United States Department of Health and Human Services

Office of the Assistant Secretary for Preparedness and Response

Project BioShield Annual Report to Congress

January 2010 – December 2010

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1.0 Project BioShield Authorities & Reporting Requirements

THE PROJECT BIOSHIELD ACT OF 2004 (PROJECT BIOSHIELD; Public Law [P.L.] 108-276) was designed to provide additional and more flexible authorities and funding to financially support the development and procurement for medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) threat agents. It was also designed to provide the government with the authority to quickly authorize their use during public health emergencies. Project BioShield authorities were further delineated, clarified, and extended by the Pandemic and All-Hazards Preparedness Act of 2006 (P.L. 109-417), the legislation that authorized the establishment of the Biomedical Advanced Research and Development Authority (BARDA).

The Project BioShield Act requires an annual report to describe use of specific provisions within the following authorities:

- **Research and Development of Qualified Medical Countermeasures** – Section Two 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. Reporting is required on use of limited competition, expedited peer review, and increased simplified acquisition thresholds.
- **Security Countermeasure Procurements and Special Reserve Fund** – Section Three authorized the appropriation of up to $5.593 billion over the period of fiscal year (FY) 2004 through FY 2013 in a Special Reserve Fund (SRF) for the procurement of security countermeasures for the strategic national stockpile (SNS). The Act specified that up to $3.4 billion could be obligated from FY 2004 through FY 2008,the balance available from FY 2009 through

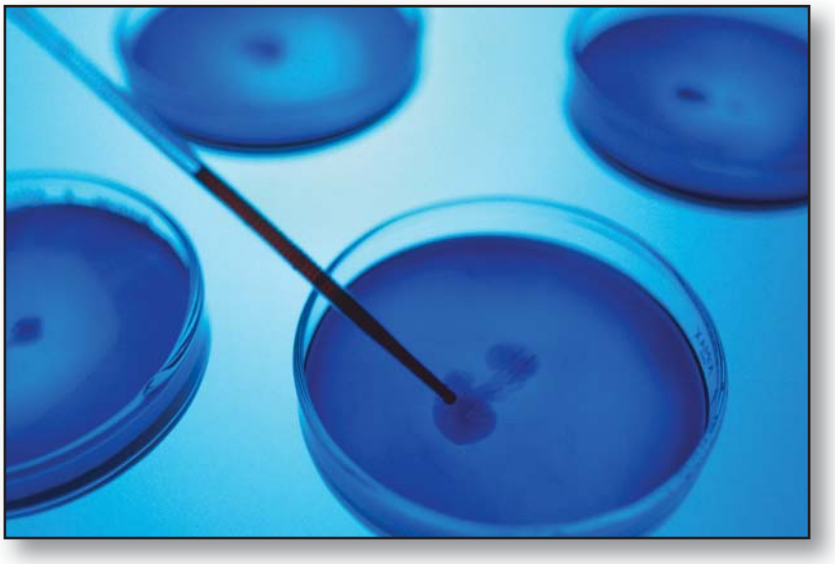
FY 2013. Furthermore, it also authorized the use of simplified acquisition procedures and the modified use of other than full and open competition, and payment of premiums in multiple-award contracts. Reporting is required on use of simplified acquisition procedures, limited competition, and premium provisions in multiple-award contracts.

- **Emergency Use Authorization for Medical Countermeasures** – Section Four allows the Secretary of Health and Human Services (HHS), after declaring that an emergency determined by the Secretary, or by the Secretary of Defense or Homeland Security justifies use of an approved product or unapproved use of an approved product, to issue an Emergency Use Authorization (EUA), permitting the use of a medical countermeasure that is not currently licensed by the Food and Drug Administration (FDA) for such usage. The HHS Secretary has delegated the authority to issue a EUA to the FDA Commissioner. Reporting is required on emergency uses of certain drugs and devices, declarations of an emergency, and conditions on authorization.

Specifically, the Act requires the report to include the following information for each use of the specific provisions within these authorities:

- The particular actions taken under each authority, including the identification of the threat agent, emergency, or medical countermeasure;
- The reasons underlying each action, including, if applicable, a description of options considered for each action;
- The number and nature of entities that received or were denied a grant, cooperative agreement, or contract; and
- Whether each countermeasure acquisition that required presidential approval resulted in a contract that was entered into within one year of such approval (the President has delegated the authority to approve acquisitions to the Director of the Office of Management and Budget [OMB]).

The Act also requires a separate summary of National Institutes of Health (NIH) activities relating to the use for research and development of (a) the increased micro-purchase threshold, (b) authority for personal services contracts, and (c) streamlined personnel authority for NIH positions. NIH did not use any of these authorities during the 2010 reporting period.



1.1 Overview

During CY 2010, HHS used two of the Project BioShield authorities that require annual reporting: procurement of security countermeasures; and issuance of Emergency Use Authorizations.

HHS did not utilize the additional authorities of expedited peer review authority, simplified acquisition procedures, procedures other than full and open competition, or premium provision in multiple-award contracts. The standard Federal Acquisition Regulation (FAR) practices were deemed adequate for all acquisition activity during the 2009 reporting period.

1.2 Expedited Peer Review

The National Institute of Allergy and Infectious Diseases (NIAID) within the NIH did not use its expedited peer review authority during the 2010 reporting period. During 2010, NIAID did make additional awards from an RFA for which expedited peer review was used during a previous reporting period.

Table 1. Expedited Peer Review Authority

Blue shading indicates activities initiated during the previous reporting period, August 2007-December 2008.

Threat Agent/ Emergency/Medical Countermeasure	Actions Taken Under Authority	Reason for Use of Authority	Number/Nature of Recipients of Awards or Contract	Number/Nature of Applicants Turned Down
Expedited peer review procedures in support of research and development activities				
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 were received	Although the threat of radiological/nuclear attacks or events continues, few medical countermeasures exist. In addition, the regular review process takes too long.	3 grants awarded to universities in summer 2010* (not previously funded in 2008-2009 due to budget limitations	25 applicants were turned down Turned down: 4 non-profit organizations, 16 universities, and 5 biotech companies

** These grants were in addition to the four awarded in 2008 and the two awarded in 2009 under this RFA, for a total of nine grants awarded under this RFA.*

1.3 Security Countermeasure Procurement

The Tables below outline cumulatively Project BioShield solicitations and acquisition contracts that were initiated, completed, or continued in CY 2010. To date, all of the listed contracts have followed normal acquisition processes.

Table 2: Project BioShield Acquisition Contracts

Countermeasure Area/Product	Date of Contract Award	Delivery to Strategic National Stockpile	Contract Recipient	Status at the Close of CY 2010	Total Funding (Millions)	Reason for Use of Authority
Anthrax Therapeutics						
Monoclonal Antibody (Raxibacumab®, formerly Abthrax))	9/2005 (Base)	Completed (2008)	HGS	20,000 doses delivered; NDA filed with FDA (2008) & additional studies required by FDA (2009)	$174	Raxibacumab is an antitoxin used to treat anthrax and, along with vaccines and antibiotics, is part of a three-pronged approach taken by the U.S. Government to prepare for and respond to an anthrax attack.
	7/2009 (Option)	Ongoing	HGS	16,102 doses delivered of 45,000 contracted	$152	
Anthrax Immune Globulin (AIG)	9/2005 (Base)	Ongoing	Cangene	7,327 doses delivered of 10,000 contracted; AIG shipped to UK for anthrax outbreaks among heroin users (2009)	$144	AIG® is an antitoxin used to treat anthrax and, along with vaccines and antibiotics, is part of a three-pronged approach taken by the U.S. Government to prepare for and respond to an anthrax attack.
Anthrax Vaccines						
AVA (BioThrax®, Anthrax Vaccine Absorbed)	5/2005	Completed (2006)	Emergent (formerly BioPort)	10 million doses delivered	$243	BioThrax® is the U.S.-licensed vaccine for anthrax and, along with antitoxins and antibiotics, is part of a three-pronged approach taken by the U.S. Government to prepare for and respond to an anthrax attack.
AVA (BioThrax®, Anthrax Vaccine Absorbed)	9/2007	Completed (2008)	Emergent	18.75 million doses delivered	$448	
rPA (Recombinant Protective Antigen)	11/2004	N/A	VaxGen	Terminated 12/19/05	$2	Contract terminated

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Table 2: Project BioShield Acquisition Contracts *continued*

Countermeasure Area/Product	Date of Contract Award	Delivery to Strategic National Stockpile	Contract Recipient	Status at the Close of CY 2010	Total Funding (Millions)	Reason for Use of Authority
Botulism Therapeutics						
Botulinum Antitoxin (hBAT) Therapeutic	9/2006	Ongoing	Cangene	96,888 doses delivered of 200,000 doses contracted	$415	Equine-derived polyclonal sera to multiple strains (A-F) of *C. botulinum* used as a therapeutic for botulism
Smallpox Vaccine						
Imvamune® MVA, (Modified Vaccinia Ankara) Smallpox Vaccine	6/2007	Ongoing	Bavarian Nordic	2.02 million delivered of 20 million contracted	$505	Imvamune® is an attenuated smallpox vaccine designated for immunocompromised persons as part of the overall strategy using vaccines and antiviral drugs for preparedness to and response to a smallpox attack.
Medical Countermeasures for Radiological, Nuclear, and Chemical Threats						
Potassium Iodide (Thyroshield)	3/2005	Complete	Fleming	4.8 million doses, deliveries complete	$18	Provides capability for pediatric treatment
IV Calcium/Zinc DTPA (Diethylene triamine pentaacetic acid)	12/2005	Complete	Akorn	473,710 doses, deliveries complete	$22	Decorporation agent for radio-nuclear treatment

Table 3: Project BioShield Solicitation

To date, the request for proposals listed has followed normal acquisition processes.

Name	URL	Pre-solicitation	Draft Solicitation	Final Solicitation	Closing Date	Expected Award Date	Reason for Use of Authority
Smallpox Antiviral Drug							
Smallpox Antiviral – RFP-BARDA-09-35		February 2009	N/A	March 2009	May 2009	May 2011	In addition to vaccines, HHS is pursuing development and procurement of smallpox antiviral drugs to treat symptomatic individuals.

1.4 Emergency Use Authorization

H1N1 Influenza Response

During the 2010 reporting period, as part of the U.S. Government's H1N1 Influenza response, the FDA Commissioner authorized the use of six medical countermeasures under the emergency use authorization (EUA) authority and amended the EUA for one medical countermeasure that had been issued in 2009 (the previous reporting period).

On June 23, 2010, the Secretary of the Department of Health and Human Services' (HHS's) April 26, 2009, Public Health Emergency determination and declaration justifying the H1N1 EUAs expired, terminating all related EUAs, whether issued in 2009 or 2010.

The attached table lists all of the H1N1 EUAs and amendments thereto issued during the H1N1 response, spanning from April 2009 to June 2010, including the name of the product, the issue dates, and the dates of declaration supporting each EUA. FDA posts all of the EUAs it issues on its website (http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm).[1]

Anthrax Preparedness

As described in the 2008 and 2009 BioShield Annual Reports, FDA issued an EUA on October 3, 2008, for the prepositioning of doxycycline hyclate tablet emergency kits for inhalational anthrax with United States Postal Service (USPS) participants and their household members as part of the Cities Readiness Initiative (CRI). FDA amended this EUA on August 23, 2010, to address a request from BARDA to permit the use of a manufacturer not covered in the original authorization. This EUA remains in effect, and, as of December 31, 2010, the conclusion of the reporting period, it is the only active EUA.

Statutory Authority

In a public health emergency, potentially useful products may be available, but are not yet FDA approved for the particular use contemplated. Section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (2 1 U.S.C. 360bbb-3), as amended by section 4 of the Project BioShield Act of 2004, permits the FDA Commissioner to issue an EUA to authorize the use of an unapproved medical product, or to authorize an unapproved use of an approved medical product, during an emergency declared by the HHS Secretary justifying the authorization. Such an emergency declaration may be issued based on a determination (a) by the Secretary of Homeland Security of a domestic emergency or a significant potential for a domestic emergency involving a heightened risk of attack with a specified CBRN agent; (b) by the Secretary of Defense of a military emergency or a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with a specified CBRN agent; or (c) by the HHS Secretary of a public health emergency that affects or has a significant potential to affect national security and that involves a specified CBRN agent or a specified disease or condition that may be attributable to such agent or agents.[2] On July 26, 2007, FDA published a guidance document on FDA's policies for authorizing the emergency use of medical products under section 564 of the FFDCA.[3] FDA will update this guidance, as needed, to reflect any additional relevant EUA-related experience.

FDA Pre-emergency Activities

As part of emergency preparedness activities, FDA continues to review and provide feedback on pre-EUA submissions for multiple products across all medical product lines.

[1]On June 21, 2010, FDA announced in the *Federal Register (75 FR 35045)* 5 new and 1 amended EUAs (1) H1N1 influenza real-time RT-PCR test; (2) H1N1-09 Prime RRT-PCR assay (amendment); (3) H1N1 influenza virus ID kit; (4) H1N1 LC RT-PCR kit; (5) H1N1 Real-Time RT-PCR assay; and (6) Liat influenza A/2009 H1N1 assay.

[2]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.

[3]http://www.fda.gov/RegulatoryInformation/Guidances/ucm125127.htm; See Notice in the *Federal Register*: 73 FR 62507, October 21, 2008.

Table 4: FDA 2009-2010 H1N1 Influenza EUA

Number	Product	Requestor	Type	Issuance Date	Federal Register Publication
Antivirals					
1	Oseltamivir phosphate	CDC	Initial	4/27/2009	74 FR 38648, August 4, 2009
1.a	Oseltamivir phosphate	CDC	Amendment	Reissued 4/28/2009	74 FR 38648, August 4, 2009
1.b	Oseltamivir phosphate (oral suspension)	CDC	Amendment	Reissued 7/15/2009	
1.c	Oseltamivir phosphate products	CDC and others	Amendment	Reissued 10/30/2009	
2	Zanamivir inhalation powder	CDC	Initial	4/27/2009	74 FR 38648, August 4, 2009
2.a	Zanamivir inhalation powder	CDC	Amendment	Not reissued	74 FR 38648, August 4, 2009
2.b	Zanamivir inhalation powder	CDC and others	Amendment	Reissued 10/30/2009	
2.c	Zanamivir inhalation powder	CDC	Amendment	Reissued 11/5/2009	
3	Peramivir IV	CDC	Initial	10/23/2009	74 FR 56640, November 2, 2009
3.a	Peramivir IV	CDC	Amendment	Reissued 11/19/2009	

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Table 4: FDA 2009-2010 H1N1 Influenza EUA *continued*

Number	Product	Requestor	Type	Issuance Date	Federal Register Publication
Personal Protective Devices					
4	N95 Respirators	CDC	Initial	4/28/2009	74 FR 38644, August 4, 2009
4.a	N95 Respirators	CDC	Amendment	Reissued 5/1/2009	74 FR 38644, August 4, 2009
In Vitro Diagnostics					
5	CDC Swine Influenza Virus Real-Time RT-PCR Detection Panel	CDC	Initial	4/27/2009	74 FR 38636, August 4, 2009
5.a	CDC Swine Influenza Virus Real-Time RT-PCR Detection Panel	CDC	Amendment	Reissued 5/2/2009	74 FR 38636, August 4, 2009
5.b	CDC Swine Influenza Virus Real-Time RT-PCR Detection Panel	CDC	Amendment	Reissued 12/18/2009	75 FR 20441, April 19, 2010
6	CDC's Previously Cleared RT-PCR Detection Panel	CDC	Initial	5/2/2009	74 FR 38636, August 4, 2009
7	Focus Diagnostics Influenza A H1N1 (2009) real-time RT-PCR	Focus Diagnostics, Inc.	Initial	7/24/2009	
7.a	Focus Diagnostics Influenza A H1N1 (2009) real-time RT-PCR	Focus Diagnostics, Inc.	Amendment	Reissued 8/14/2009	

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Table 4: FDA 2009-2010 H1N1 Influenza EUA *continued*

In Vitro Diagnostics *continued*					
Number	**Product**	**Requestor**	**Type**	**Issuance Date**	**Federal Register Publication**
7.b	Focus Diagnostics Influenza A H1N1 (2009) real-time RT-PCR	Focus Diagnostics, Inc.	Amendment	Reissued 12/18/2009	75 FR 20441, April 19, 2010
8	CDC rRT-PCR Swine Flu Panel on JBAIDS Instrument	Department of Defense	Initial	8/24/2009	
8.a	rRT-PCR Detection Panel on JBAIDS Instrument	Department of Defense	Amendment	Reissued 12/18/2009	75 FR 20441, April 19, 2010
9	Diatherix H1N1-09 Influenza Test	Diatherix Laboratories, Inc.	Initial	10/09/2009	75 FR 20441, April 19, 2010
10	Focus Diagnostics Simplexa Influenza H1N1 (2009)	Focus Diagnostics, Inc.	Initial	10/16/2009	
10.a	Focus Diagnostics Simplexa Influenza H1N1 (2009)	Focus Diagnostics, Inc.	Amendment	Reissued 12/18/2009	75 FR 20441, April 19, 2010
11	Prodesse ProFlu-ST Influenza A	Prodesse, Inc.	Initial	10/27/2009	75 FR 20441, April 19, 2010
12	ELITech Molecular Diagnostics 2009-H1N1 influenza A Virus Real-Time RT-PCR	Epoch BioSciences	Initial	11/13/2009	75 FR 20441, April 19, 2010
12.a	ELITech Molecular Diagnostics 2009-H1N1 influenza A Virus Real-Time RT-PCR	Epoch BioSciences	Amendment	Reissued 2/1/2010	75 FR 35045, June 21, 2010
13	Roche's RealTime Ready 2009 H1N1 Test	Roche Applied Science	Initial	11/13/2009	75 FR 20441, April 19, 2010

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Table 4: FDA 2009-2010 H1N1 Influenza EUA *continued*

In Vitro Diagnostics *continued*					
Number	**Product**	**Requestor**	**Type**	**Issuance Date**	**Federal Register Publication**
14	GeneSTAT 2009 H1N1 Influenza Test	DxNA, LLC	Initial	12/9/2009	75 FR 20441, April 19, 2010
15	TessArray Resquencing Influenza A Microarray Detection Panel	TessArae, LLC	Initial	12/16/2009	75 FR 20441, April 19, 2010
16	Xpert Flu A Panel	Cepheid	Initial	12/24/2009	75 FR 20441, April 19, 2010
17	ViraCor 2009 H1N1 Influenza A Real-time RT-PCR Test	ViraCor Labs	Initial	1/21/2010	75 FR 35045, June 21, 2010
18	Longhorn Influenza A/ H1N1-09 Prime RRT-PCR Assay	Longhorn Vaccines and Diagnostics	Initial	2/16/2010	
18.a	Longhorn Influenza A/ H1N1-09 Prime RRT-PCR Assay	Longhorn Vaccines and Diagnostics	Amendment	3/23/2010	75 FR 35045, June 21, 2010
19	Diagnostic Hybrids, Inc. D3 Ultra 2009 H1N1 Influenza A Virus ID Kit	Diagnostic Hybrids, Inc.	Initial	2/16/2010	75 FR 35045, June 21, 2010
20	*artus*® Inf. A H1N1 2009 LC RT-PCR Kit	Qiagen	Initial	3/11/2010	75 FR 35045, June 21, 2010
21	IMDx 2009 Influenza A H1N1 Real-Time RT-PCR Assay	IntelligentMDX	Initial	3/22/2010	75 FR 35045, June 21, 2010
22	Liat Influenza A/2009 H1N1 Assay	IQuum, Inc.	Initial	5/4/2010	75 FR 35045, June 21, 2010

Legislative Requirements

Public Law 108-276, the Project BioShield Act of 2004:

SEC. 5. REPORTS REGARDING AUTHORITIES UNDER THIS ACT.

(a) SECRETARY OF HEALTH AND HUMAN SERVICES.—

1) ANNUAL REPORTS ON PARTICULAR EXERCISES OF AUTHORITY.—

(A) RELEVANT AUTHORITIES.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall submit reports in accordance with subparagraph (B) regarding the exercise of authority under the following provisions of law:

(i) With respect to section 319F–1 of the Public Health Service Act (as added by section 2 of this Act):

(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):

(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):

(I) Subsection (a)(1) (relating to emergency uses of certain drugs and devices).

(II) Subsection (b)(1) (relating to a declaration of an emergency).

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

(B) CONTENTS OF REPORTS.—The Secretary shall annually submit to the designated congressional committees a report that summarizes—

(i) the particular actions that were taken under the authorities specified in subparagraph (A), including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

(ii) the reasons underlying the decision to use such authorities including, as applicable, the options that were considered and rejected with respect to the use of such authorities;

(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity; and

(iv) whether, with respect to each procurement that is approved by the President under section 319F–2(c)(6) of the Public Health Service Act (as added by 42 USC 247d–6c.section 3 of this Act), a contract was entered into within one year after such approval by the President.

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