United States Department of Health and Human Services

Office of the Assistant Secretary for Preparedness and Response

PROJECT BIOSHIELD ANNUAL REPORT TO CONGRESS

January 2009 – December 2009

United States Department of Health and Human Services
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FOREWORD

Today, our Nation faces a growing number of threats to our way of life. It is critical that we have the capability to be resilient as a nation after disaster strikes. We must be able to respond to all disasters with the proper resources to limit casualties and disruptions to communities. We are committed to ensuring the Nation is resilient in the face of disasters and is prepared to respond to chemical, biological, radiological, and nuclear (CBRN) events with adequate medical countermeasures (MCMs).

One of the primary responsibilities of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS) is to ensure we have safe and effective medical countermeasures available for response efforts. As the enclosed report demonstrates, Project BioShield is a vital piece of the Department's MCM enterprise, which encompasses the development, manufacturing, production, stockpiling, and distribution of products deemed critical to protecting or treating our population against a variety of naturally occurring or intentionally delivered CBRN threats.

The MCM enterprise has demonstrated unprecedented successes, including development of the first human vaccine for avian flu and establishment of a pre-pandemic influenza vaccine stockpile. In addition, the MCM enterprise has been successful in developing and procuring countermeasures to respond to CBRN threats through utilization of the Project BioShield program. Countermeasures procured under Project BioShield that have been delivered to the Strategic National Stockpile (SNS) include treatments for anthrax (vaccines and therapeutics), radiation exposure, and botulism. Research and development efforts are underway for a smallpox vaccine and additional countermeasures to diversify the SNS. While the MCM enterprise has been successful in moving the Nation forward in preparedness efforts, there is still much work to be done.

To begin the effort of strengthening the MCM enterprise, in December 2009, the Secretary of Health and Human Services, Kathleen Sebelius, requested a complete review of HHS's MCM enterprise and assigned this responsibility to ASPR. The primary goal of the MCM enterprise review was to ensure the Nation has a forward-looking, 21st-century MCM enterprise system upon which it can rely during an emergency or other public health event. This comprehensive review aims to improve the MCM enterprise so it does not exist in

a vacuum and is part of a complex, multi-component system of capabilities necessary to protect the Nation from a wide range of health threats.

In August 2010, the "Public Health Emergency Medical Countermeasures Enterprise Review: Transforming the Enterprise to Meet Long-Range National Needs" (MCM Review) was released. The MCM Review focuses on "processes, policies, and infrastructure required to take a product concept derived from a national requirement through research, early and advanced development, manufacturing, regulatory approval, procurement, and stockpiling." Specifically, this Review examined the steps involved in the research, development, and FDA approval of medications, vaccines, and medical equipment and supplies for a health emergency.

The MCM enterprise is one component of a broader response strategy to mitigate the effects of a CBRN event. To be resilient in the face of CBRN disasters, we need a fully integrated and coordinated strategy to address how services from various sectors of our healthcare system will work together to respond and save lives. We need a healthcare system that is nimble and versatile and can address patients' needs when and where necessary. After we work to procure valuable medical countermeasures to treat CBRN effects, we need adaptable distribution plans in place to deliver countermeasures to every American quickly. A larger framing of all public health infrastructure needs for national health security is described in the National Health Security Strategy (NHSS). The purpose of the NHSS is to guide the Nation's efforts to minimize the risks associated with a wide range of potential large-scale incidents that put the health and well-being of the U.S. population at risk, whether at home, in the workplace, or in any other setting. National health security is achieved when the Nation and its people are prepared for, protected from, and able to respond effectively to and recover from public health emergencies.

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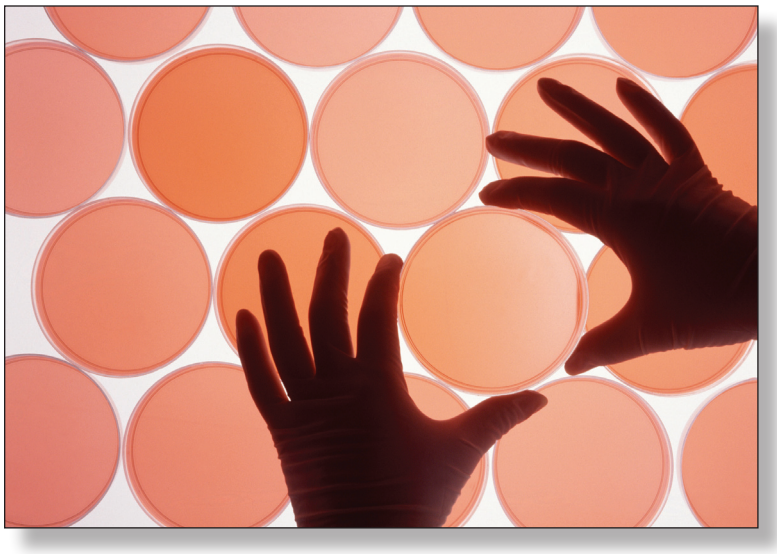
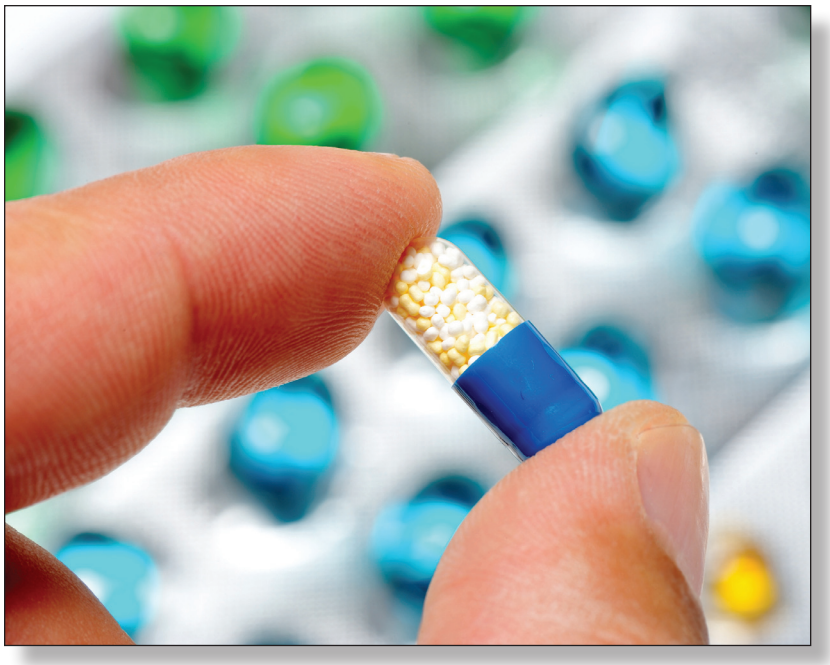
EXECUTIVE SUMMARY

THIS REPORT FULFILLS THE REQUIREMENT TO REPORT TO CONGRESS ANNUALLY ON SPECIFIED AUTHORITIES under the Project BioShield Act of 2004 (Project BioShield; Public Law [P.L.] 108-276). This report covers the period from January 2009 to December 2009. While this report has been in preparation, additional activities have occurred under Project BioShield.



Throughout calendar year 2009, antitoxins to anthrax and botulinum were delivered to the Strategic National Stockpile (SNS) through existing contracts under the Project BioShield program administered by the Biomedical Advanced Research and Development Authority (BARDA) within the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR). As a result of the success in developing smallpox antiviral drug candidates, a solicitation was issued in March 2009 to support late stage development and procurement of 1.7 million treatment courses of smallpox antiviral drugs.

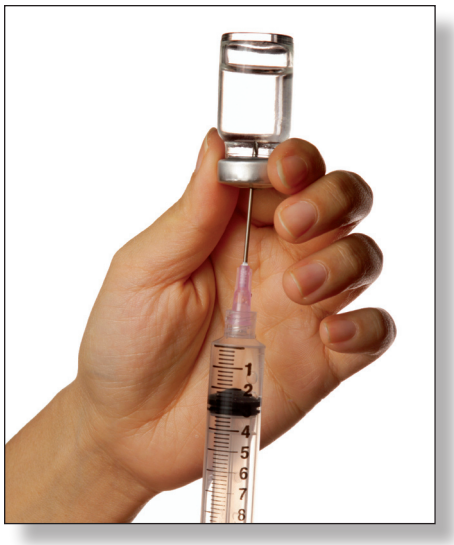
Other significant events transpired in 2009 for Project BioShield products that have further sharpened our understanding of the challenges we continue to face in the complex undertaking of medical product approval. A regulatory application for an anthrax antitoxin (developed under Project BioShield and filed with the Food and Drug Administration (FDA) for review and approval) was determined to need additional studies to better



demonstrate its added benefit to antibiotic treatments. In addition, slower than expected progress in developing stable next generation anthrax vaccine candidates resulted in the termination of a solicitation in December 2009 to support late stage development and acquisition of 20 million doses of anthrax vaccine. The termination of this solicitation resulted in greater support of advanced development of next generation anthrax vaccines in 2010 to provide more mature products in the future for Project BioShield.

During calendar year (CY) 2009, the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health (NIH) used its authority to expedite peer review of applications to award four grants to academic institutions to develop candidate products to treat radiation exposure.

In addition, as a result of the 2009 H1N1 influenza pandemic (H1N1), during CY 2009 HHS used its authority to utilize the Emergency Use Authorization (EUA) authority provided under Project BioShield to assist in the medical response to H1N1 by providing increased access to antiviral drugs, personal protective equipment, and diagnostic devices. Following an April 26, 2009 determination of a public health emergency by the then-Acting Secretary, and declarations that the determination justified use of certain antivirals, personal respiratory protection devices, and in vitro diagnostics, the FDA Commissioner authorized the use of nineteen medical countermeasures using EUA authority.



1.0 PROJECT 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 and expedite the development and procurement of medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) threat agents. It was also designed to streamline the approval process of such countermeasures, and 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 law that authorized the establishment of the office of the ASPR and BARDA. Within HHS, ASPR/BARDA has the procurement authority for Project BioShield acquisitions.

The Project BioShield Act requires an annual report to describe each use of certain authorities.

- **Research and Development of Qualified Medical Countermeasures –** Section Two 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 include expedited procurement authority, limited competition, expedited peer review, and increased simplified acquisition thresholds.

- **Security Countermeasure Procurements and Special Reserve Fund –** Section Three of the Project BioShield Act 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). This Act specified that up to $3.4 billion could be obligated from FY 2004 through FY 2008, and all remaining funds available for obligation 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.

- **Emergency Use Authorization for Medical Countermeasures –** Section Four of the Project BioShield Act allows the Secretary of HHS, based on a determination of an emergency by the Secretary of Health and Human Services, Homeland Security, or Defense, to declare that the emergency justifies use of an unapproved product or an unapproved use of an approved product (both uses are referred to as Emergency Use Authorization (EUA)). The HHS Secretary has delegated the authority to issue an EUA to the FDA Commissioner.

Specifically, the Project BioShield Act requires the report to include the following information for each use of 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.

The Project BioShield Act also requires a separate summary of activities at the National Institutes of Health (NIH) 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. During the reporting period NIH did not use any of these authorities; standard practices in these areas were deemed adequate for research and development activities.

2.0 USE OF PROJECT BIOSHIELD AUTHORITIES

2.1 Expedited Peer Review

The National Institute of Allergy and Infectious Diseases within the NIH used its authority to expedite peer review of applications to award the following grants: two grants to universities for research on medical countermeasures to enhance platelet regeneration and increase survival after radiation exposure, and one grant to a university and one grant to a hospital for the development of medical countermeasures to mitigate and/or treat radiation-induced pulmonary syndrome. The details of how this authority was used are outlined in Table 1.

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 enhance platelet regeneration and increase survival following radiation exposure	27-Sep-07: NIAID RFA-AI-07-036 Response date: 9-Jan-08 21 applications were received	Although the threat of radiological/nuclear attacks or events continues, few medical countermeasures exist. In addition, the regular review process takes a long time.	2 grants awarded in September 2009 Recipient: 2 universities	19 applicants were turned down Turned down: 5 non-profit organizations, 9 universities, and 5 biotech companies
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 30 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.	2 grants awarded in September 2009 Recipients: 1 university and 1 hospital	28 applicants were turned down Turned down: 4 non-profit organizations, 19 universities, and 5 biotech companies

2.2 Security Countermeasure Procurement

As of December 2009, there is $2.4 billion remaining in the Special Reserve Fund for Project BioShield procurements. BARDA has an open solicitation for a procurement of smallpox antivirals (see Table 3) for which it is currently in the final stages of negotiations with offerors and anticipates one or more awards in FY 2011.

The Tables below outline cumulatively Project BioShield solicitations and acquisition contracts that were initiated, completed, or continued in CY 2009. 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 2009	Total Funding (Millions)	Reason for Use of Authority
Anthrax Therapeutics						
Monoclonal Antibody (Raxibacumab, formerly Abthrax)	9/2005 (Base)[1]	Completed (2009)	HGS	20,000 treatment courses delivered; NDA filed with FDA (2008) & additional studies required by FDA (2009)	$174[2]	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)[3]	Ongoing	HGS	13,795 treatment courses delivered of 45,000 contracted	$152	
Anthrax Immune Globulin (AIG)	9/2005 (Base)	Ongoing	Cangene	6,500 treatment courses delivered of 10,000 contracted	$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.

[1] The original contract did not use SRF funding, but it was modified in 6/2006 to use SRF funding.
[2] Modified in 11/2008 to total expenditure.
[3] The original contract did not use SRF funding, but it was modified in 7/2006 to use SRF funding.

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Table 2: Project BioShield Acquisition Contracts cont.

Countermeasure Area / Product	Date of Contract Award	Delivery to Strategic National Stockpile	Contract Recipient	Status at the Close of CY 2009	Total Funding (Millions)	Reason for Use of Authority
Anthrax Vaccines						
AVA (BioThrax®, Anthrax Vaccine Absorbed)	5/2005	Completed (2007)	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 (2009)	Emergent	18.75 million doses delivered	$448	
rPA (Recombinant Protective Antigen)	11/2004	N/A	VaxGen	Terminated 12/19/06	$2	Contract terminated for failure to meet contract requirements.
Botulism Therapeutics						
Botulinum Antitoxin (hBAT) Therapeutic	6/2006	Ongoing	Cangene	96,888 doses delivered of 200,000 doses contracted	$414	Equine-derived polyclonal sera to multiple strains (A-F) of *C. botulinum* used therapeutically for botulism
Smallpox Vaccine						
Imvamune® (MVA, (Modified Vaccinia Ankara) Smallpox Vaccine	6/2007	Ongoing	Bavarian Nordic	1.15 million doses delivered of 10 million doses contracted	$505	Imvamune® is a live, 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 bottles, deliveries complete	$18	Provides capability for pediatric treatment
IV Calcium/Zinc DTPA (Diethylene triamine pentaacetic acid)	12/2005	Complete	Akorn	474,710 doses, deliveries complete	$22	Decorporation agent for internalized radionuclides

Table 3: Project BioShield Solicitation

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

Name	URL	Pre-solicitation	Draft	Final	Closing Date	Expected Award Date	Reason for Use of Authority
Smallpox Antiviral Drug							
Smallpox Antiviral – RFP-BARDA-09-35	https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=2873cabbbf1bde4204c0c157e870b72d&_cview=0	February 2009	N/A	March 2009	May 2009	FY 2011	In addition to vaccines, HHS is pursuing development and procurement of smallpox antiviral drugs to treat symptomatic individuals.

2.3 Emergency Use Authorization

FDA issued an Emergency Use Authorization (EUA) on October 3, 2008, for 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). The EUA remained in effect throughout the reporting period and was revised on February 25, 2009.

As a result of the 2009 H1N1 influenza pandemic (H1N1), HHS used its authority to utilize the EUA authority provided under Project BioShield to assist in the medical response to H1N1 by providing increased access to antiviral drugs, personal protective equipment, and diagnostic devices. On April 26, 2009, the then-Acting Secretary of HHS issued a determination that a public health emergency existed that affected national security for H1N1. Pursuant to this determination, the then-Acting Secretary of HHS declared that a public health emergency existed justifying the authorization of emergency use of 1) certain in vitro diagnostics for detection of H1N1 in clinical samples, 2) certain products from the neuraminidase class of influenza antiviral drugs - oseltamivir phosphate and zanamivir, and 3) certain personal respiratory protection devices including masks and N95 respirators.

In addition, on October 20, 2009, the Secretary of HHS declared that a public health emergency existed justifying the authorization of emergency use of the unapproved antiviral drug peramivir for intravenous administration to certain hospitalized patients for the treatment of H1N1.

Following these determinations, the FDA Commissioner authorized the use of nineteen medical countermeasures using EUA authority; these are listed in Table 4. As indicated in the table, many of the EUAs were subsequently amended.

Table 4: Emergency Use Authorizations for 2009 H1N1 Medical Countermeasures

Number	Medical	Requestor	Initial or Amended	Issuance Date	Posted on Web	Federal Register Publication
Antivirals						
1	Oseltamivir phosphate	CDC	Initial	4/27/2009	removed	74 FR 38648, August 4, 2009
1.a	Oseltamivir phosphate	CDC	Amendment	Reissued 4/28/2009	removed	74 FR 38648, August 4, 2009
1.b	Oseltamivir phosphate (oral suspension)	CDC	Amendment	Reissued 7/15/2009	removed	
1.c	Oseltamivir phosphate products	CDC and others	Amendment	Reissued 10/30/2009	posted	
2	Zanamivir inhalation powder	CDC	Initial	4/27/2009	removed	74 FR 38648, August 4, 2009
2.a	Zanamivir inhalation powder	CDC	Amendment	Not reissued	removed	74 FR 38648, August 4, 2009
2.b	Zanamivir inhalation powder	CDC and others	Amendment	Reissued 10/30/2009	removed	
2.c	Zanamivir inhalation powder	CDC	Amendment	Reissued 11/5/2009	posted	
3	Peramivir IV	CDC	Initial	10/23/2009	removed	74 FR 56640, November 2, 2009
3.a	Peramivir IV	CDC	Amendment	Reissued 11/19/2009	posted	
Personal Protective Devices						
4	N95 Respirators	CDC	Initial	4/28/2009	removed	74 FR 38644, August 4, 2009
4.a	N95 Respirators	CDC	Amendment	Reissued 5/1/2009	posted	74 FR 38644, August 4, 2009

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Table 4: Emergency Use Authorizations for 2009 H1N1 Medical Countermeasures (cont.)

Number	Medical	Requestor	Initial or Amended	Issuance Date	Posted on Web	Federal Register Publication
In Vitro Diagnostics						
5	CDC Swine Influenza Virus Real-Time RT-PCR Detection Panel	CDC	Initial	4/27/2009	removed	74 FR 38636, August 4, 2009
5.a	CDC Swine Influenza Virus Real-Time RT-PCR Detection Panel	CDC	Amendment	Reissued 5/2/2009	removed	74 FR 38636, August 4, 2009
5.b	CDC Swine Influenza Virus Real-Time RT-PCR Detection Panel	CDC	Amendment	Reissued 12/18/2009	posted	
6	CDC's Previously Cleared RT-PCR Detection Panel	CDC	Initial	5/2/2009	posted	74 FR 38636, August 4, 2009
7	Focus Diagnostics Influenza A H1N1 (2009) real-time RT-PCR	Focus Diagnostics, Inc.	Initial	7/24/2209	removed	
7.a	Focus Diagnostics Influenza A H1N1 (2009) real-time RT-PCR	Focus Diagnostics, Inc.	Amendment	Reissued 8/14/2009	removed	
7.b	Focus Diagnostics Influenza A H1N1 (2009) real-time RT-PCR	Focus Diagnostics, Inc.	Amendment	Reissued 12/18/2009	posted	
8	CDC rRT-PCR Swine Flu Panel on JBAIDS Instrument	Department of Defense	Initial	8/24/2009	removed	

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Table 4: Emergency Use Authorizations for 2009 H1N1 Medical Countermeasures (cont.)

Number	Medical	Requestor	Initial or Amended	Issuance Date	Posted on Web	Federal Register Publication
8.a	rRT-PCR Detection Panel on JBAIDS Instrument	Department of Defense	Amendment	Reissued 12/18/2009	posted	
9	Diatherix H1N1-09 Influenza Test	Diatherix Laboratories, Inc.	Initial	10/09/2009	posted	
10	Focus Diagnostics Simplexa Influenza H1N1 (2009)	Focus Diagnostics, Inc.	Initial	10/16/2009	removed	
10.a	Focus Diagnostics Simplexa Influenza H1N1 (2009)	Focus Diagnostics, Inc.	Amendment	Reissued 12/18/2009	posted	
11	Prodesse ProFlu-ST Influenza A	Prodesse, Inc.	Initial	10/27/2009	posted	
12	ELITech Molecular Diagnostics 2009-H1N1 influenza A Virus Real-Time RT-PCR	Epoch BioSciences	Initial	11/13/2009	removed	
12.a	ELITech Molecular Diagnostics 2009-H1N1 influenza A Virus Real-Time RT-PCR	Epoch BioSciences	Amendment	Reissued 2/1/2010	posted	

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Table 4: Emergency Use Authorizations for 2009 H1N1 Medical Countermeasures (cont.)

Number	Medical	Requestor	Initial or Amended	Issuance Date	Posted on Web	Federal Register Publication
13	Roche's RealTime Ready 2009 H1N1 Test	Roche Applied Science	Initial	11/13/2009	posted	
14	GeneSTAT 2009 H1N1 Influenza Test	DxNA, LLC	Initial	12/9/2009	posted	
15	Tessarray Resquencing Influenza A Microarray Detection Panel	TessArae, LLC	Initial	12/16/2009	posted	
16	Xpert Flu A Panel	Cepheid	Initial	12/24/2009	posted	
17	ViraCor 2009 H1N1 Influenza A Real-time RT-PCR Test	Viracor Labs	Initial	1/21/2010	posted	
18	Longhorn Influenza A/ H1N1-09 Prime RRT-PCR Assay	Longhorn Vaccines and Diagnostics	Initial	2/16/2010	posted	
19	Diagnostic Hybrids, Inc. D3 Ultra 2009 H1N1 Influenza A Virus ID Kit	Diagnostic Hybrids, Inc.	Initial	2/16/2010	posted	

APPENDIX A

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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