
USG	United States Government
USPS	United States Postal Service

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