

July 2009

PROJECT BIOSHIELD

HHS Can Improve Agency Internal Controls for Its New Contracting Authorities



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Highlights of [GAO-09-820](#), a report to congressional committees

Why GAO Did This Study

The Project BioShield Act of 2004 (BioShield Act) increased the federal government's ability to procure needed countermeasures to address threats from chemical, biological, radiological, and nuclear agents. Under the BioShield Act, the Department of Health and Human Services (HHS) was provided with new contracting authorities (increased simplified acquisition and micropurchase thresholds, and expanded abilities to use procedures other than full and open competition and personal services contracts) and was authorized to use about \$5.6 billion in a Special Reserve Fund to procure countermeasures. Based on the BioShield Act's mandate, GAO reviewed (1) how HHS has used its purchasing and contracting authorities, and (2) the extent to which HHS has internal controls in place to manage and help ensure the appropriate use of its new authorities. To do this work, GAO reviewed contract files and other HHS documents, including internal control guidance, which GAO compared with federal statutes and federal internal control standards.

What GAO Recommends

GAO recommends that HHS include comprehensive risk assessment statements in its written guidance on the internal controls for the BioShield contracting authorities for which the agency was required to establish controls. HHS agreed with the recommendation and said it would provide additional guidance.

[View GAO-09-820 or key components.](#)
For more information, contact John Needham,
202-512-4841, NeedhamJK1@gao.gov.

PROJECT BIOSHIELD

HHS Can Improve Agency Internal Controls for Its New Contracting Authorities

What GAO Found

Since 2004, HHS has awarded nine contracts using its Special Reserve Fund (Fund) purchasing authority under the BioShield Act to procure countermeasures that address anthrax, botulism, smallpox, and radiation poisoning. HHS may procure countermeasures that are approved by the Food and Drug Administration and ones that are unapproved, but are within 8 years of approval. Of the nine contracts, one was terminated for convenience and the remaining eight are valued at almost \$2 billion. HHS officials told GAO that additional contracts are likely to be awarded in the near future as the Fund provides funding through fiscal year 2013. In addition, HHS has used one of its new contracting authorities, simplified acquisition procedures, although it has not used this authority since 2005.

HHS has established internal controls on its new purchasing and contracting authorities. In addition to the language in the BioShield Act, which sets up a broad framework of controls over the use of the Special Reserve Fund, the internal controls for this purchasing authority are documented in a variety of internal policy and procedure documents and interagency agreements, which provide guidance on roles and responsibilities for how the controls are to be implemented. In response to BioShield Act requirements, HHS also established internal controls for three of the contracting authorities: the increased simplified acquisition threshold and its use with Special Reserve Funds, the increased micropurchase threshold, and the use of personal services contracts. Federal internal control standards state that, among other things, management needs to comprehensively identify risks, analyze them for possible effect, and determine how risks should be managed. Although some of the risk statements in a memo HHS issued identify some risks and one mentions possible negative consequences that could occur without proper controls in place, the risk statements for using the increased micropurchase threshold and increased simplified acquisition procedures lack analysis of specific risks. In particular, the memo does not discuss a key risk associated with using simplified acquisition procedures—namely, that an agency is prohibited from obtaining cost or pricing data for acquisitions at or below the simplified acquisition threshold. Without this data, the agency may not be able to determine if the price of a contract is fair and reasonable. Moreover, not having adequately documented and appropriately communicated risk assessments potentially results in future employees not knowing or understanding the risks or trade-offs involved in using the authorities. With employee turnover, HHS' reliance on the knowledge of current personnel to appropriately implement key controls will not enable future employees to make sound, informed, and consistent decisions.

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Abbreviations

BARDA	Biomedical Advanced Research and Development Authority
BioShield Act	Project BioShield Act of 2004
CBRN	Chemical, biological, radiological, and nuclear agents
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
MMFIA	Federal Managers' Financial Integrity Act of 1982
HHS	Department of Health and Human Services
HHSAR	HHS Acquisition Regulation
NIH	National Institutes of Health
OMB	Office of Management and Budget
PAHPA	Pandemic and All-Hazards Preparedness Act

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United States Government Accountability Office
Washington, DC 20548

July 21, 2009

Congressional Committees

Following the attacks using anthrax-laced letters in the United States in 2001 and other biological attacks, such as the Sarin gas attack in Japan, some members of Congress were concerned that the United States was vulnerable to threats from chemical, biological, radiological, and nuclear (CBRN) agents and did not have sufficient medical countermeasures to adequately protect the public from such threats or provide post-exposure treatment. To address this gap in national defense capability, the Project BioShield Act of 2004 (BioShield Act¹) provided the Department of Health and Human Services (HHS) with the ability to accelerate the research, development, acquisition, and availability of effective countermeasures (such as, vaccines, pharmaceuticals, and diagnostics) that are necessary to respond to an attack involving CBRN agents.

The BioShield Act provided HHS with a number of new authorities, including four new contracting authorities:

- an increased simplified acquisition threshold,
- an increased ability to use procedures other than full and open competition,
- an increased micropurchase threshold, and
- the ability to use personal services contracts.²

HHS was also authorized to use funds from a Special Reserve Fund to procure countermeasures to be added to the inventory of medical supplies and countermeasures currently stored in the Strategic National Stockpile.³ At the time of its establishment, the Fund provided HHS about \$5.6 billion to use over a 10-year period (fiscal years 2004 to 2013), with a spending

¹ Pub. L. No. 108-276 (2004).

² Under the BioShield Act, HHS is authorized to obtain by contract personal services without the limitations on period of service and pay within 5 U.S.C. § 3109.

³ The Strategic National Stockpile is the federal supply of pharmaceuticals, vaccines, medical supplies, equipment, and other items meant to provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency. 42 U.S.C. § 247d-6b.

cap of \$3.4 billion during fiscal years 2004 to 2008.⁴ This purchasing authority expanded the types of medical countermeasures that HHS could obtain to address threats from CBRN agents to include not only those that are approved by the Food and Drug Administration (FDA),⁵ but also those that are determined to be within 8 years of approval or which have been authorized for use under an emergency use authorization.⁶ Prior to the BioShield Act, HHS officials told us that the agency was, in general, only able to purchase medical countermeasures that were FDA approved.

Based on the GAO reporting requirements in the BioShield Act, this report examines: (1) how HHS has used its BioShield Act purchasing and contracting authorities to procure medical countermeasures, and (2) the extent to which HHS has designed internal controls to manage and help ensure the appropriate use of its BioShield contracting and purchasing authorities.⁷

To review HHS's use of the BioShield contracting and purchasing authorities, we reviewed legislation and HHS documentation, including annual reports to the Congress on BioShield and contract files. In reviewing contract files, we relied on HHS annual reports to the Congress and statements from officials to identify the contracts awarded by HHS using the BioShield contracting authorities. We also met with HHS officials responsible for managing procurement under the BioShield Act. To assess the internal controls related to the contracting and purchasing authorities, we reviewed HHS regulations, policies, and other forms of written guidance and met with HHS officials responsible for internal controls. We also compared HHS's internal controls with the Act's requirements and

⁴ Funding for the Special Reserve Fund was appropriated in the Department of Homeland Security Appropriations Act, 2004 (Pub. L. No. 108-90 (2003)).

⁵ According to HHS, to be administered to the public, the FDA must approve a drug, license a biological product (such as a vaccine), or clear a medical product (including diagnostics). For purposes of this report, we will use the term approved to cover approved, licensed, or cleared products.

⁶ The BioShield Act also established an emergency use authorization that allows the emergency use of countermeasures that are unapproved by the FDA, or those that are approved but not for the intended use, following a declaration by the Secretary of HHS of an emergency justifying authorization for a product on the basis of a determination (by the Secretary of DOD, DHS, or HHS) of an emergency or a significant potential for an emergency.

⁷ Based on additional reporting requirements in the BioShield Act, we will also review other issues related to the Act. These issues will be covered in a separate GAO product.

other federal internal control requirements and standards. Because HHS established controls for its new contracting authorities after it awarded contracts using one of those authorities, and it has not used the contracting authorities since that time, we limited our review of the controls to their design.

We conducted this performance audit from February 2009 to July 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

HHS' ability to use the Special Reserve Fund for the procurement of countermeasures is predicated on a six-step process involving coordination with DHS and approval by the Director of the Office of Management and Budget (OMB).⁸ As provided in the BioShield Act, the process requires:

1. the DHS Secretary, in consultation with the HHS Secretary and the heads of other agencies as appropriate, to determine that a material threat exists and issue a "material threat determination;"
2. the HHS Secretary to determine countermeasures that are necessary to protect the public health;
3. the HHS Secretary to determine that a particular countermeasure is appropriate for procurement for the Strategic National Stockpile using the Special Reserve Fund and the quantities to be procured;⁹
4. the DHS and HHS Secretaries to jointly recommend to the Director of OMB that the Special Reserve Fund should be used for the designated countermeasure acquisitions;

⁸ The BioShield Act required recommendation to the President (by the Secretaries of HHS and Homeland Security, in coordination with the Director of OMB) that the Special Reserve Fund be made available for procurement of a countermeasure and Presidential approval of the recommendation. The President delegated these functions (recommendation and approval of recommendation) to the Director of OMB. Presidential Memorandum, 69 Fed. Reg. 70,349 (Oct. 21, 2004), reprinted in 42 U.S.C. § 247d-6b (2006).

⁹ In determining if a particular countermeasure is appropriate for procurement using the Special Reserve Fund, the HHS Secretary must also consider the "feasibility of production and delivery within 8 years of sufficient quantities...[and] whether there is a lack of a significant commercial market for the product at the time of procurement..."

-
5. the director of OMB to approve the use of the Special Reserve Fund; and
 6. both Secretaries to notify designated congressional committees of the procurement.

The BioShield Act also provides HHS the ability to use four new contracting authorities for the acquisition of countermeasures. In general, these authorities expanded upon existing provisions in the Federal Acquisition Regulation (FAR). The four authorities are:

- Simplified acquisition procedures which, in general, increased HHS contract threshold amounts from \$100,000 to \$25 million.¹⁰ However, the BioShield Act does not place a threshold limit on countermeasures that are procured using the Special Reserve Fund if the HHS Secretary determines there is a pressing need for the specific countermeasure.
- Procedures other than full and open competition can be used to award contracts when the requirement is only available from one responsible source or a limited number of responsible sources. In addition, in order to conduct procurements on a basis other than full and open competition using simplified acquisition procedures, the HHS Secretary must determine that the mission of the BioShield Program under the Act would be seriously impaired without such a limitation.
- Increased micropurchase threshold from \$2,500 to \$15,000.¹¹
- Personal services contracts may be used for experts or consultants who have scientific or other professional qualifications when the HHS Secretary determines such contracts are necessary to respond to pressing countermeasure research and development needs.

In 2006, the Pandemic and All-Hazards Preparedness Act¹² (PAHPA), among other things, established the Biomedical Advanced Research and

¹⁰ The use of simplified acquisition procedures allows an agency to acquire goods and services using more streamlined approaches than ordinarily would be required. For example, under simplified acquisition procedures, an agency would be required to promote competition to the maximum extent practicable, although it would not be required to use full and open competition. Additionally, an agency could use an oral solicitation to seek competitive price quotations and would not have to follow the more formal evaluation procedures applicable to acquisitions above the threshold. See, FAR §§ 13.000, 13.104, 13.106-1, and 13.106-2(b).

¹¹ Purchases that do not exceed the micropurchase threshold may be made without seeking competitive price quotations if the contracting officer considers the price to be reasonable. See FAR §13.202(a)(2).

¹² Pub. L. No. 109-417 (2006).

Development Authority (BARDA), within HHS, to provide a coordinated, systematic approach to the development and purchases of countermeasures, including vaccines, drugs, therapies, and diagnostic tools. Later, in 2009, Congress transferred the following amounts from the Special Reserve Fund to HHS accounts: \$275 million to be used for the advanced research and development of countermeasures and \$137 million for influenza pandemic preparation.¹³

HHS Has Used New Authorities to Procure Countermeasures

HHS has used its Special Reserve Fund (purchasing) authority and one of its contracting authorities to procure countermeasures for the Strategic National Stockpile. Since 2004, HHS awarded nine contracts using Special Reserve Fund monies to procure various countermeasures, such as anthrax and botulism antitoxins, vaccines for anthrax and smallpox, and post-exposure treatments for radiation poisoning in children and adults. Of the nine contracts awarded using monies from the Fund, HHS terminated one contract, in 2006, because the contractor was unable to meet a major contractual milestone. To date, the remaining eight contracts are valued at almost \$2 billion. See table 1. In addition, HHS officials told us there are currently two requests for proposal solicitations for an anthrax vaccine and a smallpox therapeutic.

¹³ Omnibus Appropriations Act, 2009, Pub. L. No. 111-8 (2009).

Table 1: Contracts Awarded by HHS Using the Special Reserve Fund

Countermeasure	Company awarded contract	Date of contract award	Date of contract completion	Total doses	Maximum persons treatable	Total contract price ^a
Anthrax therapeutics (antitoxins)						
Raxibacumab	Human Genome Sciences	September 2005	September 2010	20,000	20,000	\$176,211,724 ^b
Anthrax immune globulin	Cangene Corporation	September 2005	September 2011	10,000	10,000	\$144,256,599 ^c
Anthrax Vaccines						
AVA anthrax vaccine	BioPort/Emergent BioDefense Operations Lansing, Inc	May 2005	September 2007	10,000,000	3,333,000	\$242,737,000
AVA anthrax vaccine	Emergent BioDefense Operations Lansing, Inc	September 2007	September 2010	18,750,000	6,250,000	\$447,650,001
Recombinant protective antigen	VaxGen	November 2004	Contract Terminated December 2006	N/A	N/A	\$1,534, 253 ^d
Botulism therapeutic						
Heptavalent botulinum antitoxin	Cangene Corporation	September 2006	May 2011	200,000	200,000	\$366,384,724
Smallpox vaccines						
MVA smallpox vaccine	Bavarian Nordic A/S	June 2007	June 2012	20,000,000	10,000,000	\$504,765,464
Radiological/Nuclear						
Liquid potassium iodide	Fleming and Company Pharmaceuticals	March 2005	March 2010	4,800,000	144,000,000	\$17,629,003
IV Calcium (Ca) DTPA	Akorn, Inc	December 2005	December 2015	Ca DTPA = 394,350	Ca DTPA = 394,350	\$21,962,448
IV Zinc (Zn) DTPA				Zn DTPA = 79,460	Zn DTPA = 79,460	
Total						\$1,923,131, 216

Source: GAO analysis of HHS contracts and other documents.

^aUnless otherwise noted, the contract price includes all options and modifications to the price of the contract.

^bThis figure contains \$1,797,372 in funds that did not come from the Special Reserve Fund.

^cThis figure contains \$422,880 in funds that did not come from the Special Reserve Fund.

^dThis figure is less than the original awarded contract price and is the total amount of money HHS paid to the contractor on the terminated contract.

Of the four contracting authorities provided under the BioShield Act, HHS has only used the simplified acquisition procedure authority. From 2004 through 2005, HHS's National Institutes of Health (NIH) used this authority to award five other contracts, including ones for research to develop a botulism antitoxin and improved treatments for radiation poisoning. Awarded with NIH funding, these contracts have a total value of almost \$30 million when options and other later modifications are included. See table 2.

Table 2: Contracts Awarded by HHS Using Simplified Acquisition Procedures

Countermeasure	Company awarded contract	Date of contract award	Date of completed delivery	Total contract price^a
Antitoxin for botulinum neurotoxin	XOMA (US) LLC	March 2005	September 2006	\$15,000,000
	DynPort Vaccine Company, LLC	May 2005	March 2008	\$3,026,999
Improved DTPA for radionuclide chelation	University of Kentucky	September 2005	September 2009	\$5,160,995
	Nanotherapeutics, Inc.	September 2005	September 2009	\$3,044,549
	SRI International	September 2005	September 2009	\$3,714,882
Total price of contracts				\$29,947,425

Source: GAO analysis of HHS contracts and other documents.

^aThe contract price includes all options and modifications to the price of the contract.

HHS officials told us that they have not used this authority since 2005. HHS officials also told us that no other BioShield contracting authorities have been used to date, although the officials noted that these authorities may be needed for use in the future.

HHS Has Established Internal Controls for Its New Authorities, but Lacks Adequate Documentation of the Risks of Using the Contracting Authorities

In response to BioShield requirements, HHS has established internal controls on its Special Reserve Fund (purchasing) and contracting authorities, but lacks adequate documentation of the risks of using the new contracting authorities.¹⁴ Language in the BioShield Act sets up a broad framework of controls over the procurement of countermeasures, including those with Special Reserve Funds, by requiring HHS to coordinate with DHS and obtain approval by OMB before the Fund may be used. In addition to the language in the Act, HHS officials told us that the internal controls for procuring countermeasures using the Fund are documented in a variety of internal policy and procedure documents and interagency agreements, which provide guidance on roles and responsibilities for how the controls are to be implemented. These documents include:

- an HHS policy document that establishes an enterprise governance board to oversee requirements and priority-setting regarding emergency medical countermeasures for the civilian population. The document also outlines the authorities, organizational structure, and guidelines for the board;
- an HHS budget execution document that delineates responsibilities and describes the processes for requesting contract actions, purchases, and interagency agreements;
- a BARDA standard operating procedure document that provides contracting and other BARDA officials with guidance on source selection procedures and outlines specific responsibilities in carrying out those procedures;
- a BARDA acquisition plan which details the pre- and post-award approval processes for procurements using the Fund;
- an interagency agreement between HHS and DHS dated September 25, 2006, that outlines the terms and conditions for when the Fund can be used; and
- an OMB Circular on transferring budget authority from one agency to another.¹⁵

¹⁴ In addition to existing requirements for HHS to establish effective internal controls, the BioShield Act required the Secretary to establish certain additional internal controls over the use of its BioShield purchasing and contracting authorities. For information on requirements apart from the BioShield Act, see 31 U.S.C. § 3512(c) and (d), commonly known as the Federal Managers' Financial Integrity Act of 1982 (FMFIA). FMFIA was repealed as part of the general revisions to title 31 U.S. Code. However, the key provisions of FMFIA were codified at 31 U.S.C. § 3512(c) and (d).

¹⁵ See OMB Circular No. A-136, Section II.4.2.5.

HHS has also established internal controls for the contracting authorities that were specified in the BioShield Act. On October 18, 2005,¹⁶ HHS issued a memorandum that provided guidance on the use of the following contracting authorities:

- the increased simplified acquisition threshold and its use with the Special Reserve Fund,
- the increased micropurchase threshold, and
- the use of personal services contracts.¹⁷

HHS's memo is structured around the five elements of internal control: the control environment, risk assessment, control activities, information and communications, and monitoring.¹⁸ Federal internal control standards state that management needs to comprehensively identify risks, analyze them for possible effect, and determine how risks should be managed. Federal internal control standards also state that controls need to be clearly documented, readily available for examination, and distributed in a form and time frame that permits people to perform their duties efficiently.

Risk assessment statements we reviewed in the memo are generally not assessments of the risks involved in using particular authorities. Some of the risk statements identify some risks and one mentions possible negative consequences that could occur without proper controls in place, but the statements lack an analysis of those risks. For example, the risk assessment statement for using the increased micropurchase threshold states that “control procedures are necessary to prevent noncompliance with specific requirements of the Act, including exceeding statutory limitation on number of contracts and selections based on improper criteria.” And, the risk assessment statement on increased simplified acquisition procedures does not mention or assess risk. It simply states

¹⁶ The HHS memo was issued after HHS used its increased simplified acquisition threshold to award the five contracts discussed previously.

¹⁷ Although the BioShield Act did not direct HHS to establish internal controls for using procedures other than full and open competition, agency officials told us the internal controls on this authority are in the Federal Acquisition Regulation (subpart 6.3) and in the HHS Acquisition Regulation (HHSAR). See HHSAR §§ 306.302 through 306.304 on circumstances permitting other than full and open competition.

¹⁸ See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999).

that “control procedures are necessary to prevent noncompliance with specific requirements of the Act.” In particular, the risk statement on simplified acquisition procedures in the memo does not discuss a key risk associated with using simplified acquisition procedures—namely, that an agency is prohibited from obtaining cost or pricing data for acquisitions at or below the simplified acquisition threshold.¹⁹

According to a senior BARDA procurement official, while using simplified acquisition procedures can expedite the procurement process, the agency will not have cost and pricing data, which may be needed to determine that the price of a contract—especially those valued in the tens of millions or hundreds of millions—is fair and reasonable. In a subsequent meeting, he stated that he is aware of these trade-offs based on his own experience and knowledge of the FAR. He also confirmed that an explanation assessing the trade-offs and risks involved when using the new contracting authorities is not contained in other HHS documents. Instead, this official acknowledged that HHS’s written guidance on the controls for the contracting authorities does not document known risks and trade-offs of using the authorities. As a result, implementation of these controls depends on the experience and knowledge of current personnel. Moreover, the consistent application of these controls is not likely to be sustained over time as employees leave their positions and new ones take their place. Not having adequately documented and appropriately communicated risk assessments, which institutionalize agency policies, may potentially result in future employees not knowing or understanding the risks or tradeoffs involved in using the various contracting authorities.

Conclusions

Since the enactment of the BioShield Act in 2004, HHS has awarded almost \$2 billion in contracts to either procure medical countermeasures or to facilitate their development. Although HHS has established internal controls for its new purchasing and contracting authorities, the risk assessment statements related to the agency’s internal controls for the contracting authorities are not sufficiently specific. In particular, the failure to mention and lack of analysis of specific risks in the risk statements associated with using the increased micropurchase threshold and increased simplified acquisition procedures is not consistent with requirements under federal internal control standards.

¹⁹ FAR 15.403-1(a) prohibits obtaining cost or pricing data for acquisitions at or below the simplified acquisition threshold.

With employee turnover, the lack of adequately documented risk assessment statements could create a situation in which employees do not know the risks or trade-offs involved in using the various authorities. The effectiveness of the internal controls now in place is dependent on the knowledge of individuals currently working at the agency. Without appropriately documented risk assessments that institutionalize agency policies, HHS will be unable to ensure that sound, informed, and consistent decisions will be made in the face of employee turnover.

Recommendation for Executive Action

We recommend that the Secretary of Health and Human Services include comprehensive risk assessment statements in written guidance on the internal controls for the BioShield contracting authorities for which the agency was required to establish controls.

Agency Comments and Our Evaluation

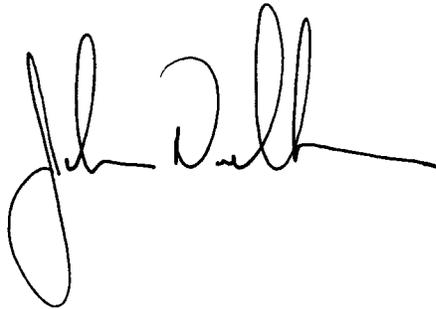
HHS provided us with written comments on a draft of this report. The comments appear in appendix I.

HHS agreed with our recommendation and said that it will revise its internal control guidance on risk assessments for using BioShield contracting authorities. We believe that this is a positive step toward helping ensure that sound, informed, and consistent risk assessments will be made in BioShield acquisitions. HHS also provided observations on the Special Reserve Fund and risk assessments, which appear in appendix I.

We are sending copies of this report to the Secretary of Health and Human Services. The report is also available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-4841 or NeedhamJK1@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last

page of this report. GAO staff who made major contributions to this report are listed in appendix II.

A handwritten signature in black ink, appearing to read "John K. Needham". The signature is fluid and cursive, with a large loop on the left side and a horizontal line extending to the right.

John K. Needham,
Director, Acquisition and Sourcing Management

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Appendix I: Comments from the Department of Health & Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUL 14 2009

John K. Needham
Director, Acquisition and Sourcing Management
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Needham:

Enclosed are the Department's comments on the U.S. Government Accountability Office's draft report entitled, "Project BioShield: HHS Can Improve Agency Internal Controls for Its New Contracting Authorities" (GAO-09-820).

The Department appreciates the opportunity to review and comment on this draft report before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Pisaro Clark".

Barbara Pisaro Clark
Acting Assistant Secretary for Legislation

Enclosure

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED: PROJECT BIOSHIELD: HHS CAN IMPROVE AGENCY INTERNAL CONTROLS FOR ITS NEW CONTRACTING AUTHORITIES (GAO 09-820)

HHS agrees with the recommendation and will revise the internal controls dated October 18, 2005, to provide more guidance on risk assessments for using BioShield contracting authorities.

Additional Comments:

GAO says (page 5) that HHS used "Special Reserve Fund monies to procure various countermeasures, such as anthrax and botulism antitoxins, vaccines for anthrax and smallpox, and post-exposure treatments for radiation poisoning in children and adults." We note that the fund authorized under the Project BioShield Act of 2004 made possible the variety of medical countermeasures and quantity of doses procured by HHS during the first five years of the ten-year authorization period.

Page 10 discusses the assessment of trade-offs and risks of using simplified acquisition procedures, one of the BioShield contracting authorities. The example given of a risk is the prohibition on obtaining cost or pricing data that a contracting officer may need for determining whether or not the proposed price of a multi-million dollar contract is fair and reasonable. The concern about this risk is held more widely in BARDA than solely being the opinion of the individual interviewed.

Appendix II: GAO Contacts and Acknowledgments

GAO Contact

John K. Needham, (202) 512-4841 or NeedhamJK1@gao.gov

Acknowledgments

In addition to the contact named above, Carol Dawn Petersen, Assistant Director; Angela D. Thomas, Kelly Bradley, Robert S. Swierczek, Marie P. Ahearn, and Kenneth E. Patton made key contributions to this report.

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