ANTHRAX PROTECTION: PROGRESS OR PROBLEMS?

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS, AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

SECOND SESSION

MAY 9, 2006

Serial No. 109–207

Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.gpoaccess.gov/congress/index.html
http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE

32–438 PDF WASHINGTON : 2007

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ANTHRAX PROTECTION: PROGRESS OR PROBLEMS?

TUESDAY, MAY 9, 2006

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS, AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:08 p.m., in room 2154, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Duncan, Porter, and Van Hollen.

Staff present: R. Nicholas Palarino, Ph.D., staff director; Kristine Fiorentino, professional staff member; Robert A. Briggs, analyst; Andrew Su, minority professional staff member; and Jean Gosa, minority assistant clerk.

Mr. SHAYS. The Government Reform Committee Subcommittee on International Relations and National Security is called to order. This is a hearing on anthrax protection progress or problems.

In September and October 2001, envelopes containing anthrax were mailed to post offices and public office buildings. Twenty-two individuals in four States and Washington, DC, contracted anthrax. Five died.

The investigation to date has not revealed who converted letters and packages into vectors of disease. The only things we have are the lessons learned from these events. They remain our best defense against further attempts to contaminate the mail and other public places with anthrax.

Today we ask two questions: How effective has our Government been in developing medical countermeasures against an anthrax attack? How accurate are anthrax detection techniques?

The Department of Homeland Security is responsible for coordinating Federal operations within the United States to prepare for, respond to, and recover from terrorist attacks, major disasters, and other emergencies. Other Government agencies with a stake in applying the lessons learned from the anthrax attack include the Departments of Defense and Health and Human Services, the Centers for Disease Control and Prevention, and the Environmental Protection Agency.

In 2004, President Bush authorized $5.6 billion over 10 years through Project BioShield, for the Government to purchase and stockpile vaccines and drugs to fight anthrax, smallpox, and other potential agents of bioterror. This program represents a critical tool in the war against terrorism as a flexible streamlined means to

identify, develop, procure, and stockpile medical countermeasures. However, there are indications inadequate planning and bureaucratic finger-pointing are challenging the measures President Bush put in motion to defend the United States.

Mr. Alex Azar, Deputy Assistant Secretary in the Department of Health and Human Services acknowledged in congressional testimony on April 6th that the lack of a strategic plan for BioShield has left industry guessing about the Government's priorities.

A Government Accountability Office [GAO] report on anthrax detection addressed our inability to accurately detect anthrax. The report recommended the Secretary of Homeland Security work with all agencies to "ensure appropriate validation studies of the overall process of sampling activities."

The Department of Homeland Security responded to the GAO report by stating the Environmental Protection Agency has the primary responsibility establishing the strategy's guidelines and plans for recovery from a biological attack, while the Department of Health and Human Services has the lead role for any related public health response guidelines. After 2 years, we are still waiting for a strategic plan and a validation of sampling process to determine, for instance, whether Madison Square Garden or even the room we are sitting in right now is free from anthrax.

I believe these issues merit our earnest attention. We owe it to those who contracted anthrax, and particularly to those who died from the infection, including Ms. Ottilie Lundgren from Oxford in my own State of Connecticut.

To help us understand the issues involved, we have two panels of distinguished witnesses, including representatives from the Government Accountability Office, the Departments of Defense, Health and Human Services, and Homeland Security, and the Environmental Protection Agency, and the Centers for Disease Control and Prevention.

We appreciate the time our witnesses took out of their schedules to be with us today and we look forward to hearing their testimony explaining agency preparations to defend the Nation from another anthrax attack.

[The prepared statement of Hon. Christopher Shays follows:]

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"Anthrax Protection: Progress or Problems?"

Statement of Rep. Christopher Shays
May 9, 2006

In September and October 2001, envelopes containing anthrax were mailed to post offices and public office buildings. Twenty-two individuals in four states and Washington, DC contracted anthrax; five died.

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- How effective has our government been in developing medical countermeasures against an anthrax attack?
- How accurate are anthrax detection techniques?

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Other government agencies with a stake in applying the lessons learned from the anthrax attack include the Departments of Defense and Health and Human Services; the Centers for Disease Control and Prevention; and the Environmental Protection Agency.

In 2004, President Bush authorized $5.6 billion over 10 years through Project BioShield for the government to purchase and stockpile vaccines and drugs to fight anthrax, smallpox and other potential agents of bioterror. This program represents a critical tool in the war against terrorism as a flexible, streamlined means to identify, develop, procure and stockpile medical countermeasures.

However, there are indications inadequate planning and bureaucratic finger pointing are challenging the measures President Bush put in motion to defend the United States.

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I believe these issues merit our urgent attention. We owe it to those who contracted anthrax and particularly to those who died from the infection, including Ms. Ottilie Lundgren from Oxford, in my own state of Connecticut.

To help us understand the issues involved we have two panels of distinguished witnesses including representatives from the Government Accountability Office; the Departments of Defense, Health and Human Services, and Homeland Security; and the Environmental Protection Agency; and Centers for Disease Control and Prevention.

We appreciate the time our witnesses took out of their schedules to be with us today, and look forward to hearing their testimony explaining agency preparations to defend the nation from another anthrax attack.

Mr. SHAYS. At this time, the Chair would call on my colleague Mr. Porter to see if he has any statement he would like to make.

Mr. PORTER. Thank you, Mr. Chairman. I appreciate your holding I think a very important hearing today regarding anthrax protection and some of the problems in our progress. With the element of time, I am submitting for the record an opening statement and also a number of questions for DOD and HHS that I would appreciate their response.

But again, I just want to say thank you very much for this opportunity. I think it is very important for the security of our Nation.

[The prepared statement of Hon. Jon C. Porter follows:]

STATEMENT FOR THE RECORD
CONGRESSMAN JON C. PORTER (R-NV-3)
"Anthrax Protection: Progress or Problems?"
May 9, 2006

Mr. Chairman, thank you for holding this hearing on the progress of anthrax science and vaccinations. I look forward to hearing the testimony of the witnesses present as they discuss ways to continue to protect our nation after an anthrax attack.

When the Administration introduced Project BioShield in 2003, the goal of the program was to address the lack of countermeasures against biological terrorism agents. Project BioShield, following Congressional approval, developed a three-pronged focus: to relax procedures for bioterrorism funding, to create a market guarantee for companies and ensure that their product will be purchased by the government, and to allow the emergency use of products not yet approved by the Food and Drug Administration or the Department of Health and Human Services.

As contracts were awarded after the enactment of the Project BioShield Act of 2004 was passed, it was essential that aggressive efforts were made by contract recipients to produce an anthrax vaccine that would provide greater protection against anthrax exposure than what was originally produced.

It was the intent of Congress and the Administration to relax existing procurement procedures in hopes that a new anthrax vaccine would be expedited. When VaxGen received nearly $900 million in 2004 for the creation of a new vaccine, the timetable given was three years. Recently, VaxGen has announced that it will not be able to meet that expected date, instead delays are anticipated to last until 2009—nearly 8 years after our nation was shocked into action by the initial anthrax mailing deaths.

The results now beg the questions—with more resources and more concentrated efforts on creating a vaccine, are we any safer? Have our tax dollars gotten what we have bargained for? Can the American people feel secure in knowing that the government will protect them?

As these questions are universal in so many areas of government, when it comes to the expediency of responding to an emergency situation, they take on an entirely new meaning. The reality of a vaccine being fulfilled and one that is a concept needing just "one more year," becomes the difference between life and death. While companies such as VaxGen continue to develop these technologies, as a nation we still remain exposed to some very real and recurring bioterrorism threats. There remains a need for more companies to be involved in the manufacturing and supply process of an anthrax vaccine. Allowing more minds to find solutions to the problem not only encourages competition but encourages greater scientific accuracy.

More substantive questions remain, which may or may not be addressed in this hearing. Should a full scale anthrax attack occur on our major cities, I am concerned that the vaccines, even if fully developed, would have difficulty reaching the people who would need it most, when they would need it most. There are other vaccines, such as Biothrax, already existing which could be used in advance of a bioterrorism incident or potentially following exposure to a bioterrorism agent, with limited doses. The ready stockpile of one million doses of that vaccine could treat hundreds of thousands. Should competition for vaccine production become a factor, I would be encouraged that our cities would finally become better protected against this threat.

While it is a laudable goal that Health and Human Services has in desiring to make progress in an anthrax preparedness program, it is more than disconcerting that, after 5 years, nothing is concrete. At what point will the bureaucracy be able to move out of the planning stage and into the action stage of emergency preparedness? Hopefully, it will occur long before another bioterrorism attack occurs.

Again, Mr. Chairman, thank you for this hearing. I will be submitting questions to be answered for the record and I look forward to hearing testimony from the witnesses.

***

Questions for DoD:

1. Can you tell me what your experience has been with the administration of BioThrax to military personnel? Approximately how many members of the military services have been immunized?

2. In your procurement of BioThrax, have you experienced any unreasonable or costly delays?

Questions for HHS:

1. Until very recently, I understand HHS had placed all its eggs for anthrax vaccine procurement in one company's basket. I also understand that there have been serious concerns leveled about the viability of both the company and the product. Why hasn't HHS mitigated the risk in its procurement for the Strategic National Stockpile and involved multiple suppliers?

2. Just last week, HHS announced the procurement of another 5mil doses of BioThrax for the Strategic National Stockpile (in addition to the 5 million doses it ordered late last year). In your procurement of BioThrax, have you experienced any unreasonable or costly delays?

3. In your experience over the last 5 years with anthrax exposures around the country, has HHS chosen to administer BioThrax in a post-exposure environment? If so, does HHS believe that BioThrax may be beneficial in the post-exposure environment?

4. Are you aware of CDC does-reduction studies that may provide evidence that BioThrax can be effective with a 3-dose regimen versus 6? What impact would this have on the relative favorability of BioThrax usage?

Mr. SHAYS. Thank you, gentlemen.

At this time, with a quorum being present, I would ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record. The record will remain open for 3 days for that purpose. Without objection, so ordered.

I ask further unanimous consent that all witnesses be permitted to include their written statements in the record. And without objection, so ordered.

I would ask unanimous consent to submit a statement prepared by the Emergent Bio Solutions Corp. Without objection, so ordered.

At this time, the Chair would recognize our first witness. We appreciate him being here. His name is Mr. Keith Rhodes, the Chief Technologist, Center for Technology and Engineering, Applied Research and Methods, the Government Accountability Office.

Mr. Rhodes, we welcome you here. As you know, it is our practice to swear you in.

Raising your right hand—excuse me, let me ask you—you sure you want this guy?

Mr. RHODES. Yes, sir.

Mr. SHAYS. OK. We go back a long ways.

[Witness sworn.]

Mr. SHAYS. Note for the record, our witness and his colleague have responded in the affirmative. If he takes the desk, then we will make sure that our recorder knows exactly who he is.

Mr. Rhodes, we will put on the 5-minute clock, but if it is necessary for you to go over, then go over. We want to make sure your statement is in.

Thank you. Welcome.

STATEMENT OF KEITH RHODES, CHIEF TECHNOLOGIST, CENTER FOR TECHNOLOGY AND ENGINEERING, APPLIED RESEARCH AND METHODS, U.S. GOVERNMENT ACCOUNTABILITY OFFICE, ACCOMPANIED BY SUSHIL SHARMA, ASSISTANT DIRECTOR, CENTER FOR TECHNOLOGY AND ENGINEERING, APPLIED RESEARCH AND METHODS, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. RHODES. Thank you. Mr. Chairman, members of the subcommittee, I want to state for the record that I am accompanied by Dr. Sushil Sharma. We are pleased to be here today to discuss the status of our recommendations on two bodies of work that we did at your request—licensed anthrax vaccine and anthrax detection methods. In today's testimony, I will specifically report on, one, the problems we identified, two, recommendations we made, three, the actions taken by Federal agencies, and four, what remains to be done.

With regard to anthrax detection methods, last year I reported to you that the overall sampling process and the individual activities were not validated. Consequently, Federal agencies could not answer the basic question, is this building contaminated?

Well, I am sorry to report to you that we are not much further along in being able to answer this question than we were in 2001. If this building is contaminated today and tested negative, you would not know for sure whether the negative finding is due to a small number of samples collected, or the samples were collected

from places where anthrax was simply not present, or in fact anthrax is not present in this building.

We therefore recommended that the Secretary of Homeland Security ensure that appropriate validation studies of the overall process of sampling activities, including the methods, are conducted.

Although in the past there had been confusion as to which Federal agency would take the lead as well as the responsibility for ensuring that our recommendations are addressed, I am pleased to report to you that DHS is now accepting responsibility. On May 3, 2006, DHS told us that DHS recognizes it is the principal agency responsible for coordinating the Federal response and would be responsible for ensuring that sampling methods, including the process, are validated. DHS also would work toward developing a probability based sampling strategy.

While actions taken by DHS are steps in the right direction, we recommend that DHS develop a formal strategic plan that includes a roadmap outlining how individual agency efforts would lead to, one, validation of the overall process of sampling activities, including the methods; and two, development of a probability based sampling strategy that takes into account the complexity of indoor environments. This would allow both DHS and the Congress to measure its progress against its stated goals.

With regard to licensed anthrax vaccine, we identified several problems, all of which we have described in prior reports. In addition, we provided information on the disadvantages of the licensed vaccine and the status of Federal efforts to develop a next generation anthrax vaccine.

As you know, the licensed vaccine has been given primarily to military personnel. DOD, however, has a unique set of requirements, as it has a narrow, relatively young, healthy and homogeneous target population. This reduces many problems, although not all, as in the case of reactive genicity by gender. DOD requirements also assume a continuous threat for which they require pre-exposure immunization.

Civilian populations, in contrast, are much more diverse than military populations, and pre-exposure use of this vaccine in the civilian population would likely be difficult to justify based on the available biothreat assessments.

In response to the perceived threat of bioterrorism, HHS decided to develop and test a second generation anthrax vaccine. In September 2002 and September 2003, NIAID awarded contracts to develop a new recombinant PA vaccine effective against inhalation anthrax. The contracts were for developing and testing candidate vaccines with a requirement for evaluating safety, efficacy, and a potential provider's capability for manufacturing the vaccine and achieving FDA licensing.

The contracts, for $13.6 million in 2002 and $80.3 million in 2003, were awarded to VaxGen Inc., a California-based pharmaceutical company. In November 2004, in the first contract under Project BioShield, HHS awarded VaxGen a firm fixed-price contract for $877.5 million for the manufacture and delivery of 75 million doses of recombinant PA anthrax vaccine.

The normal schedule for taking a vaccine from pre-clinical studies to licensure varies, depending on what is known about both the

specific nature of the infectious disease and the planned application of the vaccine in terms of when and on whom the vaccine is to be used. These factors can prolong the development of a vaccine as long as 15 years for civilian use, or as short as 8 years for military use. Because of the U.S. Government's stated need for a vaccine that can counter a domestic biothreat against civilian populations, HHS has undertaken an aggressive procurement of a vaccine on a very short schedule.

While the Government should not pay out money to a contractor unless and until they have met the terms of their contract, the current schedule and the experimental nature of the vaccine itself are risk factors that could jeopardize the entire effort. The current schedule makes no allowance for delay. Everything must occur on time or there will be a cascading direct effect which will delay the product delivery. A schedule with no margin for error and a production cycle that has unknown elements in it are not conducive to confidence.

The variability of schedule does not just have an effect on this individual vaccine development. Rather, it could have effects on how the biotechnology sector responds to any Government overtures in the future. If this contract fails, VaxGen does more than just fail; they cease to exist as a company.

The rest of the biotechnology sector will be watching to see whether VaxGen and the U.S. Government can make this partnership work. If it fails, and VaxGen fails, then the biotechnology sector will be very wary about dealing with the U.S. Government no matter what the stated crisis levels are. Since the U.S. Government does not produce vaccines for general usage and distribution, a bad relationship between the Government and the biotechnology industry means that the Government will have to accept whatever the biotechnology sector sells—an unacceptable position of increased risk for a Government worried about bioterror threats.

Mr. Chairman, this concludes my prepared remarks. I would be happy to respond to any questions that you or other members of the subcommittee may have.

[The prepared statement of Mr. Rhodes follows:]

United States Government Accountability Office

GAO

Testimony before the Subcommittee on National Security, Emerging Threats and International Relations, Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 2:00 p.m. EDT
Tuesday, May 9, 2006

ANTHRAX

Federal Agencies Have Taken Some Steps to Validate Sampling Methods and to Develop a Next-Generation Anthrax Vaccine

Statement of Keith Rhodes, Chief Technologist, Center for Technology and Engineering, Applied Research and Methods

GAO-06-756T

May 9, 2006

GAO
Accountability·Integrity·Reliability

Highlights

Highlights of GAO-06-756T, a testimony before the Chairman, Subcommittee on National Security, Emerging Threats, and International Relations, House Committee on Government Reform, House of Representatives

ANTHRAX

Federal Agencies have taken Some Steps to Validate Sampling Methods and to Develop a Next Generation Anthrax Vaccine

Why GAO Did This Study

GAO has done many studies over the past 7 years on anthrax vaccine safety and anthrax detection methods. GAO has reported the lack of validated methods for detecting anthrax contamination and has recommended a coordinated approach to improving the overall process for detecting anthrax that included a probability-based sampling strategy.

GAO also reported that the vaccine has not been adequately tested on humans; no studies have been done to determine the optimum number of doses; the long-term safety has not been studied and data on short-term reactions are limited; however, women report higher rates of reactions than do men. Given these problems, GAO recommended the development, of a better, alternative vaccine.

What GAO Recommends

The Secretary of Homeland Security needs to develop a formal strategic plan, including a roadmap, outlining how individual agency efforts would lead to the validation of the overall sampling process.

www.gao.gov/cgi-bin/getrpt?GAO-06-756T.

To view the full product, click on the link above. For more information, contact Keith Rhodes at (202) 512-6412 or rhodesk@gao.gov.

What GAO Found

The threat of bioterrorism has long been recognized in the United States and abroad. The Department of Defense (DOD) considers inhalation anthrax to be the greatest biological warfare threat to U.S. military forces. The U.S. Army Medical Research Institute of Infectious Diseases has been conducting basic and applied research on biological threats since 1969, in order to develop medical countermeasures—prophylactics, vaccines, medical diagnostics—to protect warfighters.

The anthrax incidents in 2001 highlighted major gaps in civilian preparedness to detect and respond to anthrax attacks, leading the federal government to focus on developing new drugs, vaccines, and therapeutics to protect U.S. citizens. As a result, the Department of Health and Human Services (HHS) now has major responsibility to ensure that appropriate medical countermeasures are available for civilians. And the Department of Homeland Security (DHS) assumes major responsibility for coordinating federal responses to national incidents of chemical, biological, radiological, and nuclear release.

Despite the many recommendations GAO has made over the past few years regarding problems related to the anthrax vaccine's safety and effectiveness and the reliability of anthrax detection, deficiencies remain. While agencies have taken steps in the right direction, the government still lacks a strategic plan outlining how individual agency efforts would lead to the validation of the overall sampling process, including methods, and the development of a probability-based sampling strategy that accounts for the complexity of indoor environments.

In November 2004, HHS awarded a contract for $877.5 million to procure 75 million doses of a new anthrax vaccine–the first contract awarded under Project Bioshield for medical countermeasures procurement. The terms of the award state that the urgency of the current threat requires an accelerated pace of vaccine development, testing, approval, and procurement. While developing vaccine is known to be difficult and highly likely to encounter testing and production issues in the best of circumstances, the contract's milestones leave little room for slippage from established delivery dates.

The biotechnology sector is watching to see if government and industry can make this partnership work. Understanding the unique issues in this early phase of the biodefense strategy is important. Problems with this initial Project Bioshield contract could affect the biotechnology industry's response to future government overtures to develop and procure medical countermeasures against the many other biothreat agents still to be addressed.

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the status of our recommendations on two bodies of work that we did at your request: licensed anthrax vaccine and anthrax detection methods.[1] As you know, the threat of bioterrorism had been recognized for a considerable time in the United States, as well as internationally. The Department of Defense (DOD) has considered inhalation anthrax in an aerosolized form to be the greatest biological warfare threat to U.S. military forces for quite some time. The U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) has been conducting basic and applied research on biological threats since its inception in 1969, in order to develop medical countermeasures—for example, prophylactics, vaccines, and medical diagnostics—to protect the warfighter.

The anthrax incidents in September and October 2001 highlighted major gaps in our civilian preparedness to detect and respond. It also led the federal government to focus attention on the importance of developing new drugs, vaccines, and therapeutics to protect U.S. citizens.

Consequently, the Department of Health and Human Services (HHS) has the major responsibility to ensure that appropriate medical countermeasures are available for the civilian population, while the Department of Homeland Security (DHS) has assumed the major

[1]For our work on anthrax detection methods, see GAO, *Anthrax Detection: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results*, GAO-05-251 (Washington, D.C.: Mar. 31, 2005), and GAO, *U.S. Postal Service: Issues Associated with Anthrax Testing at the Wallingford Facility*, GAO-03-787T (Washington D.C.: May 19, 2003). For our work on anthrax vaccine, see *Gulf War Illnesses: Questions about the Presence of Squalene Antibodies in Veterans Can Be Resolved*, GAO/NSIAD-99-5 (Washington, D.C.: Mar. 29, 1999); *Medical Readiness: Safety and Efficacy of the Anthrax Vaccine*, GAO/T-NSIAD-99-148 (Washington, D.C.: Apr. 29, 1999); *Contract Management: Observations on DOD's Financial Relationship with the Anthrax Vaccine Manufacturer*, GAO/T-NSIAD-99-214 (Washington, D.C.: June 30, 1999); *Medical Readiness: Issues Concerning the Anthrax Vaccine*, GAO/T-NSIAD-99-226 (Washington, D.C.: July 21, 1999); *Anthrax Vaccine: Safety and Efficacy Issues*, GAO/T-NSIAD-00-48 (Washington, D.C.: Oct. 12, 1999); *Medical Readiness: DOD Faces Challenges in Implementing Its Anthrax Vaccine Immunization Program*, GAO/NSIAD-00-36 (Washington, D.C.: Oct. 22, 1999); *Medical Readiness: DOD Continues to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program*, GAO/T-NSIAD-00-157 (Washington, D.C.: Apr. 13, 2000); *State Department: Serious Problems in the Anthrax Vaccine Immunization Program*, GAO-01-21, (Washington, D.C.: Dec. 13, 2000); *Anthrax Vaccine: Changes to the Manufacturing Process*, GAO-02-181T (Washington, D.C.: Oct. 23, 2001); *Anthrax Vaccine: GAO's Survey of Guard and Reserve Pilots and Aircrew*, GAO-02-445 (Washington, D.C.: Sept. 20, 2002).

responsibility for coordinating federal responses to national incidents of chemical, biological, radiological, and nuclear material release.

The President's 2006 federal budget includes $1.8 billion allocated to the National Institutes of Health (NIH) to fund biodefense research and development activities, which includes the development of new and improved medical countermeasures. Additionally, under Project Bioshield, a discretionary reserve fund of $5.6 billion has been allocated to procure medical countermeasures for the Strategic National Stockpile (SNS) through fiscal year 2013.[2]

To respond to your request, we interviewed officials from federal agencies—HHS, including the Food and Drug Administration (FDA); the Centers for Disease Control and Prevention (CDC); the National Institute of Allergy and Infectious Disease (NIAID); DHS, and DOD. In addition, we reviewed documents provided by these agencies as well as those provided by the United States Postal Services (USPS). We visited and interviewed the officials of the company that is developing the new anthrax vaccine. Finally, we reviewed scientific literature on this issue. We conducted our review from March 2006 to April 2006 in accordance with generally accepted government auditing standards.

In today's testimony, I will specifically report on (1) the problems we identified with the anthrax detection methods and the licensed anthrax vaccine, (2) recommendations we made, (3) the extent to which federal agencies have taken corrective actions, and (4) what remains to be done.

Results in Brief

With regard to anthrax detection methods, federal agencies responsible for responding to the 2001 anthrax incidents adopted a targeted sampling strategy that they based on their best judgment at the time. When the level of contamination is extremely high and dispersed in a facility, the method of sampling (for example, using wipes versus swabs) may not be critical, if the purpose is to find some contaminant. However, at lower levels, away of interpreting negative results is needed, and this requirement emphasizes the importance of the validation of the methods and the need for statistically based sampling strategies.

[2]The SNS is a national repository of medical countermeasures, such as antibiotics and vaccines. It is designed to supplement and resupply state and local public health agencies in the event of a national emergency anywhere and anytime within the United States or its territories.

Therefore, it is necessary to invest in empirical studies so as to develop a probability-based sampling strategy that will account for the complex geometry and surface types of many facilities. Using a probability-based sampling strategy, together with validated methods for detecting contamination, would provide a known level of confidence with which to interpret any negative results and would thus enable agencies to be more definitive in determining necessary actions.

The lack of validated methods for assessing contamination in postal facilities in 2001 impeded the agencies in responding to the incidents. The significance of the lack of validated methods was exemplified in the case of one postal facility where negative preliminary results were obtained by field-based methods of analysis, with limitations that appear to have been not well understood by some agencies.

Given the lack of validated methods for detecting anthrax contamination in facilities, we recommended that the Secretary of Homeland Security develop a coordinated approach to (1) improve the overall process for detecting anthrax and (2) increase confidence in negative test results generated by that process. This approach would include working with agencies to ensure that appropriate validation studies of the overall process of sampling activities, including the methods, are conducted. Specifically, we recommended that the Secretary

1. take a lead role in promoting and coordinating the activities of the various agencies that have the technical expertise related to environmental testing;

2. ensure that a definition of validation is developed and agreed on;

3. guarantee that the overall process of sampling activities, including methods, is validated so that performance characteristics, including limitations, are clearly understood and results can be correctly interpreted;

4. see that appropriate investments are made in empirical studies to develop probability-based sampling strategies that take into account the complexities of indoor environments;

5. ensure that appropriate, prioritized investments are made for all biothreat agents; and

6. ensure that agency policies, procedures, and guidelines reflect the results of such efforts.

When we issued our report, CDC, DHS, and USPS agreed with our conclusion—that methods for detecting anthrax contamination in facilities were not validated—and with the thrust of our recommendations—calling for a coordinated, systematic effort to validate the methods to be used for such testing, but they (1) disagreed with or expressed concern about our conclusions or the recommendation dealing with targeted versus probability sampling, (2) emphasized that validated testing methods for anthrax were not available in 2001 and that federal and state organizations did the best they could under the circumstances, and (3) identified factors or issues that need to be considered in validating testing methods.

In addition, uncertainty over which agency would take the lead role in improving the overall process for detecting anthrax, and how studies were to be funded, continued after the release of our report. DHS stated that while it has overall responsibility for coordinating the federal response during future biological attacks, the Environmental Protection Agency (EPA) had the "primary responsibility for establishing the strategies, guidelines, and plans for the recovery from a biological attack" while HHS had the lead role for any related public health response and guidelines. DHS also stated that it coordinated regularly with EPA's National Homeland Research Center to exchange information on research needs and to discuss priorities and gaps for a wide range of security-related research areas. DHS stated that it would coordinate with EPA to ensure that appropriate investments were made to explore improved sampling. Consequently, it was unclear how DHS could ensure that appropriate prioritized investments were made for all biothreat agents, with respect to agencies other than EPA, and how such priorities and gaps would be addressed.

Although in the past there had been confusion as to which federal agency would take the lead, as well as the responsibility for ensuring that our recommendations are addressed, DHS is now accepting responsibility. On May 3, 2006, DHS told us that DHS recognizes that it is the principal agency responsible for coordinating the federal response and would be responsible for ensuring that sampling methods, including the process, are validated. DHS also would work toward developing a probability-based sampling strategy.

While actions taken by DHS are steps in the right direction, DHS needs to develop a formal strategic plan that includes a "roadmap" outlining how individual agency efforts would lead to (1) validation of the overall process of sampling activities, including the methods, and (2) development

of a probability-based sampling strategy that takes into account the complexity of indoor environments.

With regard to the licensed anthrax vaccine, we identified a number of problems, including, among others, greater understanding of

1. the need for a six-shot regimen and annual booster shots;
2. the long-term and short-term safety of the vaccine, including gender differences; and
3. the vaccine's efficacy.

In addition, we provided information on the disadvantages of the licensed anthrax vaccine and the status of federal efforts to develop an improved vaccine. Given these problems, and taking into account promising early DOD research into an alternative, recombinant protective antigen (rPA) vaccine for anthrax, we recommended the development of a second-generation vaccine, based on this technology.

In September 2002 and September 2003, NIAID awarded contracts to develop a new rPA vaccine against inhalation anthrax. These contracts to develop and test candidate rPA vaccines included the requirement to evaluate safety, efficacy, and a potential provider's manufacturing capability to achieve eventual licensing from FDA.

The objectives in these two NIAID contracts addressed some of the problems we identified with the licensed vaccine, including requiring a recombinant vaccine to address issues of purity, potency, and manufacturing consistency; the need for fewer doses for the civilian population; and the capability for postexposure use. However, studies on gender differences and long-term safety were not explicitly required.

In November 2004, in the first contract under Project Bioshield, HHS awarded a contract for $877.5 million for the manufacture and delivery of 75 million doses of rPA anthrax vaccine for SNS. In the production contract's RFP, HHS stated that the urgent nature of the current threat required an accelerated pace of development, testing, approval, and procurement of the vaccine. While developing vaccine is known to be difficult and highly likely to encounter testing and production issues, even in the best of circumstances, early development work to ensure safety of the vaccine and a solid large-scale manufacturing capability had not been completed before awarding the full procurement contract. Additionally,

the contract milestones leave little to no provision for slippage and, being a fixed-price contract, if there is an unexpected slip in schedule, the financial burden will be fully on the contractor. While the government should not pay out money to a contractor unless and until it has met the terms of its contract, contractors that do not have the resources to assume such risk will not be able to meet the contract requirements, thus limiting the pool of companies that are capable of meeting the nation's needs.

While the government should be a tough negotiator when contracting for major procurements, it is important to understand the unique issues at stake in this early phase of implementing the U.S. biodefense strategy. Failure of this initial Project Bioshield contract could have an impact on how the biotechnology industry responds to government overtures in the future for the development and procurement of medical countermeasures for the many biothreat agents still to be addressed.

Background

The History and Nature of Anthrax and the Anthrax Vaccine

Anthrax is an acute infectious disease caused by the spore-forming bacterium Bacillus anthracis. It can infect humans but occurs most commonly in warm-blooded animals (herbivores) in the agricultural regions of the countries that have less standardized and less effective public health programs. Human anthrax occurs only rarely in the United States from natural causes. However, the anthrax attacks in October 2001 through contaminated mail resulted in the death of five persons.

Human infection normally results from an occupational exposure to infected animals or animal products. For example, workers may be exposed to dead animals or to products such as wool, hides, leather, or hair products (especially goat hair). Since there have been no reports, even now, of the disease spreading from person to person, anthrax is most likely not spread in humans directly.

Anthrax infection can occur in three forms: (1) cutaneous, usually through a cut or an abrasion; (2) gastrointestinal, by ingesting contaminated meat; and (3) inhalation, by breathing anthrax spores into the lungs. Symptoms depend on how the disease is contracted but usually appear within 7 days. The disease can be treated with antibiotics: tetracycline and doxycycline are preferred, but penicillin, erythromycin, chloramphenicol, or ciprofloxacin can also be used. To be effective, treatment should be started early.

The original anthrax vaccine in the United States was developed by George Wright and others in the 1950s and was first produced on a large scale by the pharmaceutical manufacturer Merck Sharp & Dohme.[3] A 1962 clinical study that evaluated the safety and effectiveness of the Merck vaccine in mill workers formed the basis for the subsequent licensing of a modified vaccine in 1970.[4] The Division of Biologics of the National Institutes of Health issued the original license for anthrax vaccine to the Michigan Department of Public Health.[5] In 1995, the facility changed its name to Michigan Biologic Products Institute. In 1998, the facility was sold, and its name was changed to BioPort Corporation.

Anthrax Vaccine and the Federal Role

As the lead agency for public health and medical response to manmade or natural disasters, HHS has the responsibility for developing, licensing, procuring, and storing medical countermeasures, which includes vaccines, for SNS. In 2002, HHS established the Office for Public Health Emergency Preparedness (OPHEP) with responsibility for implementing HHS's strategy for protecting civilians from bioterrorism and other public health emergencies. OPHEP coordinates transitions between NIH medical countermeasures development, FDA approval and licensing, and CDC storage and maintenance within SNS.

Within NIH, NIAID is the lead agency for early candidate research and development for medical countermeasures for biodefense. NIAID issues grants and contracts for research on medical countermeasures exploration and early development but has no responsibility in taking research forward into marketable products. Within OPHEP, the Office of Research and Development Coordination (ORDC) has the primary responsibility for contracting with industry for the large-scale manufacturing of licensable products, including vaccines, for delivery into SNS. Distinct from development contracts, ORDC production contracts typically require the submission of a formal request for FDA product licensing, license supplements, long-term maintenance of the stockpiled products, and a long-term manufacturing base to continue replenishing the stockpile as product expires.

[3]Merck Sharp & Dhome is a subsidiary of Merck & Co., Inc.

[4]Anthrax infection has occurred most commonly in settings like wool mills, where workers may be exposed to infected animal products.

[5]Before FDA was established as the licensing authority for vaccines, NIH performed that function.

Through the Center for Biologics Evaluation and Research (CBER), FDA licenses biological products, which include vaccines, and the facilities they are produced in. Manufacturers are required to comply with current good manufacturing practices regulations, which regulate personnel, buildings, equipment, production controls, records, and other aspects of the vaccine manufacturing process.[6]

The Characteristics and Development of Vaccines

Vaccines have three distinguishing features that contrast with those of chemical drugs. First, either they have no clearly chemically defined composition or simple chemical analysis is insufficient for their effective characterization. Second, they are properly evaluated, qualitatively or quantitatively, usually by measuring their effects in the living organism. Third, quality can be guaranteed not from final tests on random samples but only from a combination of in-process tests, end-product tests, and strict controls of the entire manufacturing process.

The quality of a vaccine is closely linked to its manufacturing process, which must be rigorously controlled to ensure that batches of vaccines produced at different times are reproducible and consistent in quality. In general, quality is achieved by applying the current good manufacturing practice. This process is not static but involves manufacturers and regulators in continuing assessment and upgrades as scientific progress, technical development, and experience help identify deficiencies and make improvements possible. Such principles also apply to the manufacturing facilities and equipment. Accordingly, vaccine production is very highly regulated to ensure that the products are consistent in quality and safe and effective for the purposes for which regulatory approval was granted.

The development of a vaccine is similar to the development of drugs and other immunizing agents. A sponsor who has developed a candidate vaccine and wishes to begin clinical trials with human subjects must submit an investigational new drug (IND) application to FDA.[7] This starts

[6]The regulations embody a set of scientifically sound methods, practices, or principles that are implemented and documented during development and production to ensure the consistent manufacture of safe, pure, and potent products. Such principles apply to the manufacturing process as well as to the facilities products are manufactured in. (21 C.F.R., parts 600 through 680.)

[7]An IND application is a request for authorization from FDA to administer an investigational drug or biological product to humans.

an official oversight process of formal studies, regulated by CBER within FDA, typically composed of three phases of clinical trials involving an increasing number of human subjects.[8] Phase 1 trials are safety and immunogenicity studies performed in 20 to 100 healthy, volunteer subjects. Phase 2 studies, which may involve hundreds of subjects, take an in-depth look at the effectiveness of the drug and may include analysis of dose ranges and dose regimens. Finally, Phase 3 trials typically involve thousands of individuals and provide the documentation of effectiveness and important additional safety data required for licensing. At any stage of the clinical or animal studies, if the data raise significant concerns about either safety or effectiveness, FDA may request additional information or studies or may halt ongoing clinical studies. Clinical trials typically last 6 years.

After successful completion of all three phases, the sponsor submits a biologics license application for FDA's review and approval. The proposed manufacturing facility is inspected during this stage, and production of the vaccine as it is in progress is examined in detail. This FDA review process can take several years, depending on the product.

To ensure continuing safety, FDA oversees the manufacturing process for as long as the manufacturer holds a license for the product. According to industry sources, the challenge in scaling up vaccine production from a research laboratory to a large manufacturing environment while still maintaining quality requires much skill, sophisticated facilities, and a great deal of experience.

Anthrax Detection in Postal Facilities and the Federal Role

The federal agencies involved in the response in the postal facilities had differing responsibilities. CDC and state and local health departments primarily provided public health advice and assistance to USPS. CDC has had primary responsibility for national surveillance of specific diseases, including anthrax; it has also conducted epidemiologic investigations to determine, among other things, the source of the disease. The Federal Bureau of Investigation (FBI) has been responsible for criminal

[8]In May 2002, FDA published *Approval of Biological Products When Human Efficacy Studies Are Not Ethical or Feasible* (21 C.F.R. 601, Subpart H, as well as 21 C.F.R. 314, Subpart I for New Drugs). This rule, known as the "Animal Rule," permits the substitution of animal studies for human trials where human efficacy studies are not ethical and field trials are not feasible, provided a scientifically valid animal model for the disease exists. This rule does not obviate the need for safety data, which must still be established.

investigations involving interstate commerce and the mail and crimes committed on federal property. EPA has been the nation's lead agency for responding to a release of hazardous substances into the environment.

Responding to health emergencies, including bioterrorist attacks, is generally a local responsibility, but localities could and did request CDC's assistance in fall 2001. CDC performed the tests needed to confirm cases of anthrax and analyzed the substances in the two contaminated letters recovered in New York City. The Agency for Toxic Substances and Disease Registry and the National Institute for Occupational Safety and Health within CDC helped USPS conduct environmental tests of some of its facilities and advised USPS on its facilities' decontamination.

USAMRIID has conducted basic and applied research in the diagnosis, treatment, and prevention of hazardous infectious diseases for the military. It analyzed some environmental samples from postal facilities. It also performed detailed analyses, for the FBI, of anthrax spores in the letters addressed to Senators Tom Daschle and Patrick Leahy. The Occupational Safety and Health Administration, responsible for employee health and safety issues, provided technical assistance and guidance to USPS on the decontamination of postal facilities.

The response to the incident in the American Media Incorporated building in Florida in September 2001 led to the identification of mail as the potential source of contamination; eventually, it led to the sampling of the postal facilities. The agencies began sampling on October 12, 2001, in Florida and stopped on April 21, 2002, when the Wallingford, Connecticut, facility was sampled for the last time.

On October 8, 2001, the President created the Office of Homeland Security to develop and coordinate a comprehensive national strategy for dealing with domestic terrorist threats or attacks. The office, which had limited involvement in the 2001 response, was superseded by the Homeland Security Act of 2002, which transferred many of its functions to DHS. DHS, which became operational in 2003, was created by combining many previously separate agencies. It is assigned the lead role in coordinating the efforts of federal agencies that respond to acts of terrorism in the United States.

Agency Sampling Detection Methods Were Not Validated

As you know, the agencies that sampled postal facilities in 2001—USPS, CDC, and EPA—did not use validated sample collection and analysis methods to perform their tests. According to these agencies, validated methods were not available at that time. They conducted several interdependent activities, including sample strategy development, followed by sample collection, transportation, and analysis of the samples to detect anthrax. Neither these activities nor the overall process had been validated for anthrax testing.

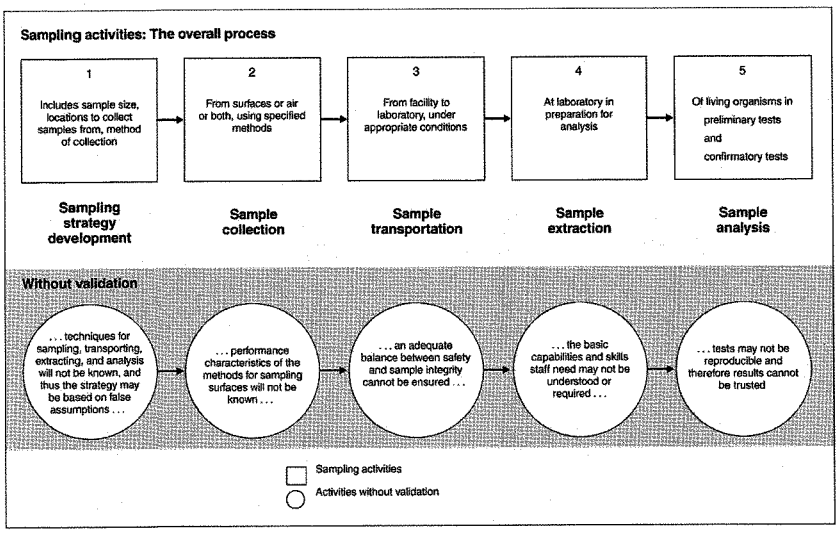
Validation is a formal, empirical process in which an authority determines and certifies the performance characteristics of a given method. Therefore, investments are also needed to validate these methods, as well as the overall anthrax detection process. Validating the overall process is important because operational and health-related decisions are made on the basis of testing results that the process generates.

CDC and USPS officials said that they used targeted sampling; that is, they collected samples from specific areas considered—based on agencies' technical judgments—more likely to be contaminated. Such judgments can be effective in some situations, for example, in determining the source of contamination in a disease outbreak investigation, provided results are positive. However, if the results are negative, the basic question—Is this building contaminated?—cannot be answered with statistical confidence.

When the level of contamination is extremely high and dispersed in a facility, the method of sampling (for example, wipes versus swabs) may not be as critical if the purpose is to find some contaminant. However, at lower levels, a way of interpreting negative results is needed, and this requirement emphasizes the importance of the validation of the methods and the need for statistically based sampling strategies. This emphasizes the need for methods that have been validated and sampling strategies that are likely to find contamination at low levels. Probability-based sampling does allow conclusions at specific levels of confidence about testing results.

Using a probability-based sampling strategy, together with validated methods for detecting contamination, would provide a known level of confidence with which to interpret any negative results. This would allow agencies to be more definitive in determining necessary actions. Figure 1 shows how lack of validation could affect individual activities—which include the sampling strategy—as well as the results generated by the overall process.

Figure 1: Lack of Validation Can Affect Individual Activities and the Overall Process



Source: GAO analysis of CDC, EPA, and USPS data.

The lack of validated methods for assessing contamination in postal facilities impeded the agencies in responding to the incidents. The significance of the lack of validated methods was exemplified in the case of the one postal facility, where negative preliminary results were obtained by field-based methods of analysis, with limitations that appear to have been not well understood by some agencies. Negative results do not necessarily mean a facility is free from contamination. As we reported, results can be negative if (1) samples were not collected from places where anthrax was present, (2) the detection limit of the method was greater than the actual contamination level, (3) not enough samples were recovered from the sample material, (5) analysis of the sample extract did not detect spores, or (6) anthrax was not present in the facility.

Given the lack of validated methods for detecting anthrax contamination in facilities, we recommended that the Secretary of Homeland Security develop a coordinated approach to (1) improve the overall process for detecting anthrax and (2) increase confidence in negative test results generated by that process. This approach would include working with agencies to ensure that appropriate validation studies of the overall process of sampling activities, including the methods, are conducted. Specifically, we recommended that the Secretary

1. take a lead role in promoting and coordinating the activities of the various agencies that have the technical expertise related to environmental testing;

2. ensure that a definition of validation is developed and agreed on;

3. guarantee that the overall process of sampling activities, including methods, is validated so that performance characteristics, including limitations, are clearly understood and results can be correctly interpreted;

4. see that appropriate investments are made in empirical studies to develop probability-based sampling strategies that take into account the complexities of indoor environments.

When we issued our report, CDC, DHS, and USPS agreed with our conclusion—that methods for detecting anthrax contamination in facilities were not validated—and with the thrust of our recommendations—calling for a coordinated, systematic effort to validate the methods to be used for such testing, but they (1) disagreed with or expressed concern about our conclusions or the recommendation dealing with targeted versus probability sampling, (2) emphasized that validated testing methods for anthrax were not available in 2001 and that federal and state organizations did the best they could under the circumstances, and (3) identified factors or issues that need to be considered in validating testing methods.

Also, at that time, uncertainty over which agency would take the lead role in improving the overall process for detecting anthrax, and how studies were to be funded, continued after our report was released. DHS stated that while it has overall responsibility for coordinating the federal response during future biological attacks, EPA had the "primary responsibility for establishing the strategies, guidelines, and plans for the recovery from a biological attack" while HHS had the lead role for any related public health response and guidelines. DHS also stated that it

coordinated regularly with EPA's National Homeland Research Center to exchange information on research needs and to discuss priorities and gaps for a wide range of security-related research areas. DHS stated that it would coordinate with EPA to ensure that appropriate investments were made to explore improved sampling. Consequently, it was unclear how DHS could ensure that appropriate prioritized investments were made for all biothreat agents, with respect to agencies other than EPA, and how such priorities and gaps would be addressed.

DHS Has Taken Some Actions to Implement Our Recommendations on the Validation of Sampling Methods and Strategies

Concerning our recommendation about probability-based sampling strategies, DHS said that it first wanted to develop sampling requirements and then evaluate both targeted and probability-based sampling against those requirements. While CDC and USPS stated that they agreed with the importance of using validated testing methods, they raised various concerns about our discussion of targeted versus probability-based sampling.

DHS formally responded to our recommendations on September 19, 2005, stating that it agreed with them and was taking several actions to address them. These actions included working with agencies through interagency memorandums of understanding, interagency committees, working groups, and collaborations, with various federal agencies such as HHS and EPA. In particular, a memorandum of understanding for coordinating and monitoring biological threat agents among DHS, DOD, HHS, USPS, and the Department of Justice was signed on May 9, 2005. Another involved several agencies—DOD, EPA, HHS, Justice, and the Department of Agriculture, to name a few—and was to establish an integrated consortium of laboratory networks. Also, in fiscal year 2005, DHS said it was to standardize and validate the method by which hazardous materials technicians (for example, first responders) collect, transport, and store suspicious powder samples.

In preparation for this testimony, we asked USPS, CDC, DHS, and EPA for comments regarding actions they have taken to implement our recommendations. EPA did not provide us comments. Comments from USPS, CDC, and DHS are summarized below.

USPS, on April 24, 2006, reported to us that it has been assisting DHS to implement our recommendations. DHS has asked USPS to become part of a subject matter expert team as a result of the real-world experience gained during the 2001 anthrax attacks and the subsequent response,

clean-up, and remediation efforts at a number of mail processing facilities and post offices. (For more on USPS's actions, see app. I.)

CDC, on May 5, 2006, told us it is taking steps we believe are in the right direction. CDC officials told us that CDC has not changed its position on using targeted sampling as its primary strategy for initial response sampling but is exploring probability-based sampling to augment this approach. CDC officials told us that CDC has also developed a program to expand its microbiology objectives; the program's focus areas include plans for evaluating priority biothreat agents, including anthrax, in a variety of media. Further, CDC told us it has completed or has ongoing studies on the recovery of Bacillus anthracis spores from various types of surfaces. (More on CDC's actions is in app. II.)

On May 3, 2006, DHS stated that it

> "concurs with the GAO that use of stratified and probabilistic sampling strategies, together with validated methods for detecting contamination, would provide a known level of confidence with which to interpret any negative results and would thus enable agencies to be more definitive in determining necessary actions."

DHS reported to us several actions it had taken toward implementing the recommendations. (For more on DHS's actions, see app. III.)

While we believe that DHS's individual actions are in the right direction, DHS needs to develop a formal strategic plan that includes a "roadmap" outlining how individual agencies' efforts would lead to (1) the validation of the overall process of sampling activities, including methods, and (2) the development of a probability-based sampling strategy that takes into account the complexities of indoor environments. Such a plan would assist DHS in monitoring progress and measuring agency performance toward improving the detection of anthrax and other prioritized threat agents.

The Licensed Anthrax Vaccine Had Several Limitations

Starting in 1999, we identified a number of problems with the licensed anthrax vaccine. These included, among others, (1) the need for a six-shot regimen and annual booster shots; (2) questions about the long-term and short-term safety of the vaccine, including how safety is affected by gender differences; and (3) uncertainty about the vaccine's efficacy. In addition, we provided information on the disadvantages of the licensed vaccine and the status of federal efforts to develop an improved anthrax vaccine.

The dosing regimen, or protocol, for the licensed anthrax vaccine calls for a series of six shots over 18 months. An initial series of three shots is given at 2-week intervals, followed by a series of three shots at 6-month intervals. Annual boosters are required thereafter. The required six-dose schedule and annual boosters complicate the logistics and increase the cost of vaccination. At the time of our earlier reports, no studies had been done on the optimum dosing regimen. Recently, however, CDC has begun conducting studies to determine the feasibility of a three-dose schedule. FDA would have to review and approve any change in product labeling.[9]

The long-term safety of the licensed vaccine has not been studied. Data on the prevalence and duration of short-term reactions to the vaccine are limited but suggest that women experience a higher rate of adverse reactions, both local and systemic, than men do.

Before the vaccine was licensed, a study on the efficacy of the original vaccine concluded that it provided protection to humans against cutaneous anthrax. In the 1980s, DOD began testing the efficacy of the licensed vaccine on animals, focusing on its protection against inhalation anthrax. DOD's studies, while showing some positive results, may not be extrapolated to humans until serologic correlates of immunity in an animal model that can be applied to humans are established.

According to researchers and the Institute of Medicine of the National Academy of Sciences, the licensed anthrax vaccine has several additional disadvantages.[10] The amount of protective antigen in the vaccine varies from lot to lot, because the manufacturing process cannot precisely quantify the antigen.[11] Also, there is some evidence that the current anthrax vaccine may have diminished efficacy against certain virulent strains of anthrax.

The licensed vaccine has been given primarily to military personnel. DOD, however, has a unique set of requirements, as it has a narrow, relatively

[9]CDC is conducting a wide range of anthrax vaccine research activities, including ensuring the vaccine's safety while minimizing the number of doses.

[10]P. S. Brachman and A. Friedlander, "Anthrax," in *Vaccines*, eds. S. A. Plotkin and E. A. Mortimer Jr. (Philadelphia: W. B. Saunders Company, 1994), p. 737, and Institute of Medicine, *Chemical and Biological Terrorism: Research and Development to Improve Civilian Medical Response* (Washington, D.C.: National Academy Press, 1999), p. 135.

[11]Institute of Medicine, *Chemical and Biological Terrorism*, p. 135.

young, healthy, and homogenous, target population. This reduces many problems, although not all, as in the case of reactogenicity by gender. DOD requirements also assume a continuous threat for which they require preexposure immunization. Civilian populations, in contrast, are much more diverse than military populations, and immunization of civilians would likely be difficult to justify, based on the available bio-threat assessments.

HHS Has Taken Steps to Fund the Development of a Second-Generation Anthrax Vaccine

In the late 1980s, DOD research identified a second-generation recombinant protective antigen (rPA) anthrax vaccine, created with a process that is fully defined, quantified, and controlled in terms of protective antigen; that can be developed; and that requires fewer doses.[12] DOD research also showed that an rPA anthrax vaccine could be created with modern techniques to produce highly purified protective antigen. This process not only would remove unwanted bacterial proteins but would also enable precise amounts of the purified protective antigen to be incorporated into the vaccine. A further potential benefit was that compared to the current vaccine, the protective antigen could be produced in a nonspore-forming organism. As a result, according to DOD officials, manufacturers could use their buildings and equipment to produce the anthrax vaccine as well as other vaccines.

In 1995, the USAMRIID developed a pilot lot of a new rPA vaccine against anthrax. It has been tested successfully in experiments using animals but has not been tested on humans. USAMRIID officials stated that this testing would take about 3 years; FDA approval of the manufacturing could take years longer. In 1999, DOD considered further development of this vaccine an unfunded requirement. In response to the perceived threat of bioterrorism, HHS's NIAID formed a working group to develop and test a second-generation anthrax vaccine and, accordingly, funded several active research grants.

[12]B. Ivins and others, "Immunization Studies with Attenuated Strains of *Bacillus anthracis*," *Journal of Infection and Immunity* 52 (1986): 454–58; B. E. Ivins, "The Search for a New-Generation Human Anthrax Vaccine," *Clinical Immunology Newsletter* 9 (1988): 30–32; and Y. Singh and others, "Study of Immunization against Anthrax with the Purified Recombinant Protective Antigen of *Bacillus anthracis*," *Journal of Infection and Immunity* 66 (1998): 3447–48.

In September 2002 and September 2003, NIAID awarded contracts to develop a new rPA vaccine effective against inhalation anthrax.[13] The contracts were for developing and testing candidate vaccines, with a requirement for evaluating safety, efficacy, and a potential provider's capability for manufacturing the vaccine and achieving FDA licensing. The contracts—for $13.6 million in 2002 and $80.3 million in 2003—were awarded to VaxGen Inc., a California-based biopharmaceutical company.[14]

The 2002 RFP called for developing, manufacturing, characterizing, and evaluating pilot lots of an rPA anthrax vaccine developed under conditions necessary to support the product's use as an investigational new drug. The 2003 RFP built on the 2002 work and was to further develop a vaccine candidate suitable for commercial-scale manufacturing that demonstrated safety and immunogenicity in clinical and animal studies.

The stated objectives in these two RFPs addressed some of the problems we identified with the licensed vaccine, including our recommendation. First, they required the development of a recombinant vaccine. As noted, DOD research showed that modern recombinant techniques could produce a vaccine that would contain highly purified and precise amounts of protective antigen, thereby reducing lot-to-lot variation, whose disadvantage was noted with the licensed anthrax vaccine.

Second, as we reported, the six-dose, 18-month immunization regimen, followed by annual booster shots, was problematic. In the 2002 RFP, NIAID required that the rPA candidate vaccines be administered in not more than three doses.

We also reported that the long-term safety of the licensed vaccine had not been studied and that data on short-term reactions, although limited, suggested that women experience a higher rate of adverse reactions, both local and systemic, than men do. NIAID requirements in the two development RFPs included Phase I and Phase II clinical trials to evaluate short-term safety, but neither RFP included analysis of gender differences. In discussions with company officials, however, VaxGen has stated that it

[13]The RFP for the 2002 contract was NIH-NIAID-DMID-02-26; for the 2003 contract, NIH-NIAID-DMID-03-29.

[14]For the 2002 RFP, two awards totaling $22.5 million were given—$13.6 million to VaxGen and $8.9 million to Avecia Ltd. of Manchester, England.

included both male and female subjects in its clinical trials and is examining this issue.

An issue that remains outstanding, however, is that long-term safety studies have not been conducted or required before making awards for full procurement.

We also found that because terrorist events would be likely to occur with little or no warning, postexposure immunization capability would be beneficial. A stated objective in the 2002 RFP was to investigate candidate vaccines that would provide protection when administered both before exposure and in a postexposure immunization regimen, when combined with antibiotics.

NIAID has taken steps to anticipate downstream, large-scale manufacturing issues by requiring a feasibility plan for the manufacture and delivery of 25 million doses in the 2002 contract and, in the 2003 contract, the actual delivery of 3 million to 5 million doses of rPA anthrax vaccine from at least three consistency lots, following good manufacturing practices. The 2003 RFP also included objectives to develop and validate product release and characterization criteria to support eventual submission to FDA for licensing.

HHS's Procurement Strategy Is Very Aggressive

In November 2004, in the first contract under Project Bioshield, ORDC awarded VaxGen a contract for $877.5 million for the manufacture and delivery of 75 million doses of rPA anthrax vaccine in prefilled syringes for SNS. Among other things, the contract requires VaxGen to obtain FDA licensure for both preexposure use and postexposure use with antibiotics, and the initiation and completion of special population clinical trials, including pediatric and geriatric populations.

In the RFP for the contract, ORDC stated that the urgent nature of the current threat required an accelerated pace of development, testing, approval, and procurement of the vaccine and anticipated that it would have to be administered under a "contingency use"

IND protocol, held by CDC, if needed, prior to licensure by FDA. However, the RFP also specified that all vaccine manufactured and acquired under the contract must meet the regulatory deliverables as required for licensure.

The normal schedule for taking a vaccine from preclinical studies to licensure varies, depending on what is known about both the specific nature of the infectious disease and the planned application of the vaccine in terms of when and on whom the vaccine is to be used. These factors can prolong the development of a vaccine as long as 15 years (for civilian use) or as short as 8 years (for military use). Because of the U.S. government's stated need for a vaccine that can counter a domestic biothreat against civilian populations, HHS has undertaken an aggressive procurement of a vaccine on a very short schedule.

The NIAID development and test contracts, whose purpose was presumably to aid in making the best procurement award decision, are not yet completed and, in fact, overlap to a great degree with the procurement contract. At the time the full procurement contract was awarded in November 2004, the initial 2002 development contract to study the basic safety and immunogenicity of candidate vaccines was still ongoing, and the 2003 contract was only part way through Phase II clinical trials. In fact, today, neither the 2002 nor the 2003 contract—intended to ensure a candidate vaccine with appropriate characteristics and a provider's manufacturing capability sufficient for licensing and successful delivery—has yet been completed, only 6 months before first delivery of 25 million doses of SNS-ready product is required. HHS officials acknowledge that the procurement contract's milestones are very aggressive and agree that the contract contains little to no provision for slippage. Additionally, the procurement contract is fixed-price and specifies that no payment will be made before delivery. The financial burden is fully on the contractor should additional costs arise because of an unexpected slip in schedule.

In conclusion, a contract schedule with no margin for error, especially for vaccine development, which is known to be risky, is not conducive to building confidence that a vaccine will be available for use within the arbitrarily defined time period. While the government should not pay out money to a contractor unless and until it has met the terms of its contract, contractors that do not have the resources to assume such risk will not be able to meet the contract requirements, thus limiting the pool of companies that are capable of meeting the nation's needs.

While the government should be a tough negotiator when contracting for major procurements, it is important to understand the unique issues at stake in this early phase of implementation of the biodefense strategy. The rest of the biotechnology sector will be watching to see whether the industry and the U.S. government can make this partnership work. Issues with this contract might have an effect beyond just this individual vaccine

procurement. They could have an impact on how the biotechnology industry responds to government overtures in the future for the development and procurement of medical countermeasures for the many biothreat agents still to be addressed.

Mr. Chairman, this concludes my prepared remarks. I would be happy to respond to any questions that you or other members of the subcommittee may have at this time.

Contacts and Acknowledgments

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Abbreviations

AVA	anthrax vaccine adsorbed
AVRP	Anthrax Vaccine Research Program
AVST	Anthrax Vaccine Safety Team
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
DOD	Department of Defense
EPA	Environmental Protection Agency
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
IND	investigational new drug
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
OPHEP	Office for Public Health Emergency Preparedness
ORDC	Office of Research and Development Coordination
rPA	recombinant protective antigen
SDST	Subcommittee of Decontamination Standards Technology
SNS	Strategic National Stockpile
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USPS	United States Postal Service

Appendix I: United States Postal Service Initiatives

U.S. Postal Service (USPS) officials reported to us these activities in responding to our recommendations:

On the recommendation addressed to the Department of Homeland Security (DHS) to develop appropriate validation studies of various activities in detecting anthrax:

- USPS has been helping DHS implement that recommendation. It has been working with its federal partners to further examine existing biological coordination and protocol efforts, within the National Capital Region.
- USPS is also working with state and local public health departments by participating in several biological working groups chartered to help clarify and reduce variance in procedures and protocols and, per GAO's recommendations, to develop validation procedures to help ensure that biothreat test results are reliable and can be clearly understood and correctly interpreted.
- DHS has asked USPS to become part of a subject matter expert team as a result of the real-world experience USPS gained in the 2001 anthrax attacks, its response, and its cleanup and remediation efforts at a number of mail processing facilities and post offices.
- USPS was asked to help develop and implement the guidance as part of the National Capital Region BioWatch Advisory Council.

Appendix II: Centers for Disease Control and Prevention Initiatives

Centers for Disease Control and Prevention (CDC) officials reported information on their work on anthrax detection and anthrax vaccine. With respect to anthrax detection, CDC said it is developing a probabilistic sampling approach. This project will augment the targeted sampling approach that it uses for initial response sampling. CDC officials told us that CDC is "exploring the need for probability sampling in those instances when statistical inferences are necessary."

CDC has also developed a program that will expand its environmental microbiology objectives. This program has several focus areas. One is identifying priority agents, through sampling strategy development, sample collection, sample transportation, and sample analysis. Another is risk reduction activities, such as determining the risk of infection and evaluating techniques and procedures for reducing risk, including improving decontamination methods.

Further, CDC has completed studies and has studies in progress on the recovery of Bacillus anthracis spores from various types of surfaces using different collection methods, including macrofoam swabs, wipes, and HEPA vacuum. It also plans to study the survival rates of other biothreat agents on nonporous surfaces and to evaluate HEPA-vacuum samples for microbial analysis.

The National Immunization Program and the National Center for Infectious Diseases components of the proposed National Center for Immunization and Respiratory Diseases appreciated the opportunity to share information about the status of CDC's Anthrax Vaccine Research Program.

In 1999, CDC received funding to conduct studies of the safety and efficacy of the U.S. licensed anthrax vaccine—anthrax vaccine adsorbed (AVA). CDC's Anthrax Vaccine Research Program (AVRP) consists of a human clinical vaccine trial with quantitative primary serological endpoints, corroborative antibody functional analyses, and an immunological correlates of protection study in rhesus macaques.

The focus of AVRP is a large-scale, multicenter, Phase III human clinical trial with 1,564 participants. The study's objective is to optimize the use of AVA, the only licensed anthrax vaccine in the United States.[1] The study

[1]AVA, or BioThrax, is licensed to BioPort Corporation, Lansing, Michigan.

evaluates the potential for changing the route of administration, reducing the number of primary series vaccinations for the licensed vaccine, and improving the profile of side effects. A successful conclusion to the study will double the availability of AVA, increase vaccine acceptance and uptake because of a reduction in side effects, and provide animal study data demonstrating long-term protection against inhalation anthrax afforded by a priming series of three intramuscular injections.

Analysis of the human clinical trial serological and reactogenicity data at an intermediate stage in the study showed that it is possible to drop the dose at week two, change the route of administration to intramuscular, and reduce side effects without making an impact on antibody responses to a priming series of three injections. The interim report was submitted to the Food and Drug Administration (FDA) in February 2005, and subsequently the vaccine manufacturer filed a supplement to its biologics license application to add this new regimen.

The AVRP's remaining research goals are to confirm that two additional doses can be dropped from the priming series at 12 months and 18 months, thus moving to a three- injection intramuscular regimen; to adopt biennial rather than annual boosters; and to establish in nonhuman primate models the onset and duration of the protection of the three-dose intramuscular regimen (the "correlates of protection" study).

CDC's Anthrax Vaccine Safety Team (AVST) is conducting a wide range of anthrax vaccine safety research activities critical to accomplishing the objectives in CDC's 1999 congressional mandate. These activities' goals are to (1) address important anthrax vaccine safety questions, (2) build an infrastructure to ensure the anthrax vaccine's safety, (3) build a system to address concerns regarding vaccine safety and aid in resolving potential liability questions, and (4) optimize the vaccination schedule and the vaccine's administration to ensure its efficacy while minimizing the number of doses required, reducing the occurrence of adverse events, and maximizing the availability of the only licensed anthrax vaccine in the United States.

In collaboration with the Army Medical Surveillance Activity of the Department of Defense (DOD) and FDA, CDC established the Vaccine Analytic Unit in 2003 on the Walter Reed Army Medical Center Campus. It uses data from the Defense Medical Surveillance System to assess whether specific longer-term adverse events are associated with AVA and other biodefense vaccines; this system is a unique source of active surveillance data containing medical, vaccination, and deployment histories for U.S.

military personnel. The Vaccine Analytic Unit's research agenda for investigating potential AVA adverse events and an AVA study on optic neuritis are in press, and a multiple near-concurrent immunization study has been completed. Funded studies include evaluations of AVA and Stevens Johnson Syndrome/Toxic Epidermal Necrolysis, connective tissues diseases, diabetes mellitus, Guillain–Barré Syndrome, and atrial fibrillation

Studies to assess the possible effects of AVA on health-related quality of life and the role of hormones as the basis for adverse AVA events occurring more frequently in women are ongoing in participants of CDC's AVRP, begun in 2002 for administering AVA to workers occupationally at high risk for exposure to Bacillus anthracis. Also, AVST has ongoing collaborative research studies with CDC's Immunization Safety Office, FDA, and DOD to enhance AVA adverse event surveillance and improve AVA acceptability.

Appendix III: Department of Homeland Security Initiatives

Department of Homeland Security (DHS) officials reported the following activities to us in addressing our recommendations:

DHS has taken a lead role in promoting and coordinating the activities of various agencies that have technical expertise related to environmental testing. DHS

- led the formulation of a memorandum of understanding among DHS, DOD, the Department of Health and Human Services (HHS), and USPS on coordinated monitoring of biological threat agents and is leading the execution of the memorandum;
- is leading an effort to establish an Integrated Consortium on Laboratory Networks;
- has established a Federal Postal and Shipping Integrated Project Team;
- is co-chairing the Subcommittee of Decontamination Standards Technology (SDST);
- is co-sponsoring the Second (and First) National Conference on Environmental Sampling for Bio-Threat Agents.

DHS has adopted the International Quality Management Standard definition of validation.

DHS has developed a process to standardize and validate methods; it

- has validated a method for sampling suspicious powders and
- is developing a method for the validation of public health actionable assays.

DHS has invested in both targeted and probabilistic sampling strategies and in methodologies that are appropriate for monitoring facilities and that apply to wide-area and facility restoration. Its research and development efforts include

- performance characterization of three sampling methods on varied surfaces;
- developing the Building Restoration Operations Optimization Model;

- sponsoring the Visual Sample Module;
- developing Annotated Characterization and Clearance Sampling Plan Templates for preplanning the response to a biological facility attack;
- developing BioWatch Preparedness and Response Guidance, which includes Part III: BioWatch Environmental Sampling;
- developing native air sample collection strategies and protocols associated with transportation facilities.

DHS has prioritized investments for high-risk biological agents through internal and interagency coordination, to include

- SDST research and development investment strategy;
- agency-to-agency discussions on leveraging research and development opportunities;
- internal strategic planning and requirements generation.

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Mr. SHAYS. Thank you. We are going to start, Mr. Rhodes, with the professional staff asking questions.

Mr. RHODES. Fine.

Ms. FIORENTINO. Mr. Rhodes, why is it important DHS develops a formal strategic plan and roadmap for validating sample methods?

Mr. RHODES. Validation—there are two pieces. Verification is understanding whether you asked a question properly, and validation is understanding whether you asked the right question. If there is no roadmap, if there is no formal strategic plan, then there's no understanding of the methodology for validation, the sample sizes that are considered statistically acceptable, the acceptable probability analysis, the multiple factors associated with probability, the amount of money, resources, staff, and schedule associated with this.

If somebody says, for example, I am in charge and I am now responsible, but I have no plan, then you as the buyer or you as the overseer of that process have no understanding when you get anything. When do you get the answer to what question.

Ms. FIORENTINO. And do you know what DHS's response is to your suggestion about creating a strategic plan?

Mr. RHODES. They have said as recently as standing in the hallway out in front of the committee room that there is a document, there is a research and development plan, but it has not been finalized and it is now—it is being staffed throughout DHS, I'm assuming, as we speak. And that as soon as it is finished, we will get a copy of that for evaluation.

Ms. FIORENTINO. How long would you expect it to take to validate the overall sampling process?

Mr. RHODES. I can't really say what a timeframe would be. It's a function of the plan. I don't mean to be tautological here and talk in a circle, but without the plan itself, there's no way of understanding timeframes or methodologies that can be evaluated. I would assume, taking from my own experience in validating methods, that, given the right resources and the amount of materials necessary to do it, it could be done somewhere between 2 or 3 years. So it shouldn't take—this is not some continuous infinite cycle that we have to go through so long as adequate resources are applied, milestones are established, and response to basic methodology is understood.

Ms. FIORENTINO. How would you evaluate the steps the agencies have taken to address your recommendations in your GAO report?

Mr. RHODES. That, again, is going to be tied to the coordination from DHS out to the other departments and agencies. By DHS taking the role as the principal, one of the questions they have to answer is how does everyone else respond, how does everyone else answer the questions that are going to be laid out based on the DHS research methodology.

So there are two parts. There's evaluating the methodology itself, and then there's evaluating what everyone else does in relation to the methodology. Is the methodology comprehensive—Question 1. Question 2 is do the subsequent departments and agencies respond to the methodology properly; that is, do they put the resources against that methodology that DHS has asked for?

Ms. FIORENTINO. Your testimony states that, quote, GAO also reported that the anthrax vaccine has not been adequately tested on humans. No studies have been done to determine the optimum number of doses. The long-term safety has not been studied. And data on short-term reactions are limited. However, women report higher rates of reactions than do men.

What concerns do you have regarding the safety of the anthrax vaccine?

Mr. RHODES. The old—the current FDA licensed one?

Ms. FIORENTINO. Yes.

Mr. RHODES. In terms of the long-term safety, the problem is how is this vaccine safe relative to people. And there are concerns about the original vaccine being applied for inhalation anthrax when it was actually designed for mill workers. And it's been proven against cutaneous anthrax but there's too small a sample size to verify it relative to inhalation.

If you look at the 1962 Brachman study, you're looking at reactions that were relatively minor. The data on prevalence and duration of short-term reactions does suggest that women are more reactive than men. However, if you look at the DOD studies, the DOD studies are what are called passive studies; that is, they take in passive information from individuals as opposed to doing a more structured direct collection of data. So trying to understand the direct relationship between is it cellular, acellular, is it the adjuvant, is it the other material that's in the vaccine, those level of study haven't been done relative to safety. Regarding its efficacy, the studies haven't been done to verify either dose, in terms of the amount of vaccine that's given, and the number of shots that should be administered. And then there are questions on lot-to-lot consistency because of the actual design of the vaccine itself.

Ms. FIORENTINO. Thank you.

Mr. RHODES. Thank you.

Mr. SHAYS. Walk me through, if you would, the roles of DOD, HHS, DHS, EPA, and obviously, under the HHS, the Centers for Disease Control and Prevention. How do they all fit into these two areas of basically licensing of vaccines and the detection?

Mr. RHODES. In the area of detection, well, right now DHS is going to have the lead for coordinating all detection efforts in the civilian realm. So if there were a concern about this building, DHS would take the lead. EPA is the one that actually cleans the building up or oversees the cleaning up of the building. So DHS is going to be the one that initiates the emergency response plan. Then there's EPA that's actually going to clean the building up. CDC, as part of HHS, is going to be the one that says what the health implications are. DOD is sort of a self-contained entity over on one side taking care of its own locations and its own people.

Mr. SHAYS. But the technology—well, just on the detection part——

Mr. RHODES. Yes.

Mr. SHAYS [continuing]. Is basically universal, I mean, whether it is DOD or civilian. And tell me whose responsibility to determine and design and contract and design the vaccines?

Mr. RHODES. The vaccines?

Mr. SHAYS. Mm-hm.

Mr. RHODES. The vaccines——

Mr. SHAYS. I am sorry, not the vaccines.

Mr. RHODES. The detection methods?

Mr. SHAYS. Right.

Mr. RHODES. Detection methods are going to be in two tracks, as far as we understand it at this moment. There's the one for civilian environments.

Mr. SHAYS. And what Government agency?

Mr. RHODES. That's DHS. DHS will be the lead, coordinating with HHS, CDC, and EPA. And then there will be the Department of Defense.

Mr. SHAYS. But we are talking about a system, a process.

Mr. RHODES. Yes.

Mr. SHAYS. So DOD is in charge. And there is no doubt that they are in charge.

Mr. RHODES. They are in charge of their own detection efforts.

Mr. SHAYS. And DHS is in charge of all civilian, and there is no——

Mr. RHODES. Yes.

Mr. SHAYS. OK.

Mr. RHODES. So part of the DHS plan, strategic plan, should also be the coordination with the Department of Defense to leverage off what they know and what they have learned.

Mr. SHAYS. I am not clear as to why there is not a strategic plan.

Mr. RHODES. There's not a strategic plan because, as far as we know, no one, DHS, hasn't until recently said they were in charge.

Mr. SHAYS. So my questions that I am asking you are not out of the blue here. I mean, the bottom line is—and you have to explain to me, why don't they think they are in charge?

Mr. RHODES. Well, they are in charge now and they think that they are in charge now, and they told us that they are in charge. That's the update relative to——

Mr. SHAYS. Is the law unclear?

Mr. RHODES. I don't know—I don't think that the law was unclear. I think that trying to—for departments and agencies to step up and say that they are in charge of a larger group, it just seemed that other people were unwilling—it seems like the Department was unwilling to take that role.

Mr. SHAYS. Would you mind having your colleague join you here?

Mr. RHODES. Sushil.

Mr. SHAYS. How would you respond to that question?

Dr. SHARMA. At the time of issuance of our report, as you know, DHS was very new, their actions——

Mr. SHAYS. Define "very new." I know what "new" means. What does "very new" mean?

Dr. SHARMA. You know, they came after the 2001 incidents. And when CDC, EPA had already taken initiative and FBI also was, you know, in charge in terms of the forensic aspect of the incidents.

Also, another source of confusion comes from HSPD–10, which clearly delineates EPA——

Mr. SHAYS. Comes from what?

Dr. SHARMA. With the Presidential Directive No. 10, which clearly delineates EPA as the primary responsibility for developing pro-

tocols for decontamination. So, you know, I guess from DHS's perspective, and I'm sure if you asked them——

Mr. SHAYS. I am having a hard time understanding how protocols for decontamination would interfere with a plan dealing with detection. We are not talking about consequence right now, we are trying to detect. So just deal with detection.

I mean, and wherever it lies, wherever the fault lies—and maybe it lies with more than one—I just want to clearly, I want you all to be clear. You are GAO, and we are not asking them. I think it is somewhat alarming that we haven't had a sense of who is in charge.

First of all, is there any doubt on the part of either of you who should be in charge? And then explain to me why we don't know.

Mr. Rhodes.

Mr. RHODES. I have no doubt both in law and in practicality that the Department of Homeland Security should be in charge. And as I testified last year, that was the recommendation that we made.

Mr. SHAYS. Well "should be" may mean that it would be a good thing if law required it and if regulation required it and if Presidential directives required it. Are you saying that it doesn't require it and it is your recommendation they should be in charge? Or are you saying that it is clear under law they are in charge?

Mr. RHODES. It's clear under law that they are in charge and it was—when we did our analysis and we looked at the results of the detection work that was done in the fall of 2001, it was very clear that they needed to be in charge. It wasn't just that in law it says it, but it was clear that from a scientific standpoint, from a testing standpoint, from a design standpoint, they needed to be in charge.

Mr. SHAYS. OK. So——

Mr. RHODES. Because in the fall of 2001, everyone came in with their own charter. So the FBI came in collecting samples from——

Mr. SHAYS. I don't know what you mean by "the fall of 2001." What do you mean by "they came with their own charter"? I don't understand that.

Mr. RHODES. All the departments and agencies that responded to the anthrax events came in with their own roles and responsibilities.

Mr. SHAYS. Right.

Mr. RHODES. So EPA was taking samples based on cleanup, CDC was taking samples based on epidemiology, FBI was taking samples based on evidence collection, and those things. And as we saw, that made it very, very difficult for anyone to have a good set of samples. So without having——

Mr. SHAYS. I am sorry, you just introduced more information.

Mr. Duncan, I welcome you here and I am going to suspend my—I just want to get this basic point, and then Mr. Duncan. Then I am going to come back to you.

I am just wanting to be clear—I just don't understand something else you just said. When you say that since they all wanted samples, no one had good samples. Why can't they all get good samples?

Mr. RHODES. Well, I mean, good samples from being able to understand very clearly that a location was clean, that a location was

now free. From our standpoint, since they weren't using probability based samples——

Mr. SHAYS. How did we get to something being clean from the original issue of whether you could come into a building and detect—so I guess maybe this is a small point. I want to know if something that we don't think is exposed is exposed. You are talking about something that is already exposed no longer being exposed.

Mr. RHODES. Right.

Mr. SHAYS. I guess they are the same?

Mr. RHODES. They're going to ultimately—you're going to have to answer the same question. The validation of the method and the validation of the process should be applicable to both environments to answer both questions.

Mr. SHAYS. OK. Now, I am told that I can put a handful of anthrax in my hand, I would have billions of spores.

Mr. RHODES. Could be trillions.

Mr. SHAYS. Trillions. So it is conceivable that you could, even scientifically, not be able to totally and completely determine if you were anthrax-free.

Mr. RHODES. Right.

Mr. SHAYS. So it would be kind of hard for us—I mean, it would be almost—I would think it would almost be illogical for us to make an assumption that we could. Is that the goal, though? Or what is the goal?

Mr. RHODES. The goal is to make certain that you have confidence. What degree of confidence do you have that this building is anthrax-free or that this building is no longer infectious, that people who walk into this building are no longer going to run the risk of being infected by inhalation anthrax or cutaneous anthrax or gastrointestinal anthrax? That's really the direction on this validation process that we're talking about.

Mr. SHAYS. All right. So before recognizing Mr. Duncan, let me just get back to this basic point. And I am going to say what I am hearing you tell me. You are saying that with regard to the process of establishing a detection method and to validate it, and to develop that strategy, that is the Department of Homeland Security—that you don't have any doubt that it is, that the law states it, and there is logic that they should be required to undertake that. Is that correct?

Mr. RHODES. That's correct.

Mr. SHAYS. Do you agree as well?

Dr. SHARMA. Yes.

Mr. SHAYS. Are you allowed to disagree with him if you——

Dr. SHARMA. No, no, no, I'm allowed to disagree.

Mr. SHAYS. OK.

Mr. RHODES. I believe you know that he's allowed to disagree with anything.

Mr. SHAYS. Well, sometimes he disagrees even when he is not allowed, so that is another issue.

But, so—now, the last question is do they have any doubt anymore that they have that responsibility? And when did they finally agree that they had that responsibility? Or is it possible they al-

ways had the responsibility and just never did it—and they knew they always had the responsibility?

Mr. RHODES. I can't speak to your second point because I can't read people's minds. All I can——

Mr. SHAYS. Haven't they told you? Haven't you asked them?

Mr. RHODES. We have asked and they have said no.

Mr. SHAYS. Said no.

Mr. RHODES. Prior to May 3rd of—well, last week. Prior to last week.

Mr. SHAYS. They do not accept that they have the responsibility to develop the strategy?

Mr. RHODES. They have the responsibility to develop the strategy, but they don't have the responsibility to order other people. And they didn't concur——

Mr. SHAYS. What, to cooperate?

Mr. RHODES. Right. And they did not concur with the necessity for validating both the methods and the processes.

Mr. SHAYS. OK. This is not good.

Mr. Duncan.

Mr. DUNCAN. Well, thank you very much, Mr. Chairman, for calling this hearing. This is extremely important, I think. I am sorry that I was not able to get here until just a few minutes ago, and maybe you have covered most of what I wanted to ask about.

Mr. SHAYS. Well, if we did cover it and you ask it again, it will reinforce knowledge to me, so I am happy to have you bring it up.

Mr. DUNCAN. OK. Well, thank you very much.

The chairman noted in his statement that Congress passed and the President signed an authorized $5.6 billion for Project BioShield to be spread over 10 years. And this $877.5 million contract was awarded to VaxGen in 2004. It is my understanding that was to produce 75 million doses of anthrax vaccine, but there have been some problems. And what I am wondering about is how much of that $877.5 million has been expended and how many doses do we have? Or what is the current status of that contract?

And then also, I see that a company called BioPort received a $1.22 million contract, a much, much smaller contract, to manufacture 5 million doses. And are they producing a different—you know, a different thing? What is the situation now with those contracts and those doses and so forth?

Mr. RHODES. Mr. Duncan, relative to your first question about the actual contract expenditures, that was not something we reviewed. That question is probably better directed to HHS on the second panel.

Mr. DUNCAN. OK.

Mr. RHODES. Because the purpose of our review was to look at the Federal Government response to our recommendations prior, which were focused on the licensed anthrax vaccine versus a next generation anthrax vaccine, as opposed to the contract vehicle for it.

Mr. DUNCAN. OK, well, I guess the questions I am wondering about, Mr. Chairman, will hopefully be covered by the next panel.

Mr. SHAYS. Before we go to the next panel, what I am hearing you tell me is that the plan on detection and validation and so on is the responsibility of DHS, that they have never agreed that this

is their responsibility, and they certainly don't believe that they have the right to ask others—certainly I am hearing you say that they do not feel they have the power to direct others to help them in that effort.

If I am getting a distorted message from you, I need you to clarify it.

Mr. RHODES. The only thing I would alter to that is that, as of our discussion last week with DHS, that has changed.

Mr. SHAYS. You mean now, since——

Mr. RHODES. Now they accept the responsibility. Now they are willing to coordinate other departments and agencies under their authority. So that has changed. The question we still have on the table is what is that plan, what is that roadmap, how does it lead to validated methods, how does it lead to a structured response and coordination of the varying departments and agencies that would have to respond to another incident like the fall of 2001?

Mr. SHAYS. Before we get on to the next panel, let me—I must be too unclear about—has this just basically been a rather general assignment that we tasked Government to develop this strategy, or did we clearly state a while ago there would be a strategy and it would be done by a certain date? Or somewhere in between?

Mr. RHODES. You did direct them—I mean, the law states for a strategy, you did direct them in the last hearing for a strategy.

Mr. SHAYS. But DHS wasn't here last time.

Mr. RHODES. No, DHS was not here, but the recommendation was made here. And it was made in the hearing. So I guess if it didn't get to DHS directly——

Mr. SHAYS. The last panel was the session "Anthrax Detection Methods." That was just the focus of it, just this—and that was April 5, 2005. And DHS was not there and refused to provide a statement.

Mr. RHODES. Right.

Mr. SHAYS. OK.

Have there been any doubts on the part of the other departments that it was DHS's responsibility? Or is that part of the problem?

Mr. RHODES. Our experience has been that other departments and agencies, as you heard in the last testimony relative to the detection methods, they did not concur with our recommendations either. So I don't know that I can say that they wouldn't believe that DHS was responsible, but they didn't believe that validation of methods was necessary either and they didn't believe in probability sampling either. So everyone was agreeing to disagree with our recommendations.

Mr. SHAYS. Can you explain that a little differently and see if I can understand it?

Dr. SHARMA. When we issued our report, HHS did not come. And the response was very unclear as to whether they were agreeing with our recommendations or disagreeing. It was very wishy-washy, if I may use the word.

CDC, on the other hand, was very clear in their response that the sampling strategy they had used was, under the circumstances, was the best, and they were very concerned about the probability based sampling. Primarily their concerns were twofold; first, that

it will take a long time, and second also, that it would result in significant cost.

In terms of, you know, the DHS responsibility, at the time, everybody was given a—you know, they were doing what their mission required them to do. The change is now that they will still do what their mission requires them to do, but DHS would be coordinating that mission-related responsibility. In other words, they will be, then, saying that if we were going to test Rayburn building, whether or not it is contaminated, their plan should be able to tell you that in this room, if they were to collect probability based sampling using a given method, how many samples they need to collect and from where and who is going to do that.

Mr. SHAYS. I mean, does the—they can determine ultimately the level of ascertaining whether or not there is anthrax, correct? In other words, they can—the strategy can say we'll get to this level or we'll get to this level or get to this level. Is that true? Or are we saying the strategy has to get us to almost total certainty, you just have to figure out how we get there? Do they get to decide what level and get to decide how to determine it? It would strike me that would be the logical thing.

Dr. SHARMA. That strategy should describe both.

Mr. SHAYS. OK. So what I would think—I mean, one of the things that I am pretty aware of, having been involved with helping to create the Department of Homeland Security is we have given them more tasks than they can humanly do immediately or in the near future. So they are going to decide opportunity costs. But it seems to me at the very least they have to be up front with us and say we have been tasked this but we simply get to it. That, to me, would be the honest way to do it. I don't think they can do everything we have tasked them.

So, you know, I cut them a little slack that way. But I would be bothered if nobody is taking ownership. I felt no one took—I felt DHS didn't take ownership of Katrina, frankly. So I am a little concerned that we may see that behavior in other areas.

Mr. RHODES. And, Mr. Chairman, prior to May 3, 2006, when we met with DHS and we were told that not only were they going to be in charge but they were going to be responsible for this effort, I was ready to sit down here and say yes, once again, DHS has said they won't be in charge, they won't take the responsibility. Now the onus is to see what their definition of taking responsibility means—which would be, in this plan, to answer the very question you just asked. There's an opportunity, there's a cost, there's an effort that has to be applied. How does detection validation rank relative to other things on their plate?

Mr. SHAYS. Let me just jump to detection. We are taking a little longer here than I thought, but I think it will help for the next panel.

What is DOD doing in terms of detection? Have they established a strategy that they are trying to follow and implement?

Mr. RHODES. We did not look at DOD as part of this effort on this job. I mean, they have their field methods, but we did not look at them specifically relative to this job.

Mr. SHAYS. Isn't there a logic to have the civilian and the military interact with each other? I mean if they both can collectively

do the same process, or at least—I mean it would seem logical to me that they would do that.

Mr. RHODES. They do coordinate. And they should coordinate.

Mr. SHAYS. But you can't speak to the fact of whether DOD is just doing basically the same thing DHS is, which is nothing?

Mr. RHODES. No, I cannot speak to that here.

Mr. SHAYS. Let's talk about the other aspect, and that is the vaccine itself. Who has ownership of developing the vaccine?

Mr. RHODES. For civilian use, it's HHS.

Mr. SHAYS. And they have taken ownership?

Mr. RHODES. They have taken ownership and they do have ownership for civilian use relative to this recombinant PA vaccine, the next generation vaccine.

Mr. SHAYS. And within DOD, are they working through BioPort?

Mr. RHODES. DOD is using the FDA licensed vaccine from BioPort, yes.

Mr. SHAYS. OK, so they are going that route. So tell me, are we to be concerned—I circled your statement "If it fails, the VaxGen fails and the biotechnology sector will be very worried about dealing with the U.S. Government no matter what the stated crisis levels are."

Well, what happens if VaxGen simply wasn't qualified and capable, as some say—too small, etc? I would think that would just validate they were too small, not that people wouldn't want to work with the Government. So why do you make that statement?

Mr. RHODES. I make that statement because, in firm fixed price on an experimental vaccine that has unknowns associated with it, the risk is that it will be hard to pinpoint—my concern is that it will be hard to pinpoint exactly why something is not being delivered. Is it not being delivered because requirements change? Is it not being delivered because of the uncertainty of vaccine production? Is it not being delivered because, as you say, the company may be too small and it may not be able to——

Mr. SHAYS. And what is your determination?

Mr. RHODES. We haven't made that determination yet. We're highlighting that this is a risk to a firm fixed price contract. VaxGen, the financial burden is sitting on that company, and as I say——

Mr. SHAYS. So is your point that a firm fixed price is not realistic, that it——

Mr. RHODES. Firm fixed price is realistic if requirements are firm and the understanding of the vaccine production is firm. If those things begin to waver, then——

Mr. SHAYS. How does it waver?

Mr. RHODES. Well, it can waver because the Government levies other requirements on them or there is some problem in the production because the vaccine isn't as predictable as they might have thought, it doesn't do as well during certain clinical trials as it may have.

Mr. SHAYS. In the case of VaxGen, it is a question of its potency and durability? Is that the issue?

Mr. RHODES. It could be, yes. I mean, those would be questions about—those would be questions along——

Mr. SHAYS. What has delayed it right now? What are the——

Mr. RHODES. Pardon me?

Mr. SHAYS. Do you know what has delayed the process to date?

Mr. RHODES. No. We haven't looked specifically at what has delayed it. We were looking just at the followup to our recommendations relative to next-generation vaccine.

Mr. SHAYS. OK. And tell me again your recommendations?

Mr. RHODES. The recommendation was for HHS to—for the Government to look into a next-generation vaccine, develop it to overcome—to see its ability to overcome the questions in safety, efficacy, lot-to-lot consistency, and shelf life.

Mr. SHAYS. OK. About half our Government is defense and half our Government is not defense, and I have this uneasy feeling that we pay more because we have two different parts of Government do the same thing. And I realize that we do not want civilian control—I realize that DOD has to do what it has to do, but I would just like to feel better about the whole effort to coordinate, and I do not have this very good feeling at the moment.

We are going to go to the next panel, but before we do, is there something we just really did not think to ask that we should have? Is there something that you would like to put on the record? Sometimes that is the most important part of this hearing.

Dr. SHARMA. Just one additional comment I would like to make. On the recombinant vaccine, there has been very good coordination between DOD and HHS. The original pilot lot for the recombinant vaccine in these studies——

Mr. SHAYS. The recombinant vaccine VaxGen is doing——

Dr. SHARMA. No, no, no. The pilot lot for the recombinant vaccine was developed by DOD.

Mr. SHAYS. Right.

Dr. SHARMA. They transferred the technology——

Mr. SHAYS. Not by BioPort, though.

Dr. SHARMA. No. They transferred the technology to VaxGen, and VaxGen is now taking the next step, which is to take the pilot lot and try to demonstrate that they can have the—you know, scale up production and, two, to demonstrate that the vaccine that they are going to produce is safe and effective. Indeed, as part of the first and second contract, they are doing those kinds of studies, and they will be submitting the data to FDA for determination whether this vaccine is safe and effective.

Mr. SHAYS. Say the last sentence you just said again, please. I was talking. Say the last point.

Dr. SHARMA. As part of the first-year contract and second-year contract, VaxGen is expected to demonstrate that the vaccine that they are producing is safe and effective as part of Phase I and Phase II studies. Typically, all manufacturers, they submit the data to FDA. They get the comments back from FDA. Sometimes FDS would ask them to do additional studies, and that is one of the examples of unexpected risk. HHS has asked them to do, you know, necessary studies, but what is necessary is not up to HHS to determine. It is up to FDA to determine.

Mr. SHAYS. OK. Any point you would like to make, Mr. Rhodes?

Mr. RHODES. I would just like to make one point that we learned from HHS, and that is, their primary response structure to an incident would begin with antibiotics. The second stage, the second

step would be the FDA-licensed vaccine. And they have in their estimation in the stockpile enough antibiotics for 40 million doses, and they have enough of the FDA-licensed vaccine for 25 million doses. So from a national readiness standpoint, HHS is developing the recombinant PA vaccine, but they have in their stockpile right now the antibiotics and the FDA-licensed, the BioPort vaccine.

Mr. SHAYS. When we started, this committee was—you know, we had a number of hearings on anthrax before September 11th, but it related to the military. And it related to what we thought was an outrage of forced requirement of individuals to take a vaccine and the number of shots, at least six, in spite of the fact they weren't even going to be in theater. We were told, you know, if you did not do this, you would die if you contracted anthrax. And yet we know the antibiotics helped save—I mean, there is every indication that antibiotics were very purposeful in helping to prevent some deaths.

Anyway, I guess that is a side point here. I just, before going, would want to ask: Are we making more of a deal about anthrax and is avian bird flu kind of being treated as an equal when on a scale of 1 to 10 anthrax would be a 2 and the avian bird flu would be like a 10?

In other words, when we had this hearing today, would it have been more important for us to have a hearing about the avian bird flu?

Mr. RHODES. I don't know that I can answer your question without speculation. I can say that having looked at——

Mr. SHAYS. It is a trick question.

Mr. RHODES. Having looked at the pathophysiology relative to how people are getting avian flu, you have to be very close to the bird in order to get it. And we have talked to people who have taken samples out of highly contaminated locations where nobody got sick. We have sort of the——

Mr. SHAYS. But they had protective gear on?

Mr. RHODES. No. They were regular workers in Canada working on a regular bird location. So I don't know that——

Mr. SHAYS. It can change and become more aggressive, too. I mean, there is no sense that is a constant, right?

Mr. RHODES. That's correct. That is correct.

Mr. SHAYS. OK. Mr. Duncan, thank you for your patience. Do you have any questions?

Mr. DUNCAN. No.

Mr. SHAYS. So have you put everything on the record that we should have asked? If there is something that is not, please put it on the record. Is there anything else that should be put on the record?

Mr. RHODES. No. Thank you.

Mr. SHAYS. Well, you know, what I think we have fallen down on is we should have had this hearing 5 months ago, a little earlier. Your study got done recently, but, you know, for DHS not to have been here a year from now and for us to get buy-in last week is regretful.

Thank you all very much, and we will move to the next panel.

Mr. RHODES. Thank you.

Mr. SHAYS. Our next panel, our last panel, panel two, is Ms. Ellen P. Embrey, Deputy Assistant Secretary of Defense for Health Affairs for Force Health Protection and Readiness, Department of Defense; Mr. Jean Reed, Special Assistant to the Secretary of Defense for Chemical and Biological Defense Programs, Department of Defense; Dr. Gerald Parker, Deputy Assistant Secretary for Public Health Preparedness, Department of Health and Human Services; Dr. Richard Besser, Director, Office of Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention; Dr. Susan Elizabeth George, Deputy Director of Biological Countermeasures Portfolio, Department of Homeland Security; Ms. Dana Tulis, Deputy Director for the Office of Emergency Management, Environmental Protection Agency, accompanied by Mr. Mark Durno, On-Scene Coordinator.

Sorry that our table is somewhat restrictive here.

Let me thank all of you for spending the time here. I am really happy that we are having this hearing, and I am happy that we have the range of you, of agencies. And you all were here for the previous questions, so there may be something that you need to magnify or clarify in your statement, and feel free to do that.

So let me do what we need to do, and that is, to swear you in. You sat down, and now you have to stand up. And, Mr. Durno, if you are here as well, you should stand. Anyone else that you may call on that might have to—great, that way we do not have to swear in someone twice. If you would all raise your right hands.

[Witnesses sworn.]

Mr. SHAYS. We will note for the record that everyone has responded in the affirmative, so everyone is sworn in. And we will go in the way you are seated. Given the number of folks, I think it would be good if we could stay within the 5-minute limit. Obviously, if you go on a few seconds more, no big deal.

Ms. Embrey—excuse me. You mentioned members of the subcommittee. We have been joined by Mr. Van Hollen, and I am a little delinquent in not welcoming—is there any statement you would like to put in the record?

Mr. VAN HOLLEN. No. Just thank you, Mr. Chairman, for conducting this hearing. I think it is a very important subject. Sorry I missed the earlier one. I welcome the witnesses, and I am going to apologize in advance for having to leave in about half an hour, but I am looking forward to the testimony.

Mr. SHAYS. Well, if they finish in time, we will let you ask the first questions.

Ms. Embrey.

STATEMENTS OF ELLEN P. EMBREY, DEPUTY ASSISTANT SECRETARY FOR DEFENSE OF DEFENSE FOR HEALTH AFFAIRS FOR FORCE HEALTH PROTECTION AND READINESS, U.S. DEPARTMENT OF DEFENSE; JEAN REED, SPECIAL ASSISTANT FOR CHEMICAL AND BIOLOGICAL DEFENSE AND CHEMICAL DEMILITARIZATION PROGRAMS, U.S. DEPARTMENT OF DEFENSE; GERALD W. PARKER, D.V.M., PRINCIPAL DEPUTY TO THE ASSISTANT SECRETARY, OFFICE OF PUBLIC HEALTH EMERGENCY PREPAREDNESS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; RICHARD E. BESSER, M.D., DIRECTOR, COORDINATING OFFICE FOR TERRORISM PREPAREDNESS AND EMERGENCY RESPONSE, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; S. ELIZABETH GEORGE, PH.D., DEPUTY DIRECTOR, BIOLOGICAL COUNTERMEASURES PORTFOLIO, SCIENCE AND TECHNOLOGY DIRECTORATE, U.S. DEPARTMENT OF HOMELAND SECURITY, ACCOMPANIED BY JOHN VITKO, JR., PH.D., DIRECTOR, BIOLOGICAL COUNTERMEASURES PORTFOLIO, SCIENCE AND TECHNOLOGY DIRECTORATE, U.S. DEPARTMENT OF HOMELAND SECURITY; AND DANA TULIS, DEPUTY DIRECTOR, OFFICE OF EMERGENCY MANAGEMENT, U.S. ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY MARK DURNO, ON-SCENE, COORDINATOR [OSC] EPA REGION 5

STATEMENT OF ELLEN P. EMBREY

Ms. EMBREY. Thank you. I am here today as part of a two-member representation from the Department of Defense. I am here to talk specifically about Defense's programs to prevent, mitigate, and respond to anthrax incidents. Today, we have about 236,000 service men and women deployed in support of our Nation's defenses, including those serving in Afghanistan and Iraq. Protecting and preserving the health of our service members before, during, and after their deployments is our primary mission.

With respect to weapons of mass destruction, DOD policies affecting immunizations, DOD Directive 6205.3, that provides policy guidance on vaccines and vaccination policies for defense against biological warfare threats, to include the agent that causes anthrax. Vaccination is an essential layer of protection, supplemented by antibiotics and other measures, for members of the armed forces, emergency-essential DOD civilians, and contractor personnel who carry out mission-essential services.

The department currently uses two forms of medical countermeasures against anthrax: vaccines and antibiotics. Vaccines provide an effective means of preventing disease and offer an advantage of providing around-the-clock protection, even in the absence of biologic agent detectors. Antibiotics have value if given shortly after exposure. However, if prevention, detection, and treatment are delayed, people can still develop anthrax disease.

Anthrax Vaccine Adsorbed (BioThrax) is an FDA-licensed vaccine. On December 19, 2005, the Food and Drug Administration, after a review of all available scientific information and consideration of extensive public comments, published a final order reaffirming previous conclusions that the Anthrax Vaccine Adsorbed

prevents anthrax resulting from any route of exposure, including inhalation.

The Department works closely with BioPort Corp., the manufacturer of the only anthrax vaccine licensed by the FDA, to ensure a consistent supply of vaccine to meet the requirements for DOD's anthrax program. Since 2002, BioPort has doubled its production capacity and delivered more than 8.4 million FDA-licensed doses of Anthrax Vaccine Adsorbed to DOD. Inventory levels are sufficient to meet current DOD anthrax immunization program requirements.

The current contract with BioPort expires this September. DOD is currently in negotiations with BioPort for a new contract beginning in fiscal year 2007 to meet our vaccination requirements. We anticipate needing to buy Anthrax Vaccine Adsorbed through at least fiscal year 2009 and possibly longer, depending upon when the new anthrax vaccine that HHS is working on may be licensed. A decision to switch to that new vaccine will be supported by science and a thorough business case analysis.

The anthrax vaccine is safe and effective, facts that are fully supported by the Food and Drug Administration and other national experts and based on science. The National Academy of Sciences and its Institute of Medicine comprehensively reviewed the safety of anthrax vaccine in April 2002 by a report commissioned by Congress. The IOM stated in that report that adverse events after anthrax immunization are "comparable to those observed with other vaccines regularly administered to adults." As with all vaccines and pharmaceuticals that have a benefit, there are some risks, but most adverse events after vaccination are minor and temporary. Anthrax immunization may have associated temporary pain, swelling, headache, muscle aches, and other side effects, similar to all immunizations. There are several grounds for medical exemption, including pregnancy. Serious events, such as those requiring hospitalization, are extraordinarily rare. The Department has established four sites in the Vaccine Healthcare Center Network, a network of specialty clinics, to provide the best possible care in rare situations where serious adverse events follow vaccination. DOD assesses the safety of vaccines using a multi-faceted program using various scientific study designs.

Anthrax immunization remains the most effective countermeasure to prevent anthrax. Between March 1998 and this last March, in 2006, over 1.5 million personnel received over 5.5 million doses of the anthrax vaccine. Currently, DOD personnel deploying to high-risk areas, specifically Korea and areas under the Central Command, are eligible for anthrax immunization and have an option to decline. In addition, effective antibiotics against anthrax disease and other biological agents are prepositioned strategically around the globe for rapid delivery in the event of an emergency. The Department is collaborating with HHS to develop plans for the use of post-exposure anthrax immunization combined with antibiotics in those personnel who were not previously immunized. This is consistent with the prevailing medical recommendation for the best clinical response to anthrax exposure.

Although anthrax vaccine is licensed by the FDA, its approved labeling does not include post-exposure use to prevent anthrax dis-

ease. However, the Food, Drug and Cosmetic Act, part of the Project BioShield Act of 2004, allows FDA to authorize the use of unapproved medical products or an unapproved use of an approved medical product during a declared emergency involving an actual or heightened risk of attack on the public or U.S. military forces. Based on an emergency declaration by the Secretary of HHS, the FDA Commissioner can authorize emergency use of a product——

Mr. SHAYS. If you would sum up.

Ms. EMBREY. I am really glad to be here, and I will answer your questions. [Laughter.]

Mr. SHAYS. You must have one last sentence you want to say.

Ms. EMBREY. No, sir. Really, I am glad to be here and I will answer your questions.

Mr. SHAYS. OK. Thank you.

[The prepared statement of Ms. Embrey follows:]

Prepared Statement

of

Ellen P. Embrey

Deputy Assistant Secretary of Defense for Health Affairs for

Force Health Protection and Readiness

on

Anthrax Protection: Progress or Problems

Before the

House of Representatives Committee on Government Reform

Subcommittee on National Security, Emerging Threats, and

International Relations

May 9, 2006

Mr. Chairman and members of this distinguished subcommittee, it is an honor to be here today to discuss the Department of Defense's programs to prevent, mitigate and respond to anthrax incidents. Today, we have approximately 236 thousand service men and women deployed in support of our nation's defenses, including those serving in Afghanistan and Iraq. Protecting and preserving the health of our service members, before, during and after deployments is our primary mission.

As the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, I am responsible for supporting the Assistant Secretary of Defense for Health Affairs in his role as the principal health and medical advisor to the Secretary of Defense on all aspects of the DoD's military health care system, including protecting, preserving, and restoring the health of our service members against not only endemic disease but also weapons of mass destruction (WMD). In the WMD arena, DoD Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, provides policy guidance on vaccines and vaccination policies for defense against biological warfare threats, to include the agent that causes anthrax. Vaccination is an essential layer of protection, supplemented by antibiotics and other measures, for members of the armed forces, emergency-essential DoD civilians and contractor personnel carrying out mission-essential services.

Medical Countermeasures

The Department of Defense (DoD) currently uses two forms of medical countermeasures against anthrax: vaccines and antibiotics. Vaccines provide an effective means of preventing disease, and offer the advantage of providing around-the-clock protection even in the absence of biologic agent detectors. Antibiotics have value if given

shortly after exposure. However, if prevention, detection, and treatment are delayed, people can still develop dangerous anthrax disease.

Anthrax vaccine adsorbed (BioThrax™) is an FDA-licensed vaccine. On December 19, 2005, the Food & Drug Administration, after a review of all available scientific information and consideration of extensive public comments, published a final order reaffirming previous conclusions that anthrax vaccine adsorbed prevents anthrax resulting from any route of exposure, including inhalation.

The DoD works closely with BioPort Corporation, manufacturer of the only anthrax vaccine licensed by the Food and Drug Administration, to ensure a consistent supply of vaccine to meet the requirements of DoD's anthrax immunization program. Since 2002, BioPort has doubled its production capacity and delivered more than 8.4 million FDA-licensed doses of Anthrax Vaccine Adsorbed (AVA) to DoD. Inventory levels are sufficient to meet current DoD anthrax immunization program requirements.

The current contract with BioPort expires in September 2006. DoD is negotiating with BioPort for a new contract starting in FY07 to meet DoD anthrax vaccination program requirements. We anticipate needing to buy AVA through at least FY09 and possibly longer, depending on when a new anthrax vaccine may be licensed. A decision to switch to a new vaccine will be supported by science and a thorough business case analysis.

The anthrax vaccine is safe and effective, facts that are fully supported by the Food and Drug Administration and other national experts and based on sound science. The National Academy of Sciences and its Institute of Medicine (IOM) comprehensively reviewed the safety of anthrax vaccine in an April 2002 report commissioned by the U.S.

Congress. The IOM stated that adverse events after anthrax immunization are "comparable to those observed with other vaccines regularly administered to adults." As with all vaccines and pharmaceuticals that have a benefit, there are some risks, but most adverse events after vaccination are minor and temporary. Anthrax immunization may have associated temporary pain, swelling, headache, muscle aches, and other side effects, similar to all immunizations. There are several grounds for medical exemption, including pregnancy. Serious events, such as those requiring hospitalization, are extremely rare. The DoD has established four sites in the Vaccine Healthcare Center Network, a network of specialty clinics, to provide the best possible care in rare situations where serious adverse events follow vaccination. DoD assesses the safety of vaccines using a multi-faceted program using various scientific study designs.

Anthrax immunization remains the single most effective countermeasure to prevent anthrax disease. Between March 1998 and March 2006, over 1.5 million personnel received over 5.5 million doses of anthrax vaccine. Currently, DoD personnel deploying to high-risk areas, principally Korea and areas under Central Command, are eligible for anthrax immunization and have the option to decline. In addition, effective antibiotics against anthrax disease and other biological agents are pre-positioned strategically around the world for rapid delivery in the event of an emergency. The DoD is collaborating with the Department of Health and Human Services to develop plans for the use of post-exposure anthrax immunization combined with antibiotics in those personnel not previously immunized. This is consistent with the prevailing medical recommendation for the best clinical response to anthrax exposure.

Although anthrax vaccine is licensed by the FDA, its approved labeling does not include post-exposure use to prevent anthrax disease. However, section 564 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb-3), part of the Project BioShield Act of 2004 (Public Law 108-276), allows the FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving an actual or heightened risk of attack on the public or U.S. military forces. Based on an emergency declaration by the Secretary of Human Health Services (HHS), the FDA Commissioner can authorize emergency use of a product if: the product is used for a serious or life-threatening condition; there is no adequate, approved, and sufficiently available alternative; the preponderance of scientific evidence indicates that the product may be effective; and the product's known and potential benefits outweigh its known and potential risks. It is likely that, in the event of an anthrax attack that results in unvaccinated individuals being exposed to the anthrax bacteria, the public health authorities responsible for helping those individuals would ask the FDA for an Emergency Use Authorization (EUA) for post exposure administration of anthrax vaccine in conjunction with antibiotics. To be ready for a potential emergency, both DoD and the CDC are developing draft EUA requests and working with the FDA to establish the most effective and scientifically valid clinical response.

In closing, I want to reiterate that the health and safety of all service members are the top concerns of the Department. Our medical program to protect service members from this deadly biological disease is based on the best medical and scientific information available as well as by independent review of the world's best experts in the field. The Department bases its decisions on strong science and best medical practices. Our program

supports FDA regulations and is consistent with all legal requirements. It has the full support of the DoD military and civilian leadership.

Mr. SHAYS. Mr. Reed.

I am only thinking of my colleague. I want to make sure he gets some questions before he goes.

STATEMENT OF JEAN REED

Mr. REED. Mr. Chairman, distinguished committee members, thank you for the opportunity to appear before the subcommittee today to discuss the Department of Defense's capabilities regarding detection of anthrax, an area to which the Department has committed considerable resources to mitigate the effects of anthrax on our armed forces.

I am Jean Reed. I'm the Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs. In this capacity, I support Dr. Dale Klein, the Assistant to the Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs. As Special Assistant, I have responsibility for oversight of chemical and biological defense programs throughout the Department of Defense.

I have been on the job for about 5 months. I came to this job from 15 years as a professional staffer for the House Armed Services Committee. In that role, my responsibilities included staff oversight for the Department of Defense's Chemical and Biological Defense Program, and I was the staff lead for Title 16, the Defense Biomedical Countermeasures title of the National Defense Authorization Act for Fiscal Year 2004, which was closely coordinated with the Project BioShield Act of 2004.

In my current position, I find myself on the other side of the table. I am now faced with the challenge of preparing U.S. forces to operate in environments that have been contaminated by chemical and biological agents. In addition to overseas environments and operations, U.S. forces are being prepared to operate in these types of environments in support of both homeland defense and homeland security operations.

I am going to provide a brief status today of the DOD Biological Detection Systems that are relevant to the detection of anthrax, and they are, in summary, shown on the tripods to your left, my right, and I have asked committee staff to go ahead and distribute individual copies of the one labeled "Biological Detection."

Many of these systems are focused on protecting military personnel in operational environments. However, the technologies used in these systems may have applications to support protection of personnel in buildings. The Department of Defense orients its program primarily toward measures for operations of the troops in the field, but we share technologies and gain from technologies being developed by other departments in the executive branch.

The Biological Integrated Detection System [BIDS], is a vehicle-mounted, fully integrated biological detection system. It is a core-level asset. The current model is capable of detecting and identifying eight biological warfare agents simultaneously in 30 minutes.

Joint Portal Shield is an interim biological detection system used to protect high-level fixed assets. It uses an innovative network of sensors to increase the probability of detecting a biological warfare attack while decreasing false alarms and consumables. Each sensor

is modular in design and can detect and identify up to 10 biological warfare agents simultaneously in less than 25 minutes.

Mr. SHAYS. Let me encourage you to just summarize.

Mr. REED. Yes, sir. Joint Biological Detection System, also oriented now as a fully automated system that will replace both BIDS and the JPS. That program, a modular design variant, referred to as the Homeland Defense Trailer, was deployed as part of the network of eight JBPDS systems in the National Capital Region on November 28, 2001, and was fully operational on December 3, 2001.

There are a number of other programs, sir, that are in my testimony for the record. Suffice it to say that we are working with currently and fielding advanced systems and then have additional systems under development. The issue of standoff biological detection is a very, very difficult problem, and Defense Advance Research Projects Agency is working with us in that effort. Additionally, DARPA is also developing the Handheld Isothermal Silver Standard Sensor and the Spectral Sensing of Biological Aerosols as fieldable systems for handheld portable detection of biological weapons and agents on the battlefield, and one of my colleagues in Health and Human Services emphasized that the Handheld Isothermal Silver Standard Sensor is a unique device that is not being followed in the commercial sector, but is one that is very important to us.

I want to briefly underscore the importance of the anthrax detection programs within the Pentagon, such as the new mail screening facility. All mail entering the Pentagon is now screened with biosafety cabinets, and once screened and samples tested, then distributed to the recipients.

My colleague has already addressed the biological—or the Anthrax Vaccination Immunization Program. I am a very early graduate of that program, having gotten the six shots in 1972 when I was at Army Materiel Command, and I can attest to the fact that the sixth shot in that series is a loser. It hurts. All the reason for having and seeking advanced vaccines, but what we have right now, as Ms. Embrey emphasized, is the BioPort AVA vaccine for the use of our troops in the field.

Sir, with that, I will be prepared to answer any questions you might have.

[The prepared statement of Mr. Reed follows:]

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HOUSE GOVERNMENT REFORM COMMITTEE

WRITTEN TESTIMONY

STATEMENT OF MR. JEAN REED
SPECIAL ASSISTANT FOR CHEMICAL AND BIOLOGICAL DEFENSE AND CHEMICAL DEMILITARIZATION PROGRAMS

BEFORE THE
COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS, AND INTERNATIONAL RELATIONS

UNITED STATES HOUSE OF REPRESENTATIVES
SECOND SESSION 109TH CONGRESS

DOD ANTHRAX DETECTION CAPABILITIES
CURRENT AND PLANNED

MAY 9, 2006

FOR OFFICIAL USE ONLY
UNTIL RELEASED BY THE
HOUSE GOVERNMENT REFORM COMMITTEE

Mr. Chairman and distinguished committee members, thank you for the opportunity to appear before you today to discuss the Department of Defense's capabilities regarding detection of anthrax. The Department is a significant stakeholder in this area of concern, and we have committed considerable resources toward mitigation of the effects of anthrax on our Armed Forces.

I am Jean Reed, the Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs. In this capacity, I support Dr. Dale Klein, the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs, ATSD(NCB). As Special Assistant to the ATSD(NCB), I have responsibility for oversight of chemical and biological defense programs throughout the Department of Defense.

I have been on the job for about five months. I came to this job from 15 years as a professional staffer for the House Armed Services Committee. In that role, I had an extensive role assisting in the legislative process, notably having the enjoyable task of working to develop the Project BioShield Act of 2004.

In my current position, I find myself on the other side of the table. I am now faced with the challenge of preparing U.S. forces to operate in environments that have been contaminated by chemical and biological agents. U.S. forces are being prepared to operate these types of contaminated environments in support of both homeland defense and homeland security operations.

Today, I will provide a brief status update on DOD biological detection systems that are relevant to the detection of anthrax. I'll begin by laying out for you an overview of the systems that are currently being fielded. Many of these systems are focused on protecting military

personnel in operational environments. However, the technologies used in these systems may have applications to support protection of personnel in buildings.

Fielded Anthrax Detection Equipment

1. Biological Integrated Detection System (BIDS)

   BIDS uses a multiple technology approach, both developmental and off-the-shelf materiel, to detect biological agents with maximum accuracy. BIDS is a vehicle-mounted, fully integrated biological detection system. The system is a collectively-protected, High Mobility Multipurpose Wheeled Vehicle (HMMWV)-mounted shelter and is modular to allow component replacement and exploitation of new technologies. The BIDS is a Corps level asset. The current model is capable of detecting and presumptively identifying eight biological warfare (BW) agents simultaneously in 30 minutes. The next generation model is equipped with the Joint Biological Point Detection System, which I will discuss in detail a little further on.

2. Joint Portal Shield (JPS)

   JPS is an interim Joint Service biological detection system used to protect high value fixed assets. The system uses an innovative network of sensors to increase probability of detecting a biological warfare attack while decreasing false alarms and consumables. The JPS system consists of a variable number of biological sensors forming a network under the command and control of a centralized command post computer, or CPC. The CPC communicates with and monitors the operation of each sensor. Each sensor is modular in design and can detect and presumptively identify up to ten BW agents simultaneously in less than 25 minutes. In addition, the system has a chemical sensor interface and a radiological sensor interface, which provides an integrated chemical,

biological and radiological sensor network capability. The JPS has been deployed to a total of ten sites in Northeast Asia and 12 sites in the Middle East.

3. Joint Biological Point Detection System (JBPDS)

The JBPDS provides a fully-automated biological point detection capability for the Services throughout the battlespace. The system, which at end state will replace the BIDS and JPS, is more affordable and effective. The sensor suite detects and presumptively identifies ten BW agents simultaneously in less than 20 minutes. The JBPDS is highly maintainable and its modular design is suitable for integration on various platforms and configurations. The system can be operated locally or remotely, and fully automates the functions of: collection, detection, identification, and warning. Its modular design also offers the fastest possible fielding of these systems to meet urgent requirements, as well as the flexibility needed to improve the system continuously with the latest advances in the biological detection, collection, identification, information processing, and engineering sciences.

One modular design variant, referred to as the Homeland Defense Trailer (HDTR), was deployed as part of a network of eight JBPDS systems in the National Capital Region on November 28, 2001, and was fully operational on December 3, 2001. These HDTR systems are deployed in a commercial trailer configuration that was jointly developed and produced.

4. Dry Filter Unit (DFU)

The DFU was developed in response to critical needs identified after the anthrax terrorist attacks in 2001. It is a stand-alone collector that can be used to collect internal and

external ambient air samples for subsequent analysis. It is simple, has an exceptional concentration factor, is inexpensive, and extremely flexible. It is also complementary to and does not replace the role or need for more robust detection systems such as JBPDS, JPS and BIDS.

5. DOD Biological Sampling Kit

The DOD Biological Sampling Kit, with its associated handheld assays, provides a presumptive identification capability for BW agents in environmental samples and are employed for: field screening suspect munitions or munitions fragments for presence of BW agents; screening envelopes or packages that display suspicious liquids, powders or suspensions; screening suspect terrorist laboratory or weapons materials that might be associated with the manufacture or delivery of BW agents; or as a contamination identification kit for indoor areas where it is suspected a BW agent has been released in fairly high concentrations. The DOD Biological Sampling Kit contains a panel of 8 Hand Held Assays, a blue-capped tube containing a bottle of buffer solution and cotton tipped swabs, and a basic instruction card. The DOD Biological Sampling Kit must be stored at 4°C, has a one-time use only capability, and is not for diagnostic use.

The next systems are currently under development, and will significantly improve the Department's anthrax detection capabilities.

Planned Anthrax Detection Capabilities

1. Joint Biological Tactical Detection System (JBTDS)

   The JBTDS is being developed to provide the warfighter a lightweight sensor with biological agent detection, warning and sample isolation capabilities. The detector will be networked to provide a cooperative detection capability to increase the probability of warning personnel and reducing the probability of false alarm. JBTDS will be employed remotely or in an unattended configuration, on platforms to include vehicles, aircraft, and by foot-mobile forces.

2. Joint Biological Standoff Detection System (JBSDS)

   The JBSDS will use an infrared laser to detect, within 5 kilometers, and discriminate within 1 kilometer, aerosol clouds at operationally significant concentrations. An expedited version is being developed in response to an urgent demand identified by the Joint Chiefs of Staff, and provides 120 degree scanning while operating from fixed sites or mobile platforms in a stationary mode. The next generation system will provide 360 degree scanning while operating on-the-move.

The Department is also developing additional capability within the science and technology sector. First is a technology for an advanced standoff biological detection capability to both detect and discriminate biological aerosol clouds at operationally significant concentrations. Candidate technologies include long-wave and mid-wave infrared (LWIR and MWIR), differential scattering/differential absorption lidar, passive LWIR spectroscopy, and spectral resolution ultraviolet laser induced fluorescence.

In addition to programs under my direct purview, there are several biodetection efforts being developed by the Defense Advanced Research Projects Agency (DARPA). These research efforts are being evaluated for potential application in a variety of roles to support DOD. The Femtosecond Adaptive Spectroscopy Techniques for Remote Agent Detections (FAST-RAD) program, which will demonstrate the capability to detect biological agents at standoff distances. This will be accomplished by performing coherent nonlinear optical spectroscopy, laser pulse shaping techniques, and adaptive optics coupled with strategies that optimize the return signal. By using short pulse lasers with coherence effects, both the spectral and temporal information contained in the backscattered signal will be exploited. This will enable identification of specific agents and provide a mechanism to adapt the system to new agents.

Additionally, DARPA is developing the Handheld Isothermal Silver Standard Sensor (HISSS) and the Spectral Sensing of Bio-Aerosols (SSBA) programs as fieldable systems that will detect biological weapons on the battlefield using hand-held portable detect-to-protect sensors and stand-alone, standoff, detect-to-warn trigger sensors. The SSBA detect-to-warn trigger sensors will be developed for two biosensing areas; the first will be capable of stand-alone detection without consumables, the other will be semi-portable and readily interfaced with the HISSS handheld portable detect-to-protect sensor. The SSBA program addresses the urgent need for biological agent detect-to-warn trigger sensors with fast response times and very low false alarm rates. The goal of this program is to develop point detection sensors with response times of less than one minute and with at least one order of magnitude reduction in false alarm rate relative to currently fielded sensors. The SSBA program will also evaluate whether any of the proposed sensors can provide detection and localization of a biological agent at useful standoff ranges. The HISSS program addresses the urgent need for biological agent detect-to-

protect sensors. They are based on isothermal techniques that replace today's laboratory silver standards such as polymerase chain reaction (PCR), reverse transcriptase PCR, and enzyme-linked immunosorbent assay. The goal of the program is to enable battlefield detection for the full biological spectrum of bacteria, viruses, and toxins using a handheld device at or beyond laboratory performance standards.

Now we will shift to a discussion on other biological detection programs within DOD.

Other Biodefense Efforts Within DOD

In the medical field, the Department is fielding the Joint Biological Agent Identification and Diagnostic System, or JBAIDS. JBAIDS is an integrated system for rapid identification and diagnostic confirmation of biological agent exposure or infection. Based on commercial technology, JBAIDS is man-portable, reusable, and capable of the simultaneous identification of multiple biological warfare agents and other pathogens of operational concern. JBAIDS can identify biological agents in a variety of environmental and clinical samples at or below 1,000 colony-forming units or 10,000 plaque-forming units per milliliter. Its detection sensitivity exceeds 85 percent for identification of target agents at specified limit of detection concentrations, and its specificity exceeds 90 percent for identification of target agents at specified limit of detection concentrations.

I would also like to underscore the importance of anthrax detection programs within the Pentagon, such as our new mail screening facility. All mail entering the Pentagon is now screened within bio-safety cabinets in a newly renovated, negatively pressurized facility using extensive HEPA and charcoal filtration. Once mail is screened, samples are sent to an on-site laboratory to test for anthrax and other biological agent using specific DNA and antibody assays. To protect Pentagon employees and the mail screeners, mail is quarantined in an isolation facility

until results come back from the laboratory. Strict procedures ensure mail is not released before test results are returned. In the event of a positive result from the laboratory, mail will continue to be quarantined and proper notifications will be made to the U.S. Postal Service, Department of Homeland Security, Department of Health and Human Services, Environmental Protection Agency, and the White House. Samples will be sent accordingly for confirmatory testing to the U.S. Army Medical Research Institute of Infectious Diseases or another comparable laboratory.

Anthrax Vaccination Immunization Program (AVIP)

Finally, I want to provide you some information regarding the DOD Anthrax Vaccination program. To date, more than five and a half million doses of the vaccine have been administered to over 1.3 million personnel, and over 230,000 have received 6 or more doses.

In December 1997, the Secretary of Defense announced plans to begin vaccinating Service personnel deployed in high-threat areas against the BW agent anthrax. Vaccinations began in March 1998. The AVIP Agency was established in September 1998 to implement and monitor the DOD policy and Services' plans. Due to an unanticipated delay in release of FDA-approved vaccine, DOD slowed its implementation of the AVIP accordingly.

BioPort received approval of their Biologics License Application supplement from the FDA in January 2002, three anthrax vaccine production lots were released, and since then, many more have been released. DOD resumed the AVIP with a priority execution program, continuing with special-mission units, vaccinating forces in high threat areas and expanding vaccinations to early-deploying forces.

In October 2004, the U.S. District Court for the District of Columbia issued an Order declaring unlawful and prohibiting mandatory anthrax immunization to protect against inhalation anthrax, pending further Food and Drug Administration (FDA) action.

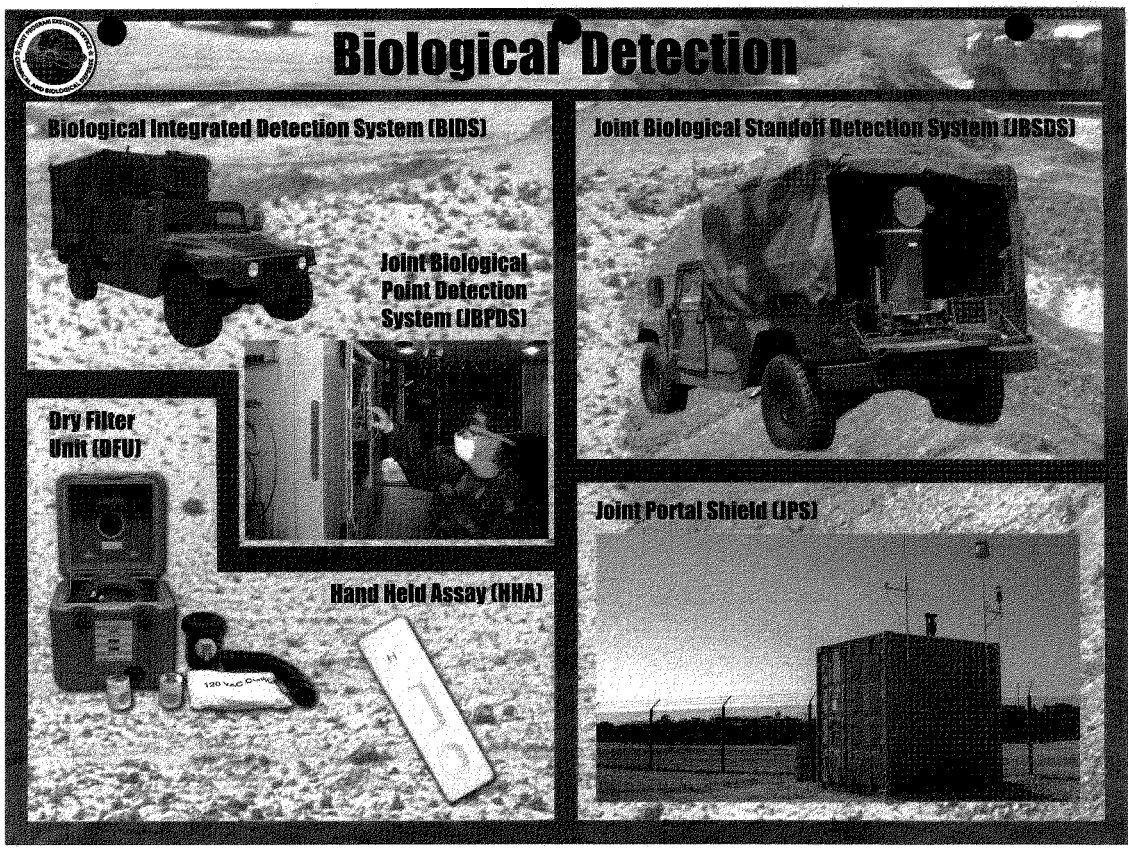
In January 2005, the FDA granted an Emergency Use Authorization (EUA) for anthrax immunization to prevent inhalation anthrax. In April 2005, the Court modified the injunction to allow anthrax immunization of designated personnel with an option to refuse. The option to refuse required that each service member eligible for immunization be informed that anthrax vaccine was offered under an EUA, provided facts about the vaccine and offered the option to decline immunization without adverse consequences to their military or civilian standing.

In April 2005, the Deputy Secretary of Defense directed the Department to resume anthrax immunizations under the conditions set forth in the EUA. The injunction against mandatory anthrax immunization continued in force. In July 2005, the FDA extended the term of the EUA until January 2006.

In December 2005, the FDA issued a new final order reaffirming its determination that anthrax vaccine is safe and effective for the prevention of anthrax disease, including inhalation anthrax. This action set the stage for further legal proceedings to clarify the legal status of the vaccine and for DOD decisions concerning the future course of the AVIP.

Final Remarks

In conclusion, I want to emphasize the Department's commitment to the development of rapid and effective detection technologies to mitigate the impacts of anthrax attacks upon our servicemen and women, and ensure their safety and well-being. We have many distinct technological challenges; however, we have been successful thus far to bolster our overall efforts in this prominent national security program, and to contribute to national homeland security needs. I welcome your comments on our program's progress, and look forward to working with you to advance our common goal to eliminate the dangers inherent in asymmetrical means of warfare such as chemical and biological weapons.


Biological Detection
Biological Integrated Detection System (BIDS)
Joint Biological Point Detection System (JBPDS)
Joint Biological Standoff Detection System (JBSDS)
Dry Filter Unit (DFU)
Hand Held Assay (HHA)
Joint Portal Shield (JPS)

JBAIDS

Joint Biological Agent Identification and Diagnostic System

Description
An integrated system for rapid identification and diagnostic confirmation of biological agent exposure or infection

Manufacturer
Idaho Technology Inc.

Capabilities
Reliable, fast and specific identification of biological agents from a variety of clinical and environmental sources to support and rapidly administer appropriate treatment with effective preventive measures and prophylaxis

Key Events
MS C/LRIP: Nov 04
IOT&E: Apr 05
First Unit Equipped: Sep 05

User
U.S. Army
U.S. Marines
U.S. Navy
U.S. Air Force

Regulatory Status
Submission of 510(k) to FDA for clearance to assist in medical diagnostics. Mar 05 (Anthrax)

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Mr. SHAYS. Thank you very much, Mr. Reed.
Dr. Parker.

STATEMENT OF GERALD W. PARKER

Dr. PARKER. Good afternoon, Mr. Chairman and subcommittee members. I am Gerald Parker, the Principal Deputy Assistant Secretary for Public Health Emergency Preparedness in the Department of Health and Human Services.

The events of October 2001 made it very clear that bioterrorism is a serious threat to our Nation and the world. Within HHS, the mission to prepare for and respond to the medical and public health consequences of this threat is coordinated by the Office of Public Health Emergency Preparedness. I will focus my remarks this afternoon on a critical component of HHS' medical and public health mission, medical countermeasure development, and acquisition to improve our preparedness to meet the threat posed by anthrax.

Development, acquisition, and deployment of safe and effective medical countermeasures to mitigate illness and prevent death in the event of an anthrax attack are top priorities for HHS. Among biological threat agents, anthrax is widely recognized as having the potential to cause catastrophic harm. Although much remains to be done, we have made substantive progress in building our Strategic National Stockpile from where it was pre-September 11th. Antibiotics are and remain a cornerstone of our anthrax response strategy, and their stockpiling demonstrates the dramatic improvements in our readiness.

Had I been in this position testifying before you before September 11th, I would have told you that we had begun to build our antibiotic stockpile. But we would have had fewer than 150,000 post-exposure prophylactic courses. By contrast, today we have a diverse and continually growing stockpile of medical countermeasures to respond to an anthrax attack. This is built on a comprehensive strategy that includes antibiotics, vaccines, and antitoxins. As our front-line response, we now have antibiotics to provide 60-day post-exposure prophylaxis for over 40 million people.

Second, we have acquired 5 million doses of a licensed anthrax vaccine, AVA, and we have begun to receive a second 5 million doses for which delivery will be completed within a year.

Third, we are aggressively developing a next-generation anthrax vaccine and have a contract to buy 75 million doses of this new vaccine.

Fourth, we can treat over 800,000 symptomatic anthrax patients with intravenous antibiotics.

And, fifth, we are increasing our stockpile of anthrax antitoxins to treat the toxemia associated with symptomatic anthrax disease.

This diverse portfolio of medical countermeasures is necessary for our preparedness strategy. Antibiotics, the front line of our defense, are FDA approved, proven effective, and relatively inexpensive.

Anthrax vaccines have the following benefits: One, they provide pre-exposure protection of individuals at increased risk of exposure to anthrax; two, they may provide additional protection in a post-exposure setting when used in combination with antibiotics and

could potentially reduce the currently recommended 60-day duration of antibiotic treatment; and, three, they provide relatively long-term protection when compared with antibiotics and would expand worker protection for remediation efforts after anthrax contamination.

HHS is also pursuing the acquisition of anthrax antitoxins to treat the toxemia that occurs as anthrax disease progresses. These antitoxins will be stockpiled as an adjunct to the antibiotic therapy for symptomatic patients.

I would now like to return to the subject of anthrax vaccine and briefly describe our next-generation anthrax vaccine program.

Today, this program to develop a next-generation anthrax vaccine represents both a development challenge and an opportunity to potentially enhance our preparedness for meeting the anthrax threat. In March 2004, the acquisition program for a next-generation anthrax vaccine based on recombinant protective antigen, a protein component of the anthrax toxin, was launched. This decision to move forward with an acquisition was based upon scientific consensus, including that of the Institute of Medicine, that a next-generation vaccine was necessary, and after two rounds of competitive milestone rPA anthrax vaccine development contracts at the National Institutes of Health and after the establishment of a requirement by the Interagency WMD Medical Countermeasures Subcommittee to acquire rPA anthrax vaccine for 25 million persons.

Utilizing a rigorous, technical, and business evaluation process that included experts from Government, industry, and academia, HHS reviewed multiple proposals received as part of a full and open competition and awarded an $877 million contract in November 2004 for the acquisition of 75 million doses of the vaccine to VaxGen of Brisbane, CA.

The contract requires the manufacturer to seek licensure for both pre-exposure and post-exposure use. The procurement anticipated a three-dose vaccination schedule for 25 million persons. In accordance with Project BioShield, no payment for product is made until a usable product is delivered to the Strategic National Stockpile.

In late 2005, VaxGen announced that it anticipated a delay in the delivery of the product to the stockpile. We are concerned about this delay, but confident that an rPA-based anthrax vaccine should reach its goal of licensure. HHS has recently modified the contract with VaxGen and established a new delivery schedule acknowledging this delay. We now anticipate up to a 3-year delay in delivery of the initial 25 million doses of rPA anthrax vaccine.

It is important to note that delays in accelerated development programs are not unexpected and unprecedented. For example, while our ACAM2000 smallpox vaccine program, which began prior to September 11th, experienced slippages in the project timeline, the program was ultimately successful and the Federal Government received full delivery of the product.

While awaiting delivery of the rPA vaccine, HHS has moved forward to meet immediate anthrax vaccine requirements through the acquisition of 10 million doses of AVA——

Mr. SHAYS. If you could summarize.

Dr. PARKER. I will be happy to answer questions, Mr. Chairman.

[The prepared statement of Dr. Parker follows:]

Testimony
Before the Committee on Government Reform
Subcommittee on National Security,
Emerging Threats, and International Relations
United States House of Representatives

Anthrax Preparedness: HHS Progress

Statement of
Gerald W. Parker, DVM, PhD, MS
Principal Deputy to the Assistant Secretary
Office of Public Health Emergency Preparedness
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00 p.m.
Tuesday, May 9, 2006

Good afternoon, Mr. Chairman, Mr. Kucinich and Subcommittee members. I am Gerald Parker, Principal Deputy to the Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services (HHS). I appreciate the opportunity to share with you information on the Department's efforts to improve our nation's preparedness for the threat of anthrax and to detail the substantial progress that has been made since the anthrax attacks of October 2001.

The events of October 2001 made it very clear that bioterrorism is a serious threat to our Nation and the world. Defending against threats such as anthrax is a top priority for the Bush Administration. The President made clear in his "Biodefense for the 21st Century" that the United States will continue to use all means necessary to prevent and protect against biological weapon attacks perpetrated against our homeland and our global interests. His policy provides a blueprint that integrates the sustained efforts of the national and homeland security, medical, public health, intelligence, diplomatic, and law enforcement communities. The essential pillars of the policy are: Threat Awareness, Prevention and Protection, Surveillance and Detection, and Response and Recovery. While HHS has a wide range of responsibilities in all domains, HHS has a leadership role in medical and public health missions.

I will focus my remarks this afternoon on critical components of HHS' medical and public health mission: Medical countermeasure development and acquisition

and specifically those designed to prevent and treat anthrax. I am pleased to have my colleague, Dr. Richard Besser, from the Centers for Disease Control and Prevention (CDC) here with me on the panel today and will defer to him to discuss other critical aspects of HHS' anthrax preparedness and response mission including surveillance and detection activities and coordination with State and local partners in the delivery and distribution of medical countermeasures. HHS and CDC are working closely with state and local public health officials on public health and bioterrorism preparedness and, including the FY07 budget request, has invested nearly $8 billion to States and territories through cooperative agreements since 2001.

The mission of the Office of Public Health Emergency Preparedness (OPHEP), in keeping with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Project BioShield Act of 2004 and the President's "Biodefense for the 21st Century" is far reaching and encompasses a myriad of responsibilities. My remarks this afternoon will focus on the progress we have made with the development and acquisition of Medical Countermeasures for the anthrax threat. However, it is important to recognize that public health threats and emergencies can ensue from multiple other causes, both naturally-occurring and man-made, and that many of the preparedness activities we are pursuing in OPHEP will have cross-cutting value. Bioterrorism preparedness is not an insular activity for HHS but rather a critical component integrated within an all-hazards readiness program. To ensure the synchronization of HHS' emergency

preparedness efforts, including the development and acquisition of medical countermeasures, OPHEP coordinates HHS-wide activities and serves as the principal point of contact at HHS for other Federal agencies and Departments.

Medical Countermeasure Development

Development, acquisition and deployment of safe, effective medical countermeasures to mitigate illness and death in the event of an anthrax attack are top priorities for HHS. Although much remains to be done, we have made substantive progress in building our Strategic National Stockpile from where it was pre-9/11to what we have available today. Antibiotics remain a cornerstone of our response strategy to anthrax and demonstrate the dramatic improvements to our readiness. In December 2000 we only had enough 60-day regimens to provide post-exposure prophylaxis for approximately 137,000 people. Today we could provide this antibiotic regimen to over 40 million individuals. The research, development and acquisition of an appropriate armamentarium of medical countermeasures is a critical element of the response and recovery component of the President's "Biodefense for the21st Century" and HHS leads these U.S. Government efforts and continues to make significant gains, particularly with regard to implementation of the Project BioShield Act of 2004 ("Project BioShield"). The acquisition and ready availability of medical countermeasures, such as antibiotics, antivirals, monoclonal and polyclonal antibodies against anthrax, and vaccines to protect against exposure are essential to our Nation's

preparedness and response capabilities in the face of the threat posed from anthrax.

Although anthrax is not transmissible from person-to-person, an attack involving the aerosol dissemination of anthrax spores, particularly in an urban setting, is considered by public health experts to have the potential to cause catastrophic damage. The potential for large-scale population exposure following aerosol release of anthrax spores, the threat demonstrated by the anthrax letters, and our knowledge that anthrax had been weaponized by state-actors, highlighted the nature of the threat. The Secretary of Homeland Security determined that anthrax poses a Material Threat to the Nation. Because untreated inhalation anthrax is usually fatal, the Secretary of HHS identified anthrax as a significant threat to public health.

The Strategic Approach to Addressing Medical Countermeasure Gaps

The initial focus of our efforts to protect the Nation was aimed largely at those threats that could do the greatest harm to the greatest number of our citizens. Among biological threat agents, anthrax is widely recognized as having the greatest potential to cause catastrophic harm. A sense of urgency has pervaded our efforts and we have defined new ways of doing business. Our new national security environment demands accelerated product development timelines and

new paradigms of interactions between industry and government with increased risk-sharing and enhanced intra-governmental collaboration.

Today we have a diverse and continually growing stockpile of medical countermeasures to respond to an anthrax attack. First, as our front line of response we have antibiotics to provide post-exposure prophylaxis for over 40 million people. Second, we have acquired 5 million doses of the vaccine anthrax vaccine adsorbed (AVA), and have recently modified the contract for 5 million additional doses within a year. Third, we are aggressively developing a next generation anthrax vaccine and have moved forward with the acquisition of 75 million doses. Fourth, we are increasing our stockpile of anthrax antitoxins to treat the toxemia associated with anthrax disease.

Developing, Acquiring and Deploying Priority Medical Countermeasures

The National Institutes of Health (NIH) is shaping and executing an aggressive biodefense research and development program to advance new and improved medical countermeasures, including next-generation vaccines and therapeutics for anthrax. Additionally, NIH supports the development of critical biodefense research infrastructure such as biocontainment facilities and the product development tools, such as animal models, required to demonstrate efficacy in support of a regulatory strategy toward Food and Drug Administration (FDA) approval. Most significantly, building on a substantial research base from the Department of Defense, the National Institute of Allergy and Infectious Diseases

(NIAID) in NIH has played a crucial role in the development of the next generation anthrax vaccine.

The Strategic National Stockpile (SNS), managed by CDC, contains large quantities of medicine and medical supplies to protect the American public in the event there is a public health emergency severe enough to exhaust local supplies or warrant specific medical countermeasures held only in the SNS. Portions of the SNS are configured in 50-ton, 12-Hour Push Packages that contain supplemental medicine and medical supplies designed to be deployed rapidly and used in mass casualty incidents. These packages can be delivered to any point in the country within 12 hours of a Federal decision to deploy. Each state is required to develop plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible in the event of a deployment SNS staff assist state and local planners with the receipt, staging, storage, distribution and dispensing of SNS assets. In the event of an anthrax attack the antibiotics, vaccines and antitoxins held in the Strategic National Stockpile, will be critical assets in efforts to mitigate loss of life and illness.

Project BioShield

The Project BioShield Act of 2004 (P.L.108-276) ("Project BioShield") is a critical part of a broader strategy to defend America against the threat of weapons of mass destruction. It provides HHS with several new authorities to speed the research, development, acquisition, and availability of medical countermeasures to defend against chemical, biological, radiological and nuclear (CBRN) threats.

In exercising the procurement authorities under Project BioShield, HHS has launched acquisition programs to address each of the four threat agents deemed to be Material Threats to the U.S. population by DHS [*Bacillus anthracis* (anthrax), smallpox virus, Botulinum toxins, and radiological/nuclear agents]. HHS has already used the Special Reserve Fund (SRF) to award two contracts for vaccines against anthrax, including a recent acquisition of 5 million additional doses of the licensed anthrax vaccine adsorbed (AVA) vaccine, and will soon acquire anthrax therapeutics for the SNS.

The focus on medical countermeasures for anthrax is a reflection of the priority that the threat of anthrax has been given by HHS. HHS is pursuing a comprehensive medical countermeasure strategy involving antibiotics, vaccines and antitoxins to address the threat of anthrax. We have already obligated over $1.1 billion for anthrax vaccines under Project BioShield and that investment will increase substantially once pending action on the anthrax therapeutics acquisition program is executed.

The FDA has approved antibiotics for post-event treatment of anthrax exposure, and these antibiotics are at the front line of our comprehensive preparedness strategy. During FY 2004 and 2005, CDC purchased a large number of anthrax antibiotics and the SNS now holds enough to provide 60-day regimens for post-exposure prophylaxis to approximately 41.5 million people. In addition, the SNS

holds intravenous antibiotics to treat approximately 831,000 symptomatic anthrax patients.

HHS is also pursuing the acquisition of therapeutic antitoxins to treat symptomatic anthrax patients. Neither vaccine nor antimicrobials are able to treat the toxemia that occurs as anthrax disease progresses. Thus, despite the current supply of antimicrobials in the SNS, and current and ongoing acquisitions for anthrax vaccines, an important gap remains in our defensive strategy against anthrax. An additional gap in our defensive strategy against anthrax is the lack of an intervention against an anthrax strain engineered to be resistant to currently available antimicrobials. To address these gaps, HHS has been pursuing acquisition of immune-based products that target the anthrax toxins, as well as other novel antitoxin interventions, that will be stockpiled as an adjunct to the antibiotic therapy for symptomatic patients. A Request for Proposals for acquisition of such products was released in 2004 and awards will be made in 2006. In addition, NIH continues to support the development of these medical countermeasures and future requirements for these products are being considered by the WMD Medical Countermeasures Subcommittee based on a material threat assessment conducted by DHS and the results of medical consequence modeling.

In addition to these anthrax medical countermeasures, anthrax vaccines are also being pursued by HHS. Anthrax vaccines are useful in certain conditions:

- They provide pre-exposure protection of individuals at increased risk of exposure to anthrax, such as laboratory workers, manufacturers and product development workers, and certain first responders.
- They potentially provide additional protection in a post-exposure setting, when used in combination with antibiotics, and as a strategy to potentially reduce the currently recommended 60-day duration of antibiotic treatment. This extended duration of antibiotic treatment poses formidable compliance challenges.
- They provide protection in the event of antimicrobial resistance.
- They provide relatively long-term protection and enable worker re-entry into areas that have been exposed to anthrax spores, for example by remediation workers.

Due to limitations inherent in the currently available anthrax vaccine, there is consensus in the scientific community about the need to develop and acquire a next-generation anthrax vaccine using 21st century technologies. An assessment of developing technologies was undertaken by HHS experts in the fall of 2001 and the decision was made that there was a sufficient scientific foundation, including a detailed understanding of the pathogenesis of anthrax and how anthrax vaccines provide protective immunity, to support the aggressive development of a next generation vaccine consisting of recombinant protective antigen (rPA). The research undertaken to develop this vaccine, spanning more

than a decade, was conducted in large part by the United States Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland. The urgency of the need for a next-generation vaccine with improved manufacturing processes that would enable more robust characterization and consistency was also articulated in a 2002 Institute of Medicine report.

HHS defined a three-stage development and acquisition strategy with open competition for awards at each stage. The early and advanced development programs were supported by the National Institute of Allergy and Infectious Diseases (NIAID) with contract awards in September 2002 and 2003, respectively. These were milestone-driven contracts with well-defined deliverables including the manufacture of clinical-grade vaccine, the conduct of Phase I and Phase II clinical trials, and consistency lot manufacturing of vaccine. Large-scale manufacturing capacity would be required to support the civilian requirement for this medical countermeasure, which was defined by the WMD Subcommittee to be the initial protection of up to 25 million persons. Senior officials from several Departments of the USG evaluated acquisition options to achieve this requirement and, in the fall of 2003, approved the decision to pursue the acquisition of rPA anthrax vaccine.

An evaluation of the NIAID rPA anthrax vaccine development program indicated that it was robust enough to suggest that the rPA vaccine could become a licensed product within 8 years. In March 2004, the acquisition program for this

vaccine, under the direction of my office, was launched using the Special Reserve Fund created in the FY 2004 DHS appropriations bill. Utilizing a robust technical and business evaluation process, we reviewed multiple proposals and negotiated a contract for the acquisition of 75 million doses of the vaccine (anticipating a three-dose regimen). Using a milestone and deliverables approach similar to the ACAM2000 smallpox vaccine development and acquisition program, and the rPA anthrax vaccine development contracts at NIAID, the rPA vaccine BioShield acquisition contract lays out an ambitious program for the production of this vaccine. In accordance with Project BioShield, a critical aspect of this acquisition contract is the fact that no payment for product is made until a usable product is delivered to the SNS. On November 1, 2005, VaxGen announced that it anticipated beginning delivery of its rPA anthrax vaccine to the U.S. Government in the fourth quarter of 2006. The company had previously planned to initiate deliveries during the first half of this year. HHS has recently modified the contract with VaxGen and established a new delivery schedule. We now anticipate initial delivery by late 2008 and completion of the delivery of 25 million doses of the rPA anthrax vaccine to the SNS no later than October 2009. Delays in accelerated development programs are not unexpected or unprecedented. For example, while ACAM2000 smallpox vaccine program experienced slippages in the projected timeline, the program was ultimately successful, the Federal government received the full delivery required under the contract, and the nation is now better prepared.

HHS maintains a commitment to develop a next-generation rPA anthrax vaccine. In addition to this acquisition contract, HHS continues, through the National Institute of Allergy and Infectious Disease (NIAID), to support funding for rPA anthrax vaccine development with contracts to VaxGen, Inc. and Avecia Biotechnology

While awaiting delivery of the rPA anthrax vaccine to the SNS, HHS has moved forward to meet immediate anthrax vaccine requirements through the acquisition of 10 million doses of AVA under the Project BioShield authorities. A contract for 5 million doses was awarded in May 2005. Delivery of this product to the SNS began soon after contract award and was completed in February 2006. Last week, HHS modified the contract and purchased an additional 5 million doses of AVA for the Strategic National Stockpile, increasing our total investment in AVA to $243 million.

Conclusion

In closing, I must re-emphasize that amongst the list of potential threats, we all recognize anthrax as a top priority. HHS efforts and investments in the 4½ years since the anthrax attacks in the fall of 2001 reflect that priority. Our investments and efforts have done much to improve our preparedness and strengthen our response capabilities. We will continue to develop our strategic approach to further combat this threat. HHS and its agencies including NIH, CDC, and FDA,

have a clear mandate from President Bush and Congress to continue to lead the charge in this arena. We have already made important strides and will continue to work to address the obstacles identified. Mr. Chairman, I look forward to working with you and members of the Subcommittee to address the challenges of anthrax preparedness.

I will be happy to answer any questions you may have.

Mr. SHAYS. Thank you. What a great way to move forward here.

Dr. Besser, thank you. And these are very helpful statements. They are on the record, and I think our questions will——

STATEMENT OF RICHARD E. BESSER, M.D.

Dr. BESSER. Good afternoon, Chairman Shays and members of the subcommittee. Thank you for the opportunity to be here. I am Dr. Richard Besser, Director of the Centers for Disease Control and Prevention's Coordinating Office for Terrorism Preparedness and Emergency Response. With me today is Mr. Max Kieffer, a scientist from CDC's National Institute for Occupational Safety and Health, who is directly involved in our anthrax detection activities. I am pleased to provide this testimony to update you on CDC's efforts to improve the Government's ability to accurately detect anthrax inside a building.

As part of the Department of Health and Human Services, CDC's responsibility is to provide national leadership in the public health and medical communities in a concerted effort to prevent, detect, diagnose, and respond to injury and illnesses, including those that occur as a result of a deliberate release of biological agents.

CDC collaborates and coordinates closely with the Department of Health and Human Services, the Department of Homeland Security, the Department of Defense, and the Environmental Protection Agency, among others.

CDC and HHS are preparing the Nation to respond to a wide range of threats to public health whether natural disasters or acts of terrorism. We are strengthening the State and local public health infrastructure, expanding lab capacity, stockpiling life-saving countermeasures for use in emergencies, and deploying CDC staff to respond to public health emergencies and other events.

CDC has made considerable improvements in a number of areas that contribute to anthrax detection. I will focus my remaining time on three specific topics: environmental sampling strategies, validating sampling protocols, and laboratory capacity building.

During the response to the 2001 anthrax attacks, CDC relied on targeted sampling strategies to determine where environmental samples should be collected within buildings. Incident-specific details such as epidemiologic data, interviews with U.S. Postal Service Personnel, and understanding of the mail-handling process were used to help identify locations considered most likely to be contaminated so that environmental samples could be collected at targeted locations within a facility.

CDC continues to believe that a targeted sampling strategy is the most rapid, efficient, and successful approach when information is available on the path and/or the vehicle of introduction of the suspect infectious agent. However, CDC agrees that there is a need to further develop probabilistic sampling approaches to provide additional sampling strategy tools that may be appropriate in certain circumstances. Toward this end, CDC recently initiated a project with the Department of Energy's Pacific Northwest National Laboratory to use the lab's "Visual Sample Plan" software tool as a platform for this approach. This project will result in the creation of a sampling tool that will be available to field investigators to

guide them through the steps needed to perform probabilistic sampling and to manage the documentation for the sample.

Detecting anthrax in buildings depends on having reliable, trusted sampling protocols. Validation of sampling protocols is an important objective, and we continue to support efforts to validate components of the detection process. CDC researchers have undertaken several laboratory studies evaluating methods for recovering and extracting Bacillus anthracis spores. In addition, CDC continues to support research to evaluate environmental sampling methods for Bacillus anthracis in collaboration with other Federal agencies. CDC is funding research that is underway at the U.S. Army's Dugway Proving Ground in Utah with the goal of improving environmental sampling methods, determining limits of detection, and evaluating inter-lab variability.

Another collaboration is between CDC and EPA with the Sandia National Laboratories in New Mexico on a study funded by DHS to evaluate current surface sample and extraction methods. The work has been completed, and our first publication is in peer review.

Detecting anthrax in buildings, however, is contingent on having laboratories with diagnostic capacity. The Laboratory Response Network is a national network of hospitals, State and local public health, Federal military, veterinary, agriculture, food, and environmental testing laboratories that provide diagnostic capacity to respond to biological and chemical terrorism and other public health emergencies. We have expanded our ability to analyze more environmental samples given additional LRN capacity building since 2001. Currently, 87 percent of the U.S. population resides within 100 miles of a Laboratory Response Network laboratory. All funded LRN laboratories have the capacity to test for Bacillus anthracis.

The LRN recently developed a new technique that permits testing for multiple-threat agents simultaneously, which saves time and frees up laboratory testing capacity. This is particularly important when dealing with credible threats involving unknown infectious agents. The Laboratory Response Network also has made advances in electronic data exchange to facilitate the rapid communication of laboratory test results in an emergency situation.

In conclusion, CDC has made many advancements in the past year. Our ability to detect anthrax has improved in a number of ways. As a result of research and planning activities, we now have better information to guide us. CDC has learned a lot since the anthrax attacks of 2001 about sampling and analysis of anthrax, and we continue to learn more so that our response to future incidents will be as fast and effective as possible.

Mr. Chairman, this concludes my oral testimony. I would be happy to answer questions.

[The prepared statement of Dr. Besser follows:]

Testimony
Before the Committee on Government Reform
Subcommittee on National Security, Emerging Threats, and International Relations
United States House of Representatives

Update on Anthrax Detection Methods

Statement of
Richard E. Besser, M.D.
Director
Coordinating Office for Terrorism Preparedness and Emergency Response
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 2:00PM
Tuesday, May 9, 2006

Good afternoon, Chairman Shays and members of the Subcommittee. I am Dr. Richard Besser, Director of the Coordination Office for Terrorism Preparedness and Emergency Response (COTPER) at the Centers for Disease Control and Prevention (CDC). On behalf of CDC, I am pleased to provide this testimony to update you on our efforts to improve the government's ability to accurately detect anthrax inside a building.

CDC is part of the Department of Health and Human Services (HHS). CDC's responsibility is to provide national leadership in the public health and medical communities in a concerted effort to detect, diagnose, respond to, and prevent injury and illnesses, including those that occur as a result of a deliberate release of biological agents.

CDC and HHS are preparing the nation to respond to a whole range of threats to public health whether natural disasters or acts of bioterrorism. We are strengthening the state and local public health infrastructure, expanding lab capacity, stockpiling life-saving countermeasures for use in emergencies, and deploying CDC staff to respond to public health emergencies and other events. Based on CDC's experience in the anthrax attacks of 2001, we have developed and made available on our Web site[1] a wealth of information about anthrax for workers, responders, clinicians, citizens and others. It includes information about symptoms, transmission, prevention and treatment among other topics. This

[1] CDC, Emergency Preparedness & Response: Anthrax, http://www.bt.cdc.gov/agent/anthrax/

information is updated as new scientific information becomes available, and after a recent incident in which a New York City resident was exposed to anthrax while handling animal hides, CDC added new information about the potential risk from such activities.

In April 2005, CDC provided testimony before this Subcommittee describing CDC's response to the anthrax attacks of 2001 and subsequent efforts to improve techniques for conducting environmental sampling to detect anthrax and laboratory analysis to confirm its presence. My testimony today will provide an update on CDC's activities since that hearing to enhance environmental sampling and lab analysis methods.

CDC's Unique Expertise in Environmental Microbiology

CDC continues to play a unique role in environmental microbiology, developing faster and more accurate assays to detect infectious agents, providing accurate assessments of health risks from these agents in the environment, and providing technical input on re-occupancy issues. Most federal, state, and local public health agencies have limited experience planning and implementing the collection and testing of environmental samples or in studying the physical characteristics of pathogens in the environment. CDC's central role in the detection and containment of public health emergencies of federal importance establishes its key role in the integration of environmental microbiology into outbreak investigations and emergency response.

As discussed during our testimony before this panel in April 2005, method validation for microbial agents is technically challenging, involving extensive and repetitive tests to verify collection efficiencies, recovery efficiencies, effects of storage, temperature and other factors, and for various combinations of methods at various test concentrations. This process is further complicated when working with select agents.

There is enormous demand for services and better and faster ways to detect microbial threats in the environment – due to terrorism, molds in buildings, and emerging infectious disease threats – and, there is a proliferation of sampling devices nationally, both in the community (BioWatch) and in facilities (U.S. Postal Service Biological Detection Systems).

In the process of developing environmental microbiology priorities, CDC arranged for external peer review of the priorities identified by a CDC environmental microbiology working group to ensure that CDC received important objective scientific feedback. The May 10, 2005, external peer review meeting, titled *Enhancing Environmental Microbiology at CDC*, which included a panel of ten reviewers, resulted in unambiguously favorable feedback on the objectives that had been outlined for the program. All individual reviewers expressed support for the concept that environmental microbiology research, as a component of CDC's preparedness activities, is consistent with the CDC

mission to protect public health. Aditionally, all reviewers responded that CDC should enhance its capabilities and expand partnerships in environmental microbiology. One of the three key focus areas identified for CDC's expanded environmental microbiology program is the identification of priority agents, which includes developing rapid and effective sampling strategies and sensitive methods of recovery from the environment. The other two focus areas relate to determining the risk of infection and developing techniques and procedures to reduce risk.

Improving Environmental Sampling Strategies

During the response to the 2001 anthrax attacks, CDC relied on targeted (also known as epidemiologically driven) sampling strategies to determine where environmental samples should be collected within buildings. Incident-specific details such as epidemiologic data, interviews with U.S. Postal Service personnel, and understanding of the mail handling process, were used to help identify locations considered most likely to be contaminated so that environmental samples could be collected at targeted locations within a facility. CDC continues to believe that a targeted sampling strategy is the most rapid, efficient, and successful approach when information is available on the path and/or the vehicle of introduction of the suspect infectious agent.

However, as noted in testimony at the April 2005 hearing, CDC agrees that there is a need to further develop probabilistic sampling approaches (i.e. using random

sampling and statistical inferences) to provide additional sampling strategy tools. In 2005, CDC developed and funded a project titled *Developing a Probabilistic Sampling Tool Kit for Initial Response Sampling*, which began in early 2006, to directly address this need. Under this project, CDC is partnering with the Department of Energy's Pacific Northwest National Laboratory (PNNL) to use the lab's "Visual Sample Plan" (VSP) software tool as a platform for this approach. The VSP software facilitates importing facility floor plans, and it assists investigators with overlaying a grid on facility surfaces for selection and tracking of random sampling locations. This project will result in the creation of a sampling tool kit that will be available to field investigators to guide them through the steps needed to perform probabilistic sampling and to manage the documentation for the sampling. As noted by the Government Accountability Office (GAO), this supplemental approach is appropriate in certain circumstances where targeted sampling results were negative and where statistical inferences and random sampling approaches are needed to increase confidence that contamination is not likely to be present.

CDC is coordinating with the Environmental Protection Agency (EPA) as the project develops to ensure that the sampling strategy platform and software developed for initial assessment can then be handed off for subsequent use by EPA and others involved with facility remediation and restoration efforts. The goal is to design the probabilistic sampling tool kit it to support further

customization by EPA to incorporate probabilistic sampling features that can be used with characterization and clearance sampling.

Improving and Validating Sampling Protocols

CDC agrees that validation of sampling protocols is an important objective, and we continue to support efforts to validate components of the detection process. As stated at the April 2005 hearing, CDC continues to believe that full validation of every possible scenario would be impractical and could not take the place of scientific judgment and evaluation of the specific event. Recent, CDC developments related to improving testing protocols are as follows:

Laboratory Studies

CDC researchers evaluated a protocol to recover *Bacillus anthracis* spores using macrofoam swabs. The resulting study, currently pending publication, evaluated the accuracy, precision, reproducibility, and limit of detection associated with the removal of spores from a steel surface using the macrofoam swabs.

CDC researchers evaluated the recovery of *Bacillus anthracis* spores from a smooth non-porous surface using rayon/polyester gauze wipes. The study, which is expected to be presented later this month, evaluated the accuracy, precision, reproducibility, and limits of detection of this recovery method. The study is part of an ongoing effort to evaluate various wipe sampling materials.

CDC researchers examined the effects of different sample filter material and extraction methods on environmental air sampling results for *Bacillus subtillis* spores used as a *Bacillus anthracis* simulant. This research found that MCE (3 micron pore size mixed cellulose ester) and PTFE (1 micron pore size polytetrafluoroethylene) filters in combination with lab procedures to vortex (spin) and shake the samples to extract the spores demonstrated the best performance. A peer reviewed journal article was published on this topic in 2005.[2]

Laboratory Response Network Enhancements

The Laboratory Response Network (LRN) is a national network of hospitals, state and local public heath, federal, military, veterinary, agriculture, food and environmental testing laboratories that provide diagnostic capacity to respond to biological and chemical terrorism and other public health emergencies. The LRN recently developed a multiplex technology (via the BioPlex instrument) which uses PCR (polymerase chain reaction) for nucleic acid detection and amplification to detect DNA from 8 agents (including *Bacillus anthracis*) in a single test—hence the name multiplex. The assay has been optimized for use with environmental samples and will soon be used by the Department of Homeland Security's (DHS) BioWatch Program. The BioPlex procedure goes beyond the currently used standard PCR approach that usually detects only a

[2] Burton, N.C, Grinshpun, A.A., and R. Hornung. 2005. The effect of filter material on bioaerosol collection of Bacillus subtilis spores used as a Bacillus anthracis stimulant, J.Environ. Monit. 2005 May; 7(5):475-80.

single product that is specific for one target agent. Using the multiplex approach, multiple threat agents can be tested for simultaneously in a single reaction vial, saving time and freeing up laboratory testing capacity. This is particularly important when dealing with credible threats involving "unknown" infectious agents. These lab-based detection assays will be linked to the improved sampling methods, which are being developed by CDC in collaboration with interagency partners. The updated protocols will be made available on the LRN's secure Web site, which serves more than 1900 end-user scientists and counter-terrorism coordinators.

The LRN also has made advances in electronic data exchange to facilitate the rapid communication of laboratory test results in an emergency situation through the development and deployment of the LRN Results Messenger. This information technology application uses vocabulary standards and specific security measures to support secure bi-directional transmission of data from an LRN member to the CDC. Further guidance has been provided to LRN members through related notification and data messaging policies, which define the types of data that are required to be submitted to CDC and the timeline for submission.

Collaborative Studies

CDC continues to support research to evaluate environmental sampling methods for *Bacillus anthracis* in collaboration with other Federal agencies.

Dugway Study

CDC is funding research that is underway at the U.S. Army's Dugway Proving Ground in Utah to improve environmental exposure sampling methods. This study uses three surface concentrations and three air concentrations of *Bacillus anthracis (Sterns strain)* and will allow for estimates of the lower limits of detection for the sampling methods. The work is conducted in a chamber specifically designed for aerosol studies and is designed to:

a) Determine the efficiency of three surface sampling methods (wet swab, wet wipe, and surface vacuum filter sampling) on two types of surfaces (stainless steel and carpet);
b) Determine the efficiency of three air sampling methods (Andersen single stage impactor, PTFE (Teflon) filters, and gel filters);
c) Determine the overall precision of the methods, encompassing sample collection, sample extraction, and sample analysis;
d) Determine intra-lab variability and sample transport factors; and
e) Determine the additional sampling collection efficiency of passing over a surface multiple times.

The research is well underway, and a journal article has been drafted which presents information on how the chamber operates and the uniformity of spore deposition in the chamber.

Sandia Study

CDC and EPA are collaborating with the Sandia National Laboratories in New Mexico on a DHS-funded effort to evaluate current surface sample and extraction methods. The study evaluates current surface sample and extraction methods. The purpose of the testing was to:

a) Determine the efficiency of three surface sampling methods (wet swab, wet wipe, and surface vacuum filter sampling) on four types of surfaces (2 non-porous - stainless steel and painted wallboard; and 2 porous – carpet and bare concrete);
b) Determine the overall collection efficiency of the methods, encompassing sample collection, sample extraction, and sample analysis; and
c) Determine if collection efficiencies are a function of the concentration of spores on the surface being tested.

All of this work was completed in 2005, and the first publication on swab sampling efficiencies is currently in peer review. Two separate publications are being prepared on the evaluations of wipes and vacuum methods.

Coordination and Collaboration

Inter-agency communication is important given the shared responsibilities that CDC maintains with EPA, FBI, DOD, and others. CDC participated in and co-sponsored a number of meetings over the year to coordinate on sampling issues.

These include: a June 13-14 Airport Preparedness Workshop in Livermore, California; and a July 19-20, 2005 meeting on "Sampling Strategies for Building Decontamination" hosted by EPA at Research Triangle Park, North Carolina; and a more recent EPA "Decontamination Workshop" in Washington, D.C. on April 26-27, 2006. CDC and EPA coordinated closely on environmental sampling during the recent New York City anthrax case involving the handling of contaminated animal hides. CDC is currently planning to host a summer 2006 meeting in Atlanta to further discuss sampling issues. CDC is also involved in planning for the October 2006 Second Annual National Conference on Environmental Sampling and Detection for Bio threat agents in New York City. Staff from CDC and EPA's National Homeland Security Research Center (NHSRC) recently met to review their respective environmental microbiology programs, share information, identify common interests and goals, and enhance collaboration inter-agency efforts. This meeting included discussions of sampling and validation issues.

In addition, the LRN helped establish and actively participates in the DHS-sponsored Integrated Consortium of Laboratory Networks (ICLN), which was officially convened in April 2005 by interagency Memoranda of Understanding involving collaboration with ten other federal partners. Current partners include the Departments of Agriculture, Commerce, Defense, Health and Human Services, Homeland Security, Interior, Justice, State, and EPA. The ICLN is an important new program for integrating activities between existing and developing

domestic laboratory networks, including the LRN, in order to identify and address gaps that are not currently being addressed by any of the member networks individually and to better define the roles of the networks for each phase of response in order to improve coordination among federal agencies.

Related Efforts

- CDC developed and funded a project in 2005 titled *Assessment of State of the Art Environmental Sampling Methods for Priority Biological and Chemical Terrorist Agents*. The purpose of this project is to: (1) develop a template and database for identifying, organizing, and evaluating information on existing environmental sampling methods for a given agent; and (2) to use the template to collect available information for *Bacillus anthracis* and for the chemical agent sarin. The template categorizes available methods into four validation status categories. Once the project is completed, the results will be shared and evaluated and the approach finalized so that it can be used for systematically gathering information on other priority agents.
- CDC is partnering with Defense R&D Canada Suffield and the Technical Support Working Group (TSWG), and the Federal Protective Service (FPS) to improve understanding of how contamination is spread in the scenario involving the opening of a letter containing anthrax spores. The results will be used to objectively assess guidelines for minimizing the

exposure risk to both a person opening a letter and to other persons in the vicinity.

- CDC is partnering with the U.S. Army Edgewood Chemical and Biological Center, the FBI, and EPA and to evaluate the risks of re-suspension of *Bacillus anthracis* spores from the outsides of retrieved letters known to be cross-contaminated from the events of 2001. The results will be used to improve understanding of the risks of cross-contamination.

Conclusion

Robust environmental microbiology capabilities are essential for detecting and analyzing anthrax and other pathogens in the environment so that they can be quickly characterized, which permits public health officials to react appropriately, law enforcement officials to initiate timely investigations and for environmental officials to properly remediate contaminated surfaces. CDC has learned a lot since the anthrax attacks of 2001 about sampling and analyzing for anthrax, and we continue to learn more so that our response to future incidents will be as fast and effective as possible.

This concludes my testimony. I would be happy to answer any questions you may have.

Mr. SHAYS. Thank you, Dr. Besser.
Dr. George.

STATEMENT OF S. ELIZABETH GEORGE

Dr. GEORGE. Good afternoon, Chairman Shays and distinguished members of the subcommittee. It is a pleasure to be with you today to discuss the role of the Department of Homeland Security Science and Technology Directorate in protecting our Nation against the biological threat, to include anthrax.

Today I will provide comment in the context of the March 2005 GAO report concerning anthrax detection. DHS concurs with the GAO that the use of stratified sampling strategies is an appropriate approach. The GAO investigation prompted valid recommendations, of which DHS has made significant progress. DHS has taken a lead role in promoting and coordinating the activities of various agencies that have technical expertise related to environmental sampling. DHS has adopted the ISO9000 definition of "validation." DHS has developed a process to standardize and validate methods. DHS has invested both in targeted and probabilistic sampling strategies, as well as methodologies that are appropriate for facility monitoring, and DHS has prioritized investments for high-risk biological agents through internal and interagency coordination.

Now, please let me briefly describe some of the supporting activities in surveillance, restoration, interagency coordination, and validation that illustrate our accomplishments.

In 2003, BioWatch, our national environmental monitoring system, was deployed, in partnership with CDC, EPA, and the FBI, to more than 30 major U.S. cities, and it continues its operation today. The BioWatch Preparedness and Response Guidance Document, which has a significant sampling component for incident characterization, was developed through a collaborative DHS, CDC, EPA, and FBI effort. The current revision will provide detail on indoor sampling strategies and techniques and will be tailored for specific agents.

DHS recently completed a facility restoration research and demonstration program in partnership with EPA, CDC, and others. In the program we developed a general restoration plan for an international airport. The restoration plan provides a detailed description of sampling strategies and currently is being implemented in partnership with the Washington Metropolitan Area Transit Authority and the New York City Metropolitan Transportation Authority. DHS has invested in several additional R&D efforts to significantly improve sampling capability within the context of surveillance and restoration.

The DHS S&T completed sampling efficiency studies this year. Last year, DHS developed an electronic data collection and data management tool that assists in gathering samples and annotates the process of merging field data with laboratory results. Also, DHS through TSWGs sponsored the development of the Visual Sample Plan module for statistically sampling buildings.

DHS has been proactive in leading and coordinating interagency efforts associated with biological detection and restoration. DHS led the formulation of an MOU to integrate and standardize the Na-

tional Biomonitoring Systems and current is implementing the MOU actions with interagency partners. Through an MOA with multiple Federal agencies, DHS is leading an effort to establish an integrated consortium of laboratory networks to develop laboratory standards and surge capability. DHS is co-chairing with EPA the Subcommittee on Decontamination Standards and Technology. The subcommittee is charged to facilitate the development of consistent guidelines and strategies to address decisionmaking regarding decontamination after a chemical or biological incident.

In fiscal year 2005, DHS, in collaboration with NIST, took the first steps to prioritize and initiate the development of standards related to biological sampling activities by standardizing and validating a method by which hazardous materials technicians collect, transport, and store suspicious powder samples. This fiscal year, DHS, in collaboration with our interagency partners and the private sector, will develop, evaluate, validate, and make available an assay set for use by the private sector that develops commercial, off-the-shelf biodetection technologies.

The March 2005 GAO report focuses on the statistical confidence associated with environmental sampling strategies and methodologies, and DHS has made significant progress in addressing each of the GAO recommendations. Sampling is an integral part of a larger system and, thus, the requirements generated for sampling performance and method selection should be within the context of the overall system to provide for higher confidence decisions in a realm of uncertainty.

Chairman Shays and distinguished members of the subcommittee, I again thank you for this opportunity to have testified before you and am happy to answer any questions that you may have.

[The prepared statement of Dr. George follows:]

STATEMENT FOR THE RECORD

of

Dr. S. Elizabeth George
Deputy Director, Biological Countermeasures Portfolio
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Regarding a Hearing Entitled

"Anthrax Protection: Progress or Problems"

Before the
U.S. House of Representatives
Committee on Government Reform
Subcommittee on National Security, Emerging Threats, and International Relations

May 9, 2006

INTRODUCTION

Good afternoon, Chairman Shays, Ranking Member Kucinich, and distinguished members of the Committee. It is a pleasure to be with you today to discuss the role of the Science and Technology Directorate (S&T) of the Department of Homeland Security (DHS) in detection of various biological threat agents, specifically anthrax.

As this committee and many of our Nation's leaders recognize, the threat of a biological attack is a very real and grave concern. Advancements in science and technology play a vital role in protecting our Nation from such an attack. We, DHS S&T, are committed to developing robust technologies and processes to more effectively and accurately detect the presence of anthrax and other biological threat agents both within buildings and the outdoor environment.

The anthrax attacks of 2001 left a wave of fear and disruption in their path and made our Nation and government realize that a more concerted effort was needed to prevent future impacts, more effectively manage the consequences of such an event, and mitigate their impact. The various components of the newly formed Department of Homeland Security assumed this challenge and took a broad systems wide approach to the problem that, among other outcomes, determined that earlier attack warning translated into saved lives. While ideally an attack will be detected and interdicted prior to its execution, we must be prepared to both detect and respond appropriately and expeditiously so that we can protect our people, economic base and critical infrastructures. Environmental sampling is a key, far-reaching component for the detection and surveillance of biological threat agents, the incident characterization subsequent to the release, and validation that a contaminated area has been successfully remediated. Therefore, environmental detection and sampling for biological threat agents has an integral and crucial role in our overarching national biodefense strategy. In the President's *Biodefense for the 21st Century* (Homeland Security Presidential Directive 10), DHS is charged to develop, in coordination with other applicable Federal departments and agencies, an integrated and comprehensive attack warning system that rapidly recognizes and characterizes the dispersal of biological agents in human and animal populations, food, water, agriculture, and the environment. Furthermore, DHS as been designated as the lead Federal agency, in coordination with other appropriate Federal departments and agencies, to protect critical infrastructures, and will therefore work to develop and deploy biodetection technologies and decontamination methodologies. Additionally, HSPD-10/NSPD-33, the President's *Biodefense for the 21st Century*, assigns DHS to act in an integral supporting role with EPA, who has the overall lead in decontamination.

DHS has been actively addressing these issues and has made significant progress. Highlights to be presented in this testimony include:

- Biological surveillance and detection, including facility biomonitoring, incident characterization, and associated technology improvements
- Restoration of biologically contaminated facilities, highlighting partnerships with transportation hubs, as well as other local, state, and Federal agencies

- Leadership and coordination of interagency efforts for surveillance, detection, and restoration
- Standards development and validation
- Progress towards the actions recommended by the Government Accounting Office (GAO) in their March 2005 report, "*Anthrax Detection: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results.*"

In addition to its own expertise, DHS leverages resources of many other Federal departments and agencies. The Department of Defense (DoD) has had a robust biodefense program for many years and currently operates biodetection systems at several military installations. Following the 2001 anthrax attacks, the United States Postal Service (USPS) instituted their Biohazard Detection System (BDS) throughout components of the postal system. The Department of Health and Human Services' (DHHS) Centers for Disease Control and Prevention (CDC) provides medical response and public health guidance and protocols, while the Environmental Protection Agency (EPA) has extensive experience in remediation and associated methodologies, and the Department of Justice (DOJ) Federal Bureau of Investigation (FBI) is responsible for the criminal and forensic investigations. This list, which is not meant to be inclusive, demonstrates the depth and breadth of the national effort and the need for coordination and standards.

BIOLOGICAL SURVEILLANCE AND DETECTION

Five years ago, the Federal government did not have a concerted, national surveillance effort for the detection of biological threat agents. Scenario driven systems studies have demonstrated that early detection of an attack will result in expedited medical intervention. DHS, in partnership with other agencies, has made several significant investments to provide biological protection to our nation's population:

- BioWatch, an environmental monitoring system that helps provide the earliest possible warning of a biological attack
- Biological Warning and Incident Characterization System (BWIC), an integrated civilian decision support system which aids local decision makers in interpreting the public health and national security significance of any BioWatch detection events

In 2003, BioWatch was deployed to approximately thirty major US cities and continues its operation today. BioWatch is led and funded solely by DHS, and is operated through close partnership with CDC, EPA, and FBI. Due to the immediate strategic national need to rapidly deploy the first BioWatch system, existing technologies and capabilities were chosen to fulfill this first generation (Gen 1) effort. Gen 1 was deployed to focus on detection of moderate to large aerosol releases of a biothreat agent. The requirement to provide increased environmental monitoring coverage to transportation hubs and critical facilities is being addressed through the second generation deployment of this system (Gen 2). However, the vision always has been to provide a still more affordable, fully integrated system with a shorter detection window and increased agent detection

capability. This vision is being realized through development and deployment of the third generation (Gen 3) system.

BioWatch Generation 1: The Gen 1 system works to provide distributed aerosol collection capabilities coupled with centralized laboratory analysis for a limited number of threat agents. This system is operated by the local environmental and public health staff and in essence, any results are owned by the local public health officer as they have responsibility for the local public health response.

BioWatch Generation 2: The Gen 2 system enhancement focuses on providing three to four fold increases in the number of collection sites, including the placement of collectors in key transportation hubs and critical facilities. The development of mature facility siting tools and high throughput detection assays are helping to facilitate this effort. At the discretion of the local officials, transportation hubs and other critical infrastructures can be selected for collector placement and integration into the local BioWatch network. Additional collectors are held in reserve by the cities for use at large events or other high profile venues at the discretion of local officials. By the end of FY2006, the top ten threat cities will have Gen 2 capability in place.

BioWatch Generation 3: Gen 3 will use cutting edge technology to provide an instrument that will allow for fully automated collection and detection on site. These fully autonomous detectors will remove the need for routine manual sample retrieval or transport to a CDC Laboratory Response Network (LRN) laboratory for agent detection. The attendant cost saving will enable a significantly increased number of collectors to be installed in thirty metropolitan areas in facilities and outdoor environments resulting in protection for approximately 50% of the U.S. population. A large portion of the Gen 3 development is encompassed in the Biological Autonomous Networked Detector (BAND) program. This program, which is on schedule, will be field tested in FY2007, and piloted in FY2008 for an initial deployment in FY2009. The BAND system will provide self contained sampling and analysis at the collection site with the same level of confidence or greater as is currently available with the existing BioWatch LRN laboratories. The results of the BAND system's analysis will be networked back to the BioWatch laboratory to alert the public health officer for any additional follow up. The BAND detector will provide detection capability for a greater number of threat agents (~20) in a shorter period of time to detection (≤ 4 hours) than what is currently available with comparable or better false positive goals and requirements to the existing system.

BioWatch Guidance: The DHS, in partnership with and concurrence from CDC, EPA, and FBI, has developed the *BioWatch Preparedness and Response Guidance* document to address incident response and characterization following a verified BioWatch positive. This guidance is provided to each of the BioWatch localities to assist them in developing a Concept of Operations (CONOPS) that will meet their specific circumstances and needs. The Guidance document, which is divided into three sections, discusses preparedness, response, and environmental sampling strategies for biological threat agents and respectively are entitled, *Part I: BioWatch Preparedness*, *Part II: BioWatch Response*, and *Part III: BioWatch Environmental Sampling*. These documents were

completed in February 2004 for the Gen 1 BioWatch system and are in the process of being revised for the Gen 2 BioWatch enhancement (FY2006). Specifically, the section covering environmental sampling will provide detail on indoor sampling strategies and techniques and will be tailored for specific microorganisms .

Biological Warning and Incident Characterization System: While a verified BioWatch positive is able to provide information that the genetic material of an organism is present, additional information is needed before one can assess the environmental health or national security significance of such a result. Decisions regarding public health actions should be based on epidemiologic and laboratory information, potential threat information provided by the FBI, and on a thoughtful strategy of follow-up environmental sampling. Therefore, DHS designed and currently is in the process of deploying the Biological Warning and Incident Characterization (BWIC) system to assist in the integration of disparate information to enhance awareness of an evolving biological situation triggered by a BioWatch detection event. BWIC will help local agencies and decision makers to respond in a timely fashion with greater certainty by providing a more unified view of an event, analysis of available environmental and health surveillance data, potential response strategies (using local capabilities and CONOPS), and resource management tools to all approved users.

RESTORATION OF FACILITIES

DHS S&T has a goal, through its restoration research and development (R&D) strategy, to develop a scientifically defensible sampling strategy and plan prior to a possible biological attack. DHS currently is conducting a systems approach to restoration research activities through its Domestic Demonstration Application Program (DDAP) in collaboration with EPA and DHHS (CDC/NIOSH). Through the DDAP, we have developed a general Restoration Plan for an international airport following release of a biological agent. San Francisco International Airport was selected as the model airport during development of the plan to illustrate specific details.

The response phases to a biological event, as defined with interagency cooperation, are Notification, First Response, Characterization, Remediation/Clean-up, Clearance, and Reoccupancy. The focus of the plan is on consequence management activities associated with the Characterization, Remediation, and Clearance Phases. Crisis management activities associated with the Notification and First-Response Phases are also briefly discussed in the Plan.

- **Characterization Phase:** The focus is on identifying the biothreat agent through use of reliable detection equipment, performing characterization environmental sampling to determine the location and extent of contamination, and obtaining positive confirmation of the agent using a reliable laboratory. Using a weight of evidence decision process, environmental characteristics of the biothreat agent (such as its survivability on surfaces), as well as potential health consequences to humans and harm to the environment, are evaluated to determine what type and

degree of remediation are needed for the affected facility and what public health (medical) measures are needed for persons who were potentially exposed.

- **Remediation Phase:** The focus is on preparing and implementing detailed plans for remediation of contaminated areas. Remediation generally begins with source reduction, pre-cleaning surfaces, and site preparation. Scenario-specific decontamination reagents and delivery systems are selected, and all systems are pre-tested before implementing chemical treatments. Remediation ends when the treatment chemicals have been removed or neutralized and all related decontamination activities, including waste disposal, are complete.

- **Clearance Phase:** The focus is on collecting key data such as clearance environmental sampling results along with any additional remediation data that are needed, applying specific criteria to judge the effectiveness of the remediation process, and concluding that it is safe to reoccupy a facility and reestablish airport operations. All applicable sampling and operational data are reviewed and evaluated by appropriate experts. Decisions are made by key public health officials and/or government agencies before airport operations are resumed.

The Restoration Plan also provides detailed description of 1) Available Biological Sampling and Analysis Methods, 2) Considerations for Sampling Design, 3) Probability-Based Sampling, as well as 4) Annotated Characterization and Clearance Sampling Plan Templates.

Available Biological Sampling and Analysis Methods: Sample collection methods can be grouped into three broad types: bulk (accumulated surface dust, HVAC filters), surface (wipe/swab/vacuum), and air sample (cassette, impactor) collection. Each sample-collection type has specific advantages in particular applications. Since limited data was available on surface sampling methods (which were extensively used during the postal sampling events), the DHS S&T completed sampling efficiency studies in FY2006 on polyester/rayon blend wipes, polyester swabs, and a vacuum filter sock and the studies currently are undergoing peer review. This information is critical for establishing the appropriate sampling design. Sample extraction and analysis methods are described with a recommendation of utilizing the LRN laboratories which employ standardized methods across the network.

DHS also is investigating the use of native air samples (e.g., building HVAC filters, filter inserts) to provide geographically resolved data as a vital input to incident characterization following a biological detection event. Native Air Sample (NAS) collection strategies and protocols associated with these interior transportation facilities will be developed and documented. In the event of an single BioWatch positive (only one sampler has a positive response and all others in the area are negative), timely collection of corroborative samples from NAS HVAC filters, pre-emplaced filter inserts or environmental surface sources in the immediate vicinity of the positive BioWatch site could be used.

Two NAS environmental sample collection strategies, the radial ray and grid search methods, have been developed for incident characterization of an outdoor event. These strategies provide a systematic approach for gathering information needed for an initial outdoor incident characterization of the estimated scale and direction of the biothreat agent aerosol that is crucial for determining appropriate and effective public health response. Subsequently, attack assessment based on a detailed survey (using a variety of NAS sources), and mapping of the exposure and residual hazard areas, will be required to identify and manage post-attack residual public health hazards and appropriate mitigation and restoration efforts.

Considerations for Sampling Design: Two major types of environmental sampling are conducted during restoration activities. Characterization environmental sampling gathers information about the extent of contamination. Clearance environmental sampling assesses the success of decontamination. Through pre-planning, all of the physical aspects of a facility are understood and the area can be divided into sampling zones and units. This information can then be used to establish a grid-based sampling scheme which can be used with several methods for choosing sample locations: 1) exhaustive sampling which occurs when every sample that could possibly be collected is actually collected, 2) judgmental sampling (Targeted sampling & Biased sampling) is the practice of choosing to sample specific locations for specific reasons, and 3) random sampling (Random (only) sampling & Statistical sampling) which is any method that includes randomizing the sample locations.

An electronic data-collection and data-management tool featuring electronic facility drawings, bar code tracking, and data visualization tool (Building Restoration Operations Optimization Model [BROOM]) has been developed by DHS S&T in FY2005 and exercised by CDC NIOSH in FY2006 to aid with the sampling zone and method selection. The tool was developed to assist in gathering samples and automates the process of merging field data with laboratory results. Information such as location, sample type, surface type, surface orientation, surface area, and surface texture is recorded for each sample. BROOM provides visual maps which can aid in highlighting patterns of contamination, validation of a single dispersion model or selection among alternative dispersion models, and identification of approximate boundaries of contaminated areas.

Probability-Based Sampling: Probability-based sampling, also called statistical sampling, is appropriate for certain kinds of questions, hypotheses, and decisions. It refers to methods for choosing sample locations so that inference from the results can involve a probability or confidence statement. For example, decision-makers might want to be able to say, "We are 95% confident that less than 1% of the floor surface is contaminated (above some specified level)." Risk-based limits for measurable *Bacillus anthracis* concentrations on surfaces do not exist at present, but if they were developed in the future for *B. anthracis* or some other biothreat agent, then statistical methods would be appropriate for testing hypotheses such as, "The average concentration of the agent on this surface is below x" (where x is a specified number in appropriate units), or "We are 95% confident that at least 98% of the surface has a concentration below x".

Because probability-based sampling uses random sampling, it is unlikely that many samples will be collected in atypical locations. It is highly unlikely, for example, that all samples will be collected in areas with the lowest concentrations, thereby failing to discover the magnitude of contamination. A sufficient number of randomly located samples will have a distribution of concentrations similar to that of the entire area being sampled, and the results will be representative.

In the context of airport restoration after a biological attack, probability-based methods are most likely to be appropriate for the assessment of relatively large surface areas where there is little information to indicate where contamination is likely (or unlikely) to be present. In FY2005, DHS sponsored a program, Visual Sample Plan (VSP) Module, through the Technical Support Working Group (TSWG) for statistically sampling buildings. This program developed statistical methods for quantifying the increased confidence one has when both judgment (biased) and probabilistic samples are utilized to demonstrate cleanliness of an area. The VSP has been evaluated by the responder community and version 4.4 is available on the internet for direct application (www.dqo.pnl.gov). DHS S&T plans to study the utility of this tool for wide area restoration starting FY2006.

Annotated Characterization and Clearance Sampling Plan Templates: The sampling plan templates are based on prior restoration efforts and required information in order to determine the area of contamination and success of decontamination. Sampling methods, qualified laboratories, and sampling design should be pre-determined with the assistance of subject matter experts.

Sampling and detection are integral parts of the response phases following a biological attack. The Characterization and Clearance phases are dependent on the selection of appropriate sampling designs which are scenario and goal dependent. In light of this, much of the effort of the DHS Restoration DDAP has been focused on sampling methodologies such as developing the BROOM and VSP tools. Annotated Characterization and Clearance Sampling Plan Templates have been developed for pre-planning the response to a biological attack. The Restoration Plan has been developed and reviewed in collaboration with EPA, CDC, and DoD. The restoration plan template for airports currently is in DHS and EPA agency final review for approval for public release and will be available in FY2006.

The Airport Restoration Plan currently is being leveraged to develop specific plans for Transit facilities. Washington Metropolitan Area Transit Authority (WMATA) and New York's Metropolitan Transportation Authority (MTA) were selected as the example transit facilities during development of the plan to illustrate specific details. DHS has initiated a Wide Area Restoration DDAP which will build off of the Airport and Transit facility Restoration Plans and continue to address associated sampling and detection issues following a large scale outdoor biological attack. It is envisioned that this type of attack will not only affect the complex outdoor environment but will also affect a large number of facilities (indoor environments). In order to conduct a Wide Area Restoration

Demonstration Program, DHS will be relying heavily on partnerships (State & local) and collaborations with various Departments and Agencies (EPA, HHS/CDC, DoD).

LEADERSHIP AND COORDINATION OF INTERAGENCY EFFORTS

DHS has been proactive in leading, co-leading, and coordinating interagency efforts associated with biological detection and restoration. Several of these efforts have been formalized by the Homeland Security Council, the National Science and Technology Council, while others are generated through the identification of a need to fill a critical biodefense gap. Aside from ongoing agency to agency discussions, DHS is leading and coordinating the following biodefense efforts which have sampling as a critical component:

- Memorandum of Understanding for Coordinated Monitoring of Biological Threat Agents
- Integrated Consortium of Laboratory Networks
- Postal and Shipping Integrated Project Team
- Subcommittee of Decontamination Standards and Technology
- Sponsorship of the National Conference on Environmental Sampling for Bio-Threat Agents

Memorandum of Understanding for Coordinated Monitoring of Biological Threat Agents: Under the aegis of HSPD-10, DHS has led the formulation of a Memorandum of Understanding (MOU) amongst DHS, DoD, DHHS, USPS on Coordinated Monitoring of Biological Threat Agents. This MOU has been finalized and agreed to by all the Parties. This MOU provides for 1) the development of an integrated system design and CONOPS, 2) the development of shared rapid notification protocols, 3) the establishment of assay equivalency (sensitivity and false positive rates) amongst the assays used by the Parties, 4) the development of a shared technology roadmap to commonly leverage advances in technology in a way compatible to the needs of all Parties, and 5) a strategy to extend the national monitoring concepts to other systems, such as other homeland security and related biodetection systems. The national biomonitoring architecture, which currently is in draft form, recommends that an integrated national biomonitoring architecture be based on three pillars: 1) standardized and validated detection techniques, 2) consistent detection, notification, and incident characterization protocols, and 3) maximization of synergy amongst the various elements. Consensus standards and an interim process for assay evaluation and validation will be completed and piloted in 2006. Development of consistent CONOPS for biological monitoring, to include mail and mail processing, is underway in the National Capital Region (NCR) and expected to be completed later this year.

Integrated Consortium of Laboratory Networks: Through a Memorandum of Agreement (MOA) with USDA, Department of Commerce (DOC), DoD, Department of Energy (DOE), DHHS, Department of the Interior (DOI), DOJ, Department of State (DOS) and EPA, DHS is leading an effort to establish an Integrated Consortium on Laboratory Networks (ICLN). The various agencies worked together to create the ICLN with the purpose of developing an organizational framework that links existing and future

laboratory networks under a single interagency umbrella to provide timely, high quality, and interpretable results for early detection and effective consequence management of acts of terrorism and other events. This integrated nationwide consortium of laboratory networks is needed to support the delivery of timely, high quality, and interpretable results through: 1) inter-network communication and information sharing, 2) resource optimization, 3) resource coordination, 4) accountability, and 5) strategic planning. Additionally, this ICLN will create an inclusive forum for Federal leadership to share ideas, work collaboratively, and build relationships that will support a more effective integrated response during emergencies.

The ICLN currently is performing a capability assessment, facilitated through the Homeland Security Institute (HSI), which uses nine scenarios to specifically challenge the ICLN networks. For example, the "Anthrax in an Urban Environment" scenario challenges multiple laboratory networks: CDC's LRN, which currently analyzes all sample types including clinical specimes, food, water, and environmental samples, and EPA's proposed environmental Laboratory Response Network (eLRN), which is primarily focused on developing capacity for chemical warfare agent testing in environmental samples, are actively involved. The results of the ICLN Capability Assessment study will help to give a much better understating of the sample analysis capacity in our Nation's laboratories. Any resulting gaps between the sample analysis demands and current capacities can then be better addressed with a more focused approach to solving this problem. The preliminary results to the ICLN Capability Assessment study will be reported to DHS in July 2006.

Postal and Shipping Integrated Project Team: DHS has also established, for Postal and Shipping, an Integrated Project Team (IPT) which includes representatives from USPS, DoD, DOJ, and GSA. Following the anthrax attacks in 2001, several Federal agencies implemented additional mail screening to include parcels and mail delivered by commercial carriers. An effort is underway to standardize Federal mail screening processes, preferably through a common mail screening facility to assure that standardized methods are employed and to reduce screening associated costs. Discussions currently are underway to implement this approach in the National Capital Region (NCR) and then nationally.

Subcommittee on Decontamination Standards and Technology: DHS is co-chairing, with EPA, the Subcommittee on Decontamination Standards Technology (SDST) assembled by the National Science and Technology Council's Committee on Homeland and National Security. The subcommittee, comprised of all Federal departments and agencies that have restoration related technology or research and development activities, is charged to facilitate the development of consistent guidelines and strategies to address decision making regarding decontamination after a chemical or biological incident. The objectives of this Subcommittee are two-fold: 1) to develop a scientifically-based risk management approach for decontamination standards applicable to a wide array of biological and chemical terrorism event scenarios, and 2) develop a coordinated R&D strategy and budget initiative to address gaps in decontamination technology

development necessary for the decontamination of open and urban (indoor and outdoor) environments after an attack using biological or chemical weapons.

One key piece of the decontamination process under consideration by the committee is sampling strategies and technologies. Guidelines for biological and chemical restoration currently are under review and an overarching chemical, biological, radiological and nuclear (CBRN) document is in preparation. The intended audience of the guidance document is local decision makers and on-scene coordinators and incident commanders.

The Coordinated Biomonitoring MOU, Integrated Consortium of Laboratory Networks MOU, Postal and Shipping IPT, and SDST subcommittee are all efforts to coordinate current biological agent sampling, monitoring, and restoration efforts conducted by various agencies. Although surface sampling is not the initial focus of these efforts, they are addressing the issues of validation, performance characteristics, interpretation of results, investment strategies, and policies as agreed upon by the interagency group. Once consensus is reached with current biological agent monitoring, the foundation will be laid to address other issues such as surface sampling.

Sponsorship of the National Conference on Environmental Sampling for Bio-Threat Agents: In addition, DHS is participating in the R&D and responder communities to address environmental sampling efforts that are applicable to biological surveillance and restoration. DHS co-sponsored, with DoD, the first National Conference on Environmental Sampling for Bio-Threat Agents in January 2005. As part of the conference, current R&D activities evaluating sampling methodology performance were identified. In addition, several sessions were held to discuss the need for consensus on standardized sampling approaches amongst the agencies. As a result of the meeting, DHS partnered with the National Institute of Standards and Technology (NIST), to gather key stakeholders together to develop a national standard for sampling of suspicious powder (described below). Due to the success of the first conference, DHS will co-sponsor the Second National Conference on Environmental Sampling for Bio-Threat Agents in October 2006 to foster collaboration and technology exchange among the research and responder communities in government, industry and academia.

STANDARDS AND VALIDATION

The first step towards validation must involve defining the necessary requirement for the sampling process or methods in specific scenarios, developing standards or minimum performance characteristics as needed, and initiating testing and evaluation to verify that those requirements are met. The Standards Portfolio within DHS S&T has a mission to develop and coordinate the adoption of national standards and the appropriate evaluation methods to meet homeland security needs.

Sampling Suspicious Powders: In FY2005, DHS in collaboration with NIST, took the first steps to prioritize and initiate the development of standards related to biological sampling activities. An American Society for Testing and Materials (ASTM) standard

was drafted to standardize and validate the method by which hazardous materials technicians collect, transport, and store suspicious powder samples. We are in the final stages of this multi-agency effort to provide a standard for visible powder sample collection that reflects the consensus of many agencies, including the FBI, CDC, EPA, and DoD. The collaborative study to validate the sample collection standard for visible powders was completed last month at Dugway Proving Grounds in Utah, and the data are being compiled into a final report for review and if appropriate, approval by the AOAC INTERNATIONAL experts next month. AOAC INTERNATIONAL, the independent, third-party scientific association well-known for its "Gold Standards," is collaborating with ASTM on the sample collection standard, and based on preliminary review, it seems fair to say that this AOAC/ASTM standard will soon be available for use by trained first responders.

Public Health Actionable Assays: As stated above, the national biomonitoring architecture requires standardized methods for biological detection assays. In FY2006, DHS, in collaboration with our interagency partners, will develop, evaluate, validate and make available an assay set of high sensitivity, high specificity, real-time PCR primers and probes or immunoassay antibodies for use by the private sector that develops commercial off-the-shelf biodetection technologies. The program will be piloted in FY2007. This will provide rapid detection capability with a high level of confidence for several biological threat agents, to include *B. anthracis*. These detection assays will be validated in partnership with industry and the validation process transitioned to the commercial sector for future assay validation efforts. As stated above, these foundational processes established in this effort will provide a framework for future validation efforts for detection-related methods.

CONCLUSION

In March 2005, the GAO submitted a report to this Subcommittee entitled, "*Anthrax Detection: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results*." The GAO was charged by this Subcommittee to describe and assess federal agencies' activities to detect anthrax in postal facilities, assess the results of agencies' testing, and to assess whether agencies' detection activities were validated. DHS concurs with the GAO that use of stratified and probabilistic "sampling strategies, together with validated methods for detecting contamination, would provide a known level of confidence with which to interpret any negative results and would thus enable agencies to be more definitive in determining necessary actions." Their investigation prompted valid recommendations of which DHS has made significant progress in addressing:

- DHS has taken a lead role in promoting and coordinating the activities of various agencies that have technical expertise related to environmental testing:
    - DHS led the formulation of a Memorandum of Understanding (MOU) amongst DHS, DoD, DHHS, USPS on Coordinated Monitoring of Biological Threat Agents and is leading the MOU execution.
    - DHS is leading an effort to establish an Integrated Consortium on Laboratory Networks (ICLN).

  - DHS has established a Federal Postal and Shipping Integrated Project Team.
  - DHS is co-chairing the Subcommittee of Decontamination Standards Technology.
  - DHS is co-sponsoring the Second (and First) National Conference on Environmental Sampling for Bio-Threat Agents.
- DHS has adopted the international quality management standard ISO 1901 definition of validation.
- DHS has developed a process to standardize and validate methods:
  - DHS has validated a method for sampling of suspicious powders.
  - DHS is in the process of developing a method for the validation of public health actionable assays.
- DHS has invested both in targeted and probabilistic sampling strategies and as well as methodologies that are appropriate for facility monitoring and applicable to wide area and facility restoration. R&D efforts include:
  - Performance characterization of 3 sampling methods on varied surfaces.
  - Development of the Building Restoration Operations Optimization Model (BROOM).
  - Sponsorship of the Visual Sample (VSP) Module.
  - Development of the Annotated Characterization and Clearance Sampling Plan Templates for pre-planning the response to a biological facility attack.
  - Development of *BioWatch Preparedness and Response Guidance*, which includes *Part III: BioWatch Environmental Sampling.*
  - Developing native air sample collection strategies and protocols associated with transportation facilities.
- DHS has prioritized investments for high risk biological agents through internal and interagency coordination to include:
  - SDST R&D Investment Strategy.
  - Agency to agency discussions on leveraging R&D opportunities
  - Internal strategic planning and requirements generation.

The March 2005 GAO report focuses on the statistical confidence associated with environmental sampling strategies and methodologies. Sampling is an integral part of a larger system such as biological surveillance and restoration and thus, the requirements generated for sampling performance (e.g., limit of detection, sensitivity, specificity, tolerance) should be determined within the context of the system. Furthermore, other aspects such as economics, capacity, public perception, decontamination goals, etc. should be factored into the decision making process to use particular sampling strategies. Understanding how to use scientifically based information and methodologies within the context of a biosurveillance or restoration framework will provide for higher confidence decisions in a realm of uncertainty.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Ranking Member Kucinich, and Members of the Committee, I thank you for the opportunity to appear before you.

Mr. SHAYS. Thank you, Dr. George.
Ms. Tulis.

STATEMENT OF DANA TULIS

Ms. TULIS. Mr. Chairman and members of the subcommittee, I am Dana Tulis, Deputy Director of the Office of Emergency Management within the Office of Solid Waste and Emergency Response at the Environmental Protection Agency. I am accompanied by Mr. Mark Durno, sitting here at my left.

I appreciate the opportunity to discuss the steps EPA is taking in response to the Government Accountability Office in their report on anthrax detection. I would also like to share with you other activities EPA and our Federal partners have underway to protect the Nation from an anthrax attack and after an anthrax attack.

I will summarize my statement, but I ask that my entire written statement be included in the hearing record.

EPA still believes that targeted sampling strategies are valid and necessary for rapidly assessing the likelihood of contamination to ensure that necessary actions can be taken quickly to protect those potentially exposed. When the source of contamination is known, targeted sampling of surfaces is determined with incident-specific details such as traffic patterns and airflow within the facility, epidemiological data, and forensic information. This was the approach used during the anthrax attacks in 2001, to ensure immediate steps were taken to protect the people potentially exposed. However, when contamination is known to exist but the source is unknown, the use of statistically based sampling may improve the probability of detecting contamination. Again, contamination must be believed or known to exist for statistical sampling.

As to Federal agency activities, EPA has recently completed developing a new, dedicated National Decontamination Team to provide technical expertise for environmental sampling and decontamination associated with weapons of mass destruction. The team is comprised of specialist technical experts who can provide round-the-clock scientific expertise and operational support during a WMD response—that is, weapons of mass destruction.

EPA is close to completing internal review of environmental sampling guidelines for biological incidents. This describes operating procedures for environmental sampling and presents a framework for developing a sampling approach for investigating biological incidents. The guidance addresses five media—air, bulk, wipes, liquids and solids—and seven agents, including anthrax.

Another draft we have developed is on standardized procedures for the collection of anthrax in environmental matrices. This is undergoing peer review within EPA and CDC. This guide will tell samplers exactly how to prepare the samples to be sent to CDC labs for analysis.

Development of these sampling guidelines is being coordinated with the multi-agency effort to improve guidance for BioWatch consequence management sampling. Over the past 2 years, our emergency responders have been working with local BioWatch Advisory Committees to develop and exercise sampling strategies for us after a positive BioWatch signal.

EPA, along with DHS, has been an active partner in Lawrence Livermore's National Lab development of biological sampling and restoration plans for an airport in San Francisco, the San Francisco International Airport. The work is a model for other airports and transportation facilities, and we plan to participate in developing a similar plan for an airport on the East Coast this year. These plans do include probabilistic sampling.

GAO noted that the anthrax sampling methods have not been validated. Method validation is a long and complex process, and EPA is working closely with our colleagues in DHS, CDC, DOD, and other agencies to validate existing methods as well as to explore new ones. The biological sampling guidelines I mentioned earlier represent those first steps.

EPA is currently participating with CDC, NIOSH, DHS, Sandia National Lab, and the U.S. Army at Dugway Proving Ground in two studies that evaluate the efficiency of surface sample methods for spore collection on porous and nonporous surfaces. Both studies provide a robust scientific and statistical evaluation of current swab, wipe, and vacuum sample collection methods.

EPA agrees there needs to be increased capacity for analyzing environmental samples for anthrax and other WMDs. The President's fiscal year 2007 budget proposed an environmental laboratory response network program within EPA to start building environmental laboratory capacity. In the interim, our Homeland Security Lab Response Work Group is working with internal and external experts to design a functional environmental lab response network. EPA, CDC, and other Federal agencies are working closely under DHS' leadership to implement the Integrated Consortium of Laboratory Networks. This consortium, as you heard, is addressing a wide range of technical and planning issues for laboratory needs, scenario planning, and consistency in methods. Design is also complete for an All Hazard Receipt Facility which will screen samples and protect laboratory personnel. With support from DHS, units will be deployed this year to EPA's Region 1 lab and New York State Health Laboratory for testing and evaluation.

We are also building on our expertise as EPA continues to look for faster, less expensive methods for recovering after an anthrax attack. EPA is advancing the science of test methods and surrogates as well as working with fumigant vendors to optimize procedures for decontamination.

We are working to reduce the timeline, and we have reduced it already dramatically. We are refining and enhancing available decontamination methodologies, for example, a bacteriophage, which is a virus that eats bacteria but is harmless to humans. EPA is constantly evaluating additional decontamination and disposal alternatives.

In conclusion, EPA is working closely with other Federal agencies to improve sampling and analytical methods, address national laboratory capacity, and refine and improve decontamination and disposal technologies. I believe we have taken significant steps in these areas addressing GAO concerns as EPA continues to look forward to our continued collaboration in the future.

Thank you, Mr. Chairman. That concludes my remarks. I will be happy to answer any questions you or the subcommittee members may have.

[The prepared statement of Ms. Tulis follows:]

STATEMENT OF DANA TULIS
DEPUTY DIRECTOR, OFFICE OF EMERGENCY MANAGEMENT
U. S. ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE
SUBCOMMITTEE ON NATIONAL SECURITY, EMERGING THREATS, AND INTERNATIONAL RELATIONS
COMMITTEE ON GOVERNMENT REFORM
U. S. HOUSE OF REPRESENTATIVES

MAY 9, 2006

Mr. Chairman and members of the Committee, I am Dana Tulis, Deputy Director of the Office of Emergency Management, within the Office of Solid Waste and Emergency Response at the Environmental Protection Agency (EPA).

I appreciate the opportunity to discuss the steps EPA is taking in response to the Government Accountability Office (GAO) report on Anthrax Detection. I would also like to share with you other activities EPA and our federal partners have underway to protect the Nation after an anthrax attack.

ENVIRONMENTAL SAMPLING STRATEGIES

EPA believes that targeted sampling strategies are valid and necessary for rapidly assessing the likelihood of contamination to ensure that necessary actions can be taken quickly to protect those potentially exposed. When the source of contamination is known, targeted sampling of surfaces is determined with incident-specific details including traffic patterns and airflow within the facility, epidemiological data and forsenic information. This was the approach used during the anthrax attacks in 2001, to ensure immediate steps were taken to protect the people potentially exposed. However, when contamination is known to exist, but the source is unknown, the use of statistically-based sampling may improve the probability of detecting contamination.

NATIONAL DECONTAMINATION TEAM (NDT)

EPA has recently completed development of a new, dedicated National Decontamination Team which will provide technical expertise for environmental sampling and decontamination of biological, chemical or radiological weapons of mass destruction. The NDT is comprised of 15 specialized technical experts charged with providing "round the clock" scientific expertise and operational support to On Scene Coordinators, from the initial to the final stages of a chemical, biological or radiological incident. They will provide access to decontamination resources in other government agencies, private industry and academia. They are also developing a National Portfolio of Decontamination Resources, which will be a web-based repository of decontamination information, guidance and databases, and will provide rapid access to state-of-the-art information on all aspects of decontamination.

QUICK REFERENCE GUIDES FOR BIOLOGICAL AGENTS

EPA, working with our colleagues on the National Response Team (NRT), has recently completed four Quick Reference Guides for biological agents, including anthrax. These guides, which are posted on the NRT website at www.nrt.org, offer first responders a quick overview of agent-specific information on toxicity, personal protective equipment, sampling and analytical methods and options for decontamination. Similar guides are underway for a group of chemical agents, and additional guides are planned for the future.

BIOLOGICAL AGENT SAMPLING GUIDELINES

EPA is completing its draft Environmental Sampling Guidelines for Biological Response Plans. The document describes operating procedures and method descriptions for environmental sampling and presents a framework for developing a sampling

approach for investigations involving biological agents. Because incident and agent characteristics may vastly differ, the document discusses a number of available sampling methods and factors to be considered in selecting the best method for the specific situation. The method descriptions include a method summary; equipment and apparatus; procedure; sample preservation, handling and storage; potential problems and interferences; and quality assurance and control. Having consistent operating procedures will ensure samples are collected uniformly. The document will soon undergo internal EPA and interagency review.

EPA has also developed a preliminary document describing a number of procedures to be used for sampling anthrax in different environmental matrices. This document, titled Standardized Procedures for the Collection of Bacillus anthracis in Environmental Matrices, is currently in draft form and is undergoing peer review within EPA and the Centers for Disease Control (CDC).

BIOWATCH AND CONSEQUENCE MANAGEMENT PLANNING

Development of Biological Sampling Guidelines is being conducted in coordination with the multi-agency effort to improve the guidance for consequence management sampling strategies for the BioWatch program, in which EPA also plays an active role. Under BioWatch, the Department of Homeland Security (DHS) utilized the existing air monitoring network that EPA operates through grants to states and local governments. Air monitors capable of detecting a number of biological agents have been installed in outdoor and indoor locations in major cities across the United States. Over the past two years, our emergency response staff have been working with local BioWatch Advisory Committees to develop consequence management plans that identify follow-up sampling locations and strategies, including federal, state and local roles and

responsibilities, should a positive BioWatch signal occur. EPA also assisted in exercising these plans.

In a related effort, EPA has been an active partner in Lawrence Livermore's development of sampling plans for consequence management of a biological warfare event at the San Francisco International Airport. These comprehensive plans identify potential sampling zones and potential places and things to sample within zones. They also offer sampling plan templates and clearance sampling strategies. This important work is a model for other airports and transportation facilities, and we intend to continue the partnership by developing similar plans for another airport.

ENHANCED BIOLOGICAL SAMPLING METHODS

While GAO has noted that sampling methods for anthrax have not been validated, EPA is working closely with our colleagues in DHS, Department of Defense (DOD), CDC, and other agencies to address this issue. Methods validation is a long and complex process. First, procedures are developed and documented, and existing techniques are optimized and standardized. Detailed procedures are developed to ensure methods can be used consistently. The biological sampling guidelines I mentioned earlier constitute EPA's effort to fulfill those first steps.

Next, initial validation studies are done to verify that the method performs acceptably, data are statistically analyzed, and preliminary performance assessments are conducted. EPA is currently participating in two sampling efficiency projects with CDC/NIOSH, DHS, Sandia National Laboratory, and the U.S. Army at Dugway Proving Ground. These studies evaluate the efficiency of surface sample methods for collection of anthrax spores on porous and non-porous surfaces. Both studies are designed to provide a robust scientific and statistical evaluation of current swab, wipe, and vacuum sample

collection methods for anthrax spores. The study with CDC and Dugway Proving Ground includes a multiple lab validation study to evaluate the effectiveness of the laboratory protocols used to analyze the samples.

The next step in validating methods is to conduct a multi-laboratory study to ensure that the method produces consistently repeatable results. The data are statistically analyzed, final performance assessments are completed, and the method is finalized, including determination of quantitative quality control criteria. Once these steps are implemented, we will enter into the next stage of validation for any current anthrax sample collection methods.

We are also working with our partners to evaluate new sampling methods. EPA is currently evaluating the use of laser-induced breakdown spectroscopy for detecting anthrax spores in suspicious white powders. This promising new technology will provide real-time in situ measurements with little to no sample preparation. It is relatively cost-effective, simple to operate, and easy to decontaminate. We are closely following CDC's work on resuspension of anthrax spores and a bio-aerosol sampler, Lawrence Livermore's work in developing rapid viability methods for building restoration, and Sandia's evaluation of spore viability analysis by flow cytometry following chlorine dioxide fumigation. Finally, in support of DHS, CDC and other agencies, EPA will be a co-sponsor of the second national bio-sampling workshop in New York this October.

ENHANCED LABORATORY ANALYTICAL METHODS AND CAPACITY

GAO noted that extensive environmental sampling efforts can strain available laboratory capacity, and they suggested that laboratory capacity can be increased. EPA and other agencies are taking a number of interim steps to address the need to increase capacity. In addition, the FY 2007 President's Budget requests funding to establish an

Environmental Laboratory Response Network Program within EPA to increase environmental laboratory capacity.

To fulfill its responsibilities, EPA continues to address these issues through its Homeland Security Laboratory Response Workgroup. The workgroup is actively working with all ten EPA Regional Laboratory Centers; cross-program chemical, biological and radiological technical experts; regional and local emergency response personnel; and administrative personnel to design a fully functional environmental lab response network (eLRN). The workgroup also analyzed five of the White House Homeland Security Council's Scenarios to determine the national need and the gap between supply and demand.

In 2004, EPA and CDC worked closely together to clarify roles and responsibilities of each Agency. During 2005, EPA and CDC worked closely with the White House Homeland Security Council to include all other federal agencies with existing or developing networks. This effort is known as the Integrated Consortium of Laboratory Networks. The Consortium is currently addressing a wide range of technical and planning issues ranging from consistency in the use of sampling and analytical methods across the agencies participating in the network to scenario planning and laboratory needs.

Progress has also been made in developing an All Hazard Receipt Facility (AHRF), designed for screening purposes to protect laboratory personnel. With support and funding from DHS, the design is complete and units will be deployed to EPA's Region 1 lab and the New York State Health Laboratory this year for testing and evaluation.

In assessing the nation's laboratory capacity, one of the more important areas needing improvement was standardization of methods used by laboratories analyzing environmental samples. To determine national capacity, EPA developed a compendium of existing laboratories which includes their capabilities for chemical, biological and radiological analyses. We also developed the Standardized Analytical Methods for Use during Homeland Security Events (SAM), which identifies those methods that would be used to determine the presence and concentrations of a chemical, biological, or radiological agent in an environmental sample. The SAM document, developed in 2004, was expanded and updated in September of 2005 to increase the list of agents and to update the methodologies.

TEST METHODS FOR EVALUATING EFFICACY OF PESTICIDES

EPA is advancing the science of test methods and surrogates used to evaluate the efficacy of antimicrobial pesticide products against spore-forming bacteria, most notably B. anthracis. This research is critical to the regulation of sporicidal pesticide products under the Federal Insecticide, Fungicide and Rodenticide Act. Working in collaboration with the Food and Drug Administration, DOD, and other federal laboratory partners, EPA has led an effort to evaluate, improve, and validate qualitative and quantitative test methods. We have already completed improvements to the current EPA standard test method, selected a quantitative method for further study, and evaluated surrogates for B. anthracis. We have also initiated research on additional pathogenic bacteria Clostridium, Yersinia pestis, and Francisella tularensis. A ten-laboratory validation of the selected quantitative method will be launched this summer. We are also preparing for new research on antimicrobial efficacy on additional indoor surface materials and new research on unique pesticide formulations such as gases and foams.

ENHANCED BIO-DECONTAMINATION AND DISPOSAL TECHNOLOGIES

EPA is building on experience to date in crafting a decontamination research program to find faster, cost-effective methods for recovering after an anthrax or other type of biological attack. We have completed a survey of available decontamination methods and are currently working closely with vendors of chlorine dioxide and vaporized hydrogen peroxide to optimize fumigant procedures for decontaminating buildings. Both the timeline and costs for decontaminating anthrax have reduced dramatically as we continue to refine and enhance available decontamination methodologies. Use of tenting to seal a building prior to fumigation has proven to be far more efficient than the sealing strategies used for contaminated postal facilities. The use of chlorine dioxide in eliminating mold in buildings in the hurricane ravaged Gulf States will also be applicable to anthrax fumigation.

We are evaluating portable chlorine dioxide systems and also looking at the use of bacteriophage systems as a potential decontamination alternative. Research is underway on fumigant reaction kinetics – taking a closer look at how a fumigant penetrates different types of materials, how it decomposes, and what types of by-products are left behind. We're also looking at how fumigants behave at different concentrations, temperatures, relative humidity and contact times, as well as material demand and materials compatibility.

Waste disposal is a critical component of an anthrax response that is often overlooked. EPA's research agenda in this area includes thermal destruction research, a portable gasifier project, and evaluation of autoclave waste sterilization. We are studying agent destruction and emissions in incinerators, and also taking a look at what happens to biologically contaminated wastes that are disposed of in landfills. Finally, we have

created a Disposal Decision Support Tool for decontamination wastes that addresses waste packaging and transportation issues, and also identifies thermal treatment locations and other types of disposal sites.

CONCLUSION

We appreciate the Committee's interest and GAO's efforts to identify ways to improve the Nation's ability to respond effectively to biological incidents, including anthrax. EPA is working closely with other federal agencies to improve sampling and analytical methods, address national laboratory capacity, and refine and improve decontamination and disposal technologies. We believe we have taken significant steps in these areas and we look forward to continued collaboration in the future.

Mr. SHAYS. Thank you. I am going to start off with Mr. Van Hollen, and then I will go to my colleague, Mr. Duncan, and then I will go.

Mr. VAN HOLLEN. Well, thank you, Mr. Chairman, and thank you again for holding this hearing. I thank all the witnesses for their testimony. I have some questions both on the detection issue and then on the vaccine issue. Let me start with the detection issue.

Dr. Besser, you mentioned the fact that we are trying to expand the Laboratory Response Network and the enhancements there. Specifically, you mentioned the multiplex technology so you would able to detect multiple agents with one test, which I think is good news.

I guess my question is: When do you predict we will be able to actually deploy that around the country so that it will really operate as a detection system to help protect the American people?

Mr. SHAYS. Just for the record, each member is going to be provided about 10 minutes, and we will do it that way.

Dr. BESSER. Mr. Van Hollen, thank you very much for that question. I think that we all agree with you about the importance of that technology, especially when you are dealing with a situation where you do not have a known agent that has been released.

I would like to get back to you for the record on that and follow-up with the researchers who are doing that work to be able to give you an appropriate update on the status of that project.

Mr. VAN HOLLEN. OK. I mean, I think it is a welcome development. Obviously, if its efficacy is shown, we would like to get it deployed as soon as possible.

We have some testimony from the representatives from DOD about biological detection equipment in the field. Obviously, we also want to prepare not just for an attack in the military, but a terrorist attack on the civilian population. And the question is whether it makes sense to deploy some of these detection devices and techniques in areas where you have lots of people congregating. We have heard over the years the scenario of a Metro system attack with anthrax or some other kind of agent. Are we at the point where we have the technology that we can deploy in Metro systems? Have we?

I have asked this of the Washington Metro representatives when they come up here, and we always get sort of fuzzy answers. I would welcome any testimony you have on that.

Mr. REED. Sir, if I may—and we will give you this for the record as well. But if you go into the Metro system, as you walk around, you will see a series of trailers or stanchions, stations, in each of the Metro stations that are, in fact, detection systems.

Mr. VAN HOLLEN. You are talking about specifically the Washington Metro system?

Mr. REED. The Washington Metro system.

Mr. VAN HOLLEN. And have we deployed that in other major cities around the country?

Mr. REED. I do not have that information, sir, but we will get it for the record.

Mr. VAN HOLLEN. OK. If the DHS folks, if you do not have the answer, if you could get us that answer, the extent to which we

have deployed anthrax detection and whatever other kinds of agent detection in Metro systems in major cities around the country.

Mr. REED. Just for clarity, sir, we will give you the type. They may not all be anthrax.

Mr. VAN HOLLEN. I am sorry?

Mr. REED. They may be more oriented toward chemical than biological, but I need to give you that for the record.

Mr. SHAYS. You need to give off—could the gentleman yield?

Mr. VAN HOLLEN. Sure.

Mr. SHAYS. Or if you would just clarify, that is all.

Mr. VAN HOLLEN. I guess what the chairman is wondering is if—you are saying you do not know or you need to tell us off the record.

Mr. REED. I have to check both of those in terms of the detail on what is there.

Mr. VAN HOLLEN. All right. Well, in whatever, you know, means of providing the information is appropriate, I think we would be interested both in terms of the extent to which we have deployed these detection systems in Metro systems in major cities around the country and what exactly it is that they are able to detect.

Dr. GEORGE. I probably will not comment on exactly what they are detecting because that would present a vulnerability, but, yes, we are focusing on placing detection technologies, both chemical and biological, in the subway systems across the country, typically at the discretion of the locals, where they want to put it, and whether it is subways or airports or whatever other transportation hubs, we are actively doing that.

Mr. VAN HOLLEN. OK, good. Let me just turn to the vaccine issue, specifically on anthrax, and the questions that it may raise about the entire BioShield program. As I understand, the anthrax contracts are sort of the major contract right now existing within the BioShield, the single largest. Is that right?

Dr. PARKER. Yes, sir, that is.

Mr. VAN HOLLEN. And we spend about close to $1 billion on this contract, which is now behind schedule. Is that right?

Dr. PARKER. Let me correct that. We have obligated—for the rPA VaxGen contract, we have obligated $877 million.

Mr. VAN HOLLEN. OK.

Dr. PARKER. But according to the BioShield authorities, payment is not made until usable product is delivered to the Strategic National Stockpile. Product has not yet been delivered to the Strategic National Stockpile.

Mr. VAN HOLLEN. OK. My question is this——

Dr. PARKER. And if I can complete that, we have also then purchased Anthrax Vaccine Adsorbed [AVA], the current licensed anthrax vaccine, from BioPort, also using the Project BioShield authority.

Mr. VAN HOLLEN. Right, and I commend you for doing that in the interim as this—because of the delay in the other contract.

With respect to the other contract, look, we obviously have problems that have been testified to with the VaxGen contract. To what extent are those due to failures of the company? To what extent are they due to failures, you know, and changes in the contract at the Department of Health and Human Services? Which, as I am sure

you know, allegations have been made to that effect. And to what extent are there problems in the structure of the BioShield Program? Because this will raise questions about the overall effectiveness of that as a design. We have heard a lot about the so-called "Valley of Death" and the fact that you do not get paid until, you know, you have shown a product that has demonstrated efficacy.

If you could sort of let us know how we got behind on this contract and how——

Dr. PARKER. Let me give you, if I may, if I could give you an overview, there are some things that I am not going to be able to specifically discuss about this contract for the—because I cannot. I have an obligation to not reveal company confidential information. But we would be glad, more than happy to come and talk in detail about some of those things, but first of all Project BioShield and some unique authorities there.

As I already mentioned, payment is conditioned on successful delivery of usable product to the Strategic National Stockpile. This was set up as a very accelerated advanced development acquisition program. Project BioShield is meant to incent pharmaceutical companies, biotechnology companies, to help us in the development of medical countermeasures that otherwise would not be developed. It is meant to provide that market.

I think we are recognizing the need for more prolonged advanced development funding, and if you will notice in our fiscal year 2007 budget, we have included $160 million to establish a new advanced development program to help support biodefense, late-stage advanced development projects. The reason is to begin to reduce—hopefully to reduce the risk prior to a product going into a BioShield acquisition contract.

Now, in regards specifically to this current contract with VaxGen and rPA, of course, we are not happy about the delay. But, on the other hand, delays in accelerated advanced development programs like this are also not unexpected. We had a similar delay in our program to develop ACAM200, a smallpox vaccine, that was initiated prior to September 11th. It ultimately was a successful program and delivered the smallpox vaccine to the Strategic National Stockpile, and I think rather than getting into very specific details about the delay in this specific project, I would like to come and have a very detailed discussion with you that we can go into much more detail, if that is fair enough.

Mr. VAN HOLLEN. That is fine. The last question I have, and I apologize that I have to leave early. But the original intent was to try and get, I think it was 75 million doses by the end of this year in terms of anthrax. Given the shortfall and the delay in the contract, does it make sense to purchase even more of the existing and approved FDA anthrax vaccine?

Dr. PARKER. Well, as you probably already know, we did purchase 5 million doses of AVA, had a contract that was initiated in May 2005, and that complete delivery was completed of those 5 million doses in February 2006. We recently modified that contract to purchase 5 million more doses of AVA, and, in fact, some of the initial deliveries are already beginning, with the anticipation of that additional 5 million doses being made by the end of the year.

Mr. VAN HOLLEN. Right. I guess to the extent that the other becomes delayed even further, potentially, does it make sense to continue——

Dr. PARKER. We will have to continue to evaluate our requirements based in this bigger context.

Mr. VAN HOLLEN. OK. Thank you.

Thank you, Mr. Chairman.

Mr. SHAYS. I thank the gentleman.

The Chair would recognize Mr. Duncan for 10 minutes, no more.

Mr. DUNCAN. Well, thank you, Mr. Chairman, and, Dr. Parker, I guess I will just followup because I want to see if I have this straight. And, first of all, let me say neither I nor anybody that I know is connected to VaxGen or BioPort or any other company that does anything like this, so I am just trying to figure out where we are on all this money.

You say in your testimony that no payment for product is made until a useful product is delivered to the SNS. And when it says no payment for product, does that mean that other payments are made for research and development? Or how much of this $877.5 million has been spent so far or has been given to VaxGen so far?

Dr. PARKER. Under the requirements of the BioShield Act, no—and I mean "no"—payment for product is made until it is delivered to the Strategic National Stockpile. Therefore, we have not made any payment for rPA vaccine to this contractor to date.

Mr. DUNCAN. OK. So the $877 million——

Dr. PARKER. By the act, you have to deliver usable product to the stockpile, and "usable" definition is in the contract, and actually as Dr. Sharma mentioned earlier, a lot of that definition is also some——

Mr. DUNCAN. And there is no exception to that. You cannot——

Dr. PARKER. There is—there is——

Mr. DUNCAN [continuing]. Pay money out for research then or——

Dr. PARKER. There is an exception. We have not exercised that exception. There is an exception. I will make sure I get it right, but advance payments of up to 10 percent as acceptable to the Secretary can be made. That exception has not been made, so this contractor has not received payment for any vaccine.

The only—let me make sure this is correct. VaxGen did receive money as part of this contract for some security upgrades, and that is it. And then before the Project BioShield contract that we commenced with VaxGen, VaxGen was also funded from two contracts from the National Institutes of Health, first in 2002 and then in 2003. Those were advanced development contracts that preceded the Project BioShield acquisition——

Mr. DUNCAN. For anthrax vaccine.

Dr. PARKER. Yes, sir, for the rPA, the next-generation anthrax vaccine.

Mr. DUNCAN. And roughly how much was that?

Dr. PARKER. I believe they were like—I will correct the record, but I believe it was on the order of magnitude of $30 million and $80 million. But please let me correct that record if I do not have that completely correct.

Mr. DUNCAN. All right. And then——

Dr. PARKER. And that was for advanced development, not delivery of vaccine.

Mr. DUNCAN. I understand. All right. Then you go on further and on the next page you say that—and you just mentioned this to Congressman Van Hollen, but you said that—it says, "Last week, HHS modified the contract and purchased an additional 5 million doses of AVA for the Strategic National Stockpile, increasing our total investment in AVA to $243 million."

Now, who was that contract with?

Dr. PARKER. That contract was for the currently licensed anthrax vaccine to BioPort.

Mr. DUNCAN. That was to BioPort?

Dr. PARKER. Yes, sir.

Mr. DUNCAN. And so how much total has BioPort gotten from you? Have they gotten all of——

Dr. PARKER. Yes, sir. That total you just read, 243, that was the first 5 million doses, plus the modified to purchase an additional 5 million doses, for a total of 10 million doses. That is the——

Mr. DUNCAN. So all the money that you are talking about that you have invested in anthrax has all gone to BioPort? Is that correct?

Dr. PARKER. Well, we have obligated, which means it is not available to make another contract on the rPA contract, but it has not been expended. The BioPort has been obligated, and vaccine is being delivered.

Mr. DUNCAN. On April 6th, there was a hearing on a lot of this before the Energy and Commerce—a subcommittee of Energy and Commerce Committee, and they mentioned in there some place that it says that there are other companies that are wanting these contracts. How many other—just for my own information now, how many other companies are there that are capable or involved in doing this or that are contacting you to——

Dr. PARKER. Well, the only——

Mr. DUNCAN [continuing]. To try and get some of this business?

Dr. PARKER. For anthrax vaccine, there is only one company that currently has a licensed anthrax vaccine. That is BioPort. From the NIH contracts, we actually have—VaxGen had that advanced development contract that was already mentioned. There is another company that has an advanced development recombinant protective antigen advanced development contract as well with NIH. And then when we did the full and open competition for the Project BioShield acquisition contract, we did have multiple awards. I don't recall offhand—I was not directly involved in that acquisition. It was before my time. But there were multiple companies that did submit a proposal. Not many. Not many.

Mr. DUNCAN. And when you say multiple awards, does that mean that——

Dr. PARKER. No, not multiple awards. There were multiple companies who submitted a proposal against that request for proposal. Not many. I will get the exact number, but it was not many. But one company was selected, and that was VaxGen.

Mr. DUNCAN. OK. And when you say, though, that the only company that has a licensed vaccine is BioPort, what does that mean in relation to VaxGen? Do they have a license for a different——

Dr. PARKER. The recombinant protective—next-generation recombinant protective antigen vaccine is not licensed yet. One of the authorities with the Project BioShield Act is also to allow the purchase, acquisition of products that are on the track to licensure. In fact, the requirement is all scientific, medical, technical data should suggest that the product has a high probability of being licensable within 8 years. So you can purchase and do an acquisition contract with companies that have a product in advance development that with the prevailing scientific and technical opinion has a high probability of being licensed. And so the next-generation vaccine candidate is not currently licensed. The plan is to develop it and get it licensed for both post-exposure use and pre-exposure use against inhalational anthrax.

Mr. DUNCAN. Let me ask you one other thing. The Congress authorized and the President signed a total bill of $5.6 billion over the next 10 years. What do you think about that? You know, you were talking about $877 billion to VaxGen, $243 million basically to BioPort. Are we doing enough? Are we doing more than we should? Are we way short? That $5.6 billion, I mean, that is a really high figure but——

Dr. PARKER. Yes, sir, it is.

Mr. DUNCAN [continuing]. Is that enough or is that——

Dr. PARKER. Yes, sir, it is——

Mr. DUNCAN [continuing]. Too much?

Dr. PARKER. It is a very high figure. But, on the other hand, medical countermeasure, advanced development procurement unfortunately it is expensive. It is a big number, but drug vaccine, diagnostic development, and particularly the advanced development, licensure, stockpiling is expensive. As far as——

Mr. SHAYS. Would the gentleman yield?

Dr. PARKER. As far as the relative investment on anthrax, yes, it is a relatively large investment out of that $5.6 billion thus far for anthrax. Nonetheless, anthrax is a top threat. I know my colleagues have heard me say before that the top three threats, in fact, are anthrax, anthrax, and anthrax. That is my personal opinion, but I probably have some that will share that opinion.

Mr. DUNCAN. Thank you very much. That is all.

Mr. SHAYS. I just wanted, if you would pursue the idea that you were developing, which is—I thought basically you were making the point it is very expensive, but I thought that Mr. Duncan's point was isn't the 5 million just a small part of what we have to do. Isn't that kind of where——

Dr. PARKER. I think that was—yes, Mr. Chairman, I think that probably was, and I did not mean to say it is too much money, because personally I do not believe it is, because medical countermeasure development is expensive. We have a lot of threats, whether they be threats that we need to be concerned about from an intentional attack, but there is also naturally occurring and emerging infectious diseases that we also need to be concerned about.

And, unfortunately, the cost to be prepared, there is a cost to improving our preparedness. We have to be and we are committed in administering the Project BioShield acquisition, on the one hand, we are committed to being—developing these products as urgently

as we can to meet the threat, but we are also committed to be as diligent as we can be in wisely expending the funds associated with the special reserve fund of Project BioShield.

So it is a—you have given us a tough job.

Mr. DUNCAN. All right. Thank you very much, Mr. Chairman.

Mr. SHAYS. What puzzles me, Dr. Parker, about your answer is that I look at anthrax as being like a chemical. I view it as not being contagious. Briefings that we have gotten on bird flu and so on are that you could literally see millions of people killed. And so I realize one is a natural event and one is potentially a manmade event. But are we making the potential mistake that we made with FEMA of getting them focused on not focusing the natural enough, thinking that we would have to look at what an enemy might do as opposed to what Mother Nature might do?

Dr. PARKER. Well, actually, I guess the way I would think about that, Mr. Chairman, is they are both important. And I looked at—anthrax is a very serious threat, and if we look at what the letter attacks did with such a small amount, and just a little bit more could do a lot more damage. And we could be attacked at multiple locations as well.

On the other hand, an anthrax attack, even if it is multiple location, is at least bounded in a relative space and time, unlike pandemic influenza that we are also working very hard now to improve our preparedness for that potential emerging infectious disease. And pandemic influenza, as you pointed out, is something that will be communicable, person to person, and will not be bounded in geographic space and time, like an intentional anthrax attack.

Mr. SHAYS. So you make a good argument for not saying anthrax, anthrax, anthrax.

Dr. PARKER. No. When I said anthrax, anthrax, anthrax, I meant it stands above and beyond some of the other biological pathogens that could be used as a weapon intentionally against us. There are other ones that are serious as well, but anthrax poses unique characteristics that make it——

Mr. SHAYS. So let me put it in a way that I think I understand you and tell me if I am correct. Your testimony is that anthrax is not potentially the greatest threat in general, but if you were talking about a weapon of choice and talking about a weapon as opposed to Mother Nature, that it would be the weapon of choice.

Dr. PARKER. Well, from my years experience in working in medical biodefense, anthrax is unique. It is not the only threat, though. We are——

Mr. SHAYS. That is not what I am saying. I do not want you to—I want to just clarify. What you were saying is anthrax, anthrax, anthrax, and I asked you a question, and you said it is what concerns you the most. Now I am trying to summarize, and it seems to me you are going off to left field here.

I have had so many hearings on anthrax, I do not like even talking about it anymore, but all I want is what you think, and then to be able to respond to what you think. You were saying to us in this hearing that not only is anthrax your primary concern, it is your second and third concern. And then you said, to amplify it, that "Anthrax is the most likely weapon of choice, in my judgment." Are you disagreeing with that? And let me just add so you

can fill in. What you were then saying is well, though, you were just talking about a weapon of choice. If we are talking about all kinds of threats, then you would not necessarily rank anthrax at the very top.

Dr. PARKER. Let me make sure—of all threats, natural man-made.

Mr. SHAYS. Yes, exactly.

Dr. PARKER. We have some very serious natural threats as well, and if you looked at the potential consequences of a pandemic influenza, for example, that could be very severe. And so there are other natural threats that probably pose a larger challenge, particularly something like a pandemic, when it is not bounded in time, it is not bounded in space, and it could be a global threat that spread from me to you. And so we have both—we need to pay attention and we should pay attention, and we do, in our preparedness activities to both natural threats and intentionally used threats.

Mr. SHAYS. Thank you.

Let me ask you, Ms. Embrey, the Rand Corp. did a study. It is entitled, "A Review of the Scientific Literature as It Pertains to Gulf War Illnesses: Volume 3–Immunizations." And they had completed the draft in 1999, and it has not been released publicly. I want to know why and I want to know when is it going to be released.

Ms. EMBREY. I did get visibility that you were going to ask me that question. I did put a call in to Rand this morning to clarify what the reasons are for their failure to release. I did not receive an answer from them prior——

Mr. SHAYS. Is it your statement that Rand is the reason why they were not released, or is it DOD? Rand does not have the authority to release something, do they?

Ms. EMBREY. In this particular case, they do because it was my predecessor organization that asked them to perform an independent review, Rand. We commissioned them to do an independent review of the literature associated with Gulf war illness and vaccinations. And Rand is responsible for the product, and as it is independent, it is their product.

Mr. SHAYS. They paid for it?

Ms. EMBREY. We paid them to do an independent review.

Mr. SHAYS. So let me get this straight. It was paid for with Federal dollars?

Ms. EMBREY. Yes, sir.

Mr. SHAYS. And it was a document for the Government?

Ms. EMBREY. Yes, sir.

Mr. SHAYS. And we are having to ask permission from Rand whether they are going to release it?

Ms. EMBREY. It is their product, sir.

Mr. SHAYS. We paid for it.

Ms. EMBREY. We did. But——

Mr. SHAYS. We own it.

Ms. EMBREY. It is independent. We should be absolutely asking them for the product.

Mr. SHAYS. No, that is not a good answer. No, it is not. I mean, you are a lovely person, but with all due respect, that is not a good

answer. And I do not think that DOD would want to imply that anytime they contracted out, it is up to the group that they contracted out. If they were paid for a product that was for the public, it is not your testimony that they get to decide whether to release it or not, is it?

Ms. EMBREY. Because of the way in which the arrangement with Rand—we asked them to do a completely independent assessment. In other words, this is not our product, it is not our DOD study——

Mr. SHAYS. That is irrelevant whether it is your product or their product. You paid for it.

Ms. EMBREY. Yes, but it is——

Mr. SHAYS. We paid for it.

Ms. EMBREY. It would be Rand's—Rand would have to sign their company's reputation to it.

Mr. SHAYS. Did they give you the document?

Ms. EMBREY. Based on what I was able to obtain this morning, they have provided us various versions of their product over the years. The most recent one was one dated in July of last year. We received it in the November timeframe, 2005. We provided comments back to the Rand Corp., but I have to say, I need to find out more, and I will be certainly happy to provide you an update for the record.

Mr. SHAYS. We had told you that we would be asking this question, correct?

Ms. EMBREY. Yes, sir. I was out of town, unfortunately, until this morning.

Mr. SHAYS. No, my point is that this was not a sneak attack here.

Ms. EMBREY. No.

Mr. SHAYS. This is kind of a basic thing. Well, I do not like your answer.

Ms. EMBREY. Acknowledged.

Mr. SHAYS. And we will talk to Rand directly.

Ms. EMBREY. Thank you.

Mr. SHAYS. I would like each of you to tell me what you think your role is as it relates to—if you have any role whatsoever, as it relates to the licensing of an anthrax vaccine and as it relates to anthrax detection methods. And we will start with you, Ms. Tulis.

Ms. TULIS. Thank you. With regards to the vaccination, we do not have a role. With regards to detection, we are working on sampling methodologies, and we have two guidances I did mention. The next step with those guidances would be validation. That is our role at this point.

Mr. SHAYS. OK. I wrote down, staff wrote down that EPA is primary responsible for coordination of the recovery process.

Ms. TULIS. Decontamination, definitely.

Mr. SHAYS. Yes. Do you agree with that?

Ms. TULIS. Yes, I do.

Mr. SHAYS. Would you add anything to it?

Ms. TULIS. I would say that sampling and analysis is certainly a critical part of the decontamination process, and that is why we are focusing on it.

Mr. SHAYS. OK.

Ms. TULIS. In collaboration with other agencies.

Mr. SHAYS. I am going to come back to you, Dr. George. First of all, how long have you been working with the Department of Homeland Security?

Dr. GEORGE. I have been working at the Department of Homeland Security since it stood up on March 1, 2003.

Mr. SHAYS. And you came from where before that?

Dr. GEORGE. I came from the Department of Energy's Chemical and Biological National Security Program.

Mr. SHAYS. So it is really a continuation of the work you have been doing?

Dr. GEORGE. Yes, sir.

Mr. SHAYS. So even though the Department of Homeland Security is new, the tasks and responsibilities are somewhat similar?

Dr. GEORGE. Well, since DHS stood up, we now have this Homeland Security Presidential Directive No. 10, the President's Biodefense for the 21st century, which clearly delineates agencies' roles and responsibilities. And so we did not have that prior to a couple years ago.

Mr. SHAYS. Dr. Besser, what we have written down for you is you support efforts to validate components of the detection process. I would ask you, one, your reaction to that; and, two, your role in licensing anthrax vaccines and anthrax detection methods, what roles you have in either.

Dr. BESSER. Thank you, Mr. Chairman. The CDC role in terms of the detection validation is really multifold. For CDC, the initial role of sampling is in a public health response to determine whether an area is contaminated and whether action has to be taken. And that is a very directed approach during an investigation.

CDC has a role in terms of working with other agencies to validate assays, and there are situations, as I said in my testimony, where you will be faced with a situation where it is not a known release, where you are trying to determine whether people in an area are at risk, but you are trying to determine whether a building may have had a release in which you are going to need a probabilistic method.

CDC's role there is to bring its scientific expertise in collaboration with other agencies to make sure that we help to develop products that are going to be useful in applied public health.

In terms of the vaccine side, CDC is actively involved in collaboration with the Department of Defense on studies to look at dose reduction and change in route of administration for the currently licensed AVA vaccine, and there are a number of reasons for that. One is that the feeling that a change from a subcutaneous administration to an intramuscular administration is likely to result in fewer side effects; and, two, the number of doses that are required for administration of that licensed vaccine is quite high. And so if we are able to demonstrate protection with lower number of doses, it would be very useful to DOD in terms of troops. It would also be very useful in terms of a public health response. And so that is a collaborative effort.

Mr. SHAYS. OK. That is not with anthrax. That is with——

Dr. BESSER. That is anthrax. That is for the AVA vaccine. That is the currently licensed——

Mr. SHAYS. BioPort, right.

Dr. BESSER. Yes, sir.

Mr. SHAYS. As it relates to HHS, obviously you are purchasing vaccines and so on. So that is the role. But basically your responsibility is developing medical countermeasures to anthrax. Is that one way I would describe your role here?

Dr. PARKER. Yes, Mr. Chairman. Within my office, we have the Office of Research and Development Coordination, which has the responsibility for implementing, overseeing, and managing the BioShield acquisition contracts, but also has the role of coordinating the within-HHS activities that span from the basic research, biodefense, all the way to the Strategic National Stockpile that is managed and implemented at CDC. Also a focal point for interacting with our interagency colleagues, and I know you are going to go to the Department of Homeland Security in a minute, but there is a dual role between HHS and DHS in the administration of the Project BioShield. And it really gets down to what is the threat, what are the high-priority threats, and then what are the medical countermeasures that need to be developed against those threats.

And so our role within HHS is the development and acquisition of the medical countermeasures against those threats that are deemed to be material threats against the U.S. population.

Mr. SHAYS. Let me go to DOD before I go to Homeland Security. Basically, I view—I would be leaving this hearing with the general view that the civilian side is handled by a plethora of agencies, and DOD does the duplicative process, and then draws on certain of the other departments as a resource. But basically it is going to decide how to detect say, for instance, anthrax and it is going to decide what it wants to do in terms of vaccines, and it is going to do what it wants separate from what the Government wants. And I am not passing judgment—even though I said it in a way that seemed like I was, I am not passing judgment. I am just thinking that is the way it is.

Maybe you both could respond to that.

Mr. REED. I do not think I would characterize it precisely that way, sir. I think the Department does have ongoing efforts. Those efforts are coordinated with what is going on in the civilian sector. Much of the work that has been done—for instance, the AVA vaccine that is currently there was developed by the Department of Defense over the years. The recombinant vaccine came out of USAMRIID at Fort Detrick and was transitioned to the civilian sector.

But specifically with regard to what my responsibilities are with respect to the Department or to procure and field existing capabilities for detection of biologicals and specifically among those for anthrax in support of the forces in the field and in their garrison locations here in the United States and overseas, to develop advanced capabilities for such fielding, to procure the existing vaccines for defense of the force, and to develop advanced vaccines and other therapeutics for treatment of the force, and in concert with the brothers and sisters, if you will, in the civilian side to share that information so that we do, in fact, have a coordinated program.

Is it perfect? No. But we are working on that.

Mr. SHAYS. Ms. Embrey.

Ms. EMBREY. With respect to my responsibility within the Department, our focus is on force health protection and the clinical protocols and policies for immunization, assuring that clinical practice guidelines are effective and that the appropriate scope of who is covered at what risks to help define the requirements as part of the internal process for what kind of protective measures we need against what kinds of threats, and also to prepare the military health system to execute an immunization response as well as to monitor the adverse effects.

That is our primary objective internally. I would say that we do so in very close collaboration with the Centers for Disease Control and Prevention. In fact, what we have in the way of clinical protocols and response is identical and developed in coordination, full cooperation with CDC on the response side.

Where we have differences are in our laboratory networks. DOD does have laboratory capacity and assays and protocols that are slightly different, primarily because we develop those for our deployable assets in theaters around the globe. We are making a concerted effort to ensure that those assays and protocols here in the United States, if they are not identical, they are at least equivalent, and we have studies working to ensure that is the case.

Mr. SHAYS. And how long have you been in your position?

Ms. EMBREY. Just a little over 4 years.

Mr. SHAYS. I would think that if you—when you heard Dr. Parker say that his big concern in terms of human intervention would be anthrax, anthrax, anthrax, that would be probably your answer as well?

Mr. REED. I think from a threat standpoint, there are number——

Mr. SHAYS. Let me just ask you, why did you answer this question instead of Ms. Embrey? I am just curious. No, I am just curious. Not because I thought women should go first. I was just wondering if——

Mr. REED. I was going to give you——

Mr. SHAYS. No, I just need to know why are you the one who would answer instead of Ms. Embrey.

Mr. REED. I think because I was going to approach it from the standpoint of—from a technical standpoint, what do we consider the threat that is out there.

Mr. SHAYS. Based on your responsibilities in what way? I am still trying to sort this out a little bit.

Mr. REED. From the standpoint of an assessment of the threat that faces U.S. forces in the field today, and potentially in the homeland.

Mr. SHAYS. Fair enough.

Mr. REED. There are a series of agents that lend themselves to asymmetric warfare, to employment on the battlefield, and one of the worst of those from the standpoint of, if you will, most capable war agents is anthrax. But there are others, like tularemia, like Venezuelan equine encephalitis, smallpox today, that present very real threats from that standpoint.

And so the program of research and development is focused in those areas, and looking now at the possibility of the threat of bioengineered agents that could be employed on the battlefield.

Ms. EMBREY. From a force health protection perspective, I think there are multiple answers to your question. But the first, I think, consideration—to me, anyway—is that—and we learned this primarily in our preparations for pandemic influenza—is that this Nation needs to have a capacity to produce vaccines of all types and that is my burning platform, that our capacity as a Nation to develop and accelerate the production of vaccines against many threats needs to be enhanced significantly, and we need to have the agility to move from one threat to another with agility, and that requires, I think, some investments that I believe the pandemic is helping to kick-start for us, but I think it has much broader applicability to the larger threats. So that is a generic answer.

Specifically, I view threats in the context of how many people would be vulnerable to an attack. From a force health protection perspective, there are threats that exist, but in employment as a weapon would affect small numbers of individuals. Anthrax is the kind of a threat that to me implies a much larger number of individuals who we would have to prepare a response for, and because of that, I believe we need to have the capacity to respond to that and should invest in that heavily.

Equally, there is in a pandemic a similar kind of vulnerability because the human population does not have the immunity to deal with—that is why it is a pandemic. So I can't—I have a difficult time evaluating which one of those two is more important because they are both of great concern.

Mr. SHAYS. Well, as it relates to other biological threats, the question is how easy can you weaponize it, and the testimony that we have had continually—and it has been the argument for the immunization plan of DOD is then that anthrax can be weaponized; whereas, biological agents can't be as easily.

Ms. EMBREY. As easily, correct. But anthrax is a biological agent. It is just—and it occurs naturally, but it could be weaponized; whereas, a pandemic influenza—Mother Nature is the best terrorist.

Mr. SHAYS. OK. Let's go to the Department of Homeland Security. You heard the dialog that was in the first panel. Walk me through, without me having to ask the questions, walk me through the dialog and tell me how you would answer those basic points. And let me say to you that, on a scale of 1 to 10, denying that you have a responsibility that you have is a worst offense than saying to me that we did not do something we should have and now we are doing it.

Dr. GEORGE. Exactly, and I appreciate the opportunity to provide clarification on the statements that were made earlier.

In terms of detection—detection and surveillance, attack warning, DHS clearly has the leadership role, and we are taking that role. My oral testimony as well as my written testimony provide examples of what we are doing. I am happy to walk through each one of those particular steps with you right now, if that is the way you want to approach it.

Mr. SHAYS. Right. What I would want, though, is not to suggest that has been the case forever. If it has not, I do not need to dwell on it. But given that no one was even at our hearing last year, it is hard to think that this was a high priority. And so was it just

something that DHS was finally able to pay more attention to? And if so, when?

Dr. GEORGE. OK. Let me try to provide some clarification for you to understand the sampling process. I assume you want to specifically address sampling and sampling strategies and sampling validation? Because sampling is a continuum.

Mr. SHAYS. OK. Well, let me just say that when GAO did its report, it was last year. They are saying you really did not take ownership of that issue until a few weeks ago, or at least acknowledge to them. You know, maybe you all have been communicating for a number of months. I just want to know, before you give me the rest of the story, I would like to know that part of the story.

Dr. GEORGE. OK. Detection and sampling in terms of decontamination, according to Homeland Security Presidential Director No. 10—and with your permission, I would like to read this to you to make sure I get it right: "The Administrator of the Environmental Protection Agency, in coordination with the Attorney General and the Secretaries of Defense, Agriculture, Labor, Health and Human Services"——

Mr. SHAYS. More slowly.

Dr. GEORGE. I am sorry. It is in HSPD–10. But, anyway, there is a variety of organizations——

Mr. SHAYS. No, no, no. Start over again. You were trying to make a point to me, but if you talk too quickly——

Dr. GEORGE. Certainly.

Mr. SHAYS. The nice thing is no one else is here. I do not have to worry about my time.

Dr. GEORGE. I apologize. "The Administrator of the Environmental Protection Agency, in coordination with the Attorney General and the Secretaries of Defense, Agriculture, Labor, Health and Human Services, and Homeland Security, is developing specific standards, protocols, and capabilities to address the risks"—and that is a key word, "risks"—"of contamination following a biological weapons attack and developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities."

With that said—and now I am not reading anymore—DHS is supporting EPA in their decontamination role.

Mr. SHAYS. That is not a good answer.

Dr. GEORGE. I apologize.

Mr. SHAYS. No, you do not need to apologize because that may be the answer you want to give. But you had testimony of GAO that basically said that you all have taken ownership. That statement that you read me is that you do not have ownership. And I do not think you can have it both ways. I mean, Ms. Tulis, if you want to jump in——

Dr. GEORGE. We are happy to take ownership——

Mr. SHAYS. No, "happy" is not the word.

Dr. GEORGE. DHS will take ownership for this problem, if that is appropriate.

Mr. SHAYS. No, but that is different than what was said by GAO. They said you were taking ownership. If you disagree with them, then let's put it on the record. But we have on the record something very different.

Dr. GEORGE. May I please defer the comment to Dr. Vitko?

Mr. SHAYS. Sure.

Dr. GEORGE. He is behind me here.

Mr. SHAYS. So what you need to do, Doctor, is give a card to our transcriber. Please come on up here, and if you could just pick up the mic, it will be on.

Mr. VITKO. Sure. I am happy to pick up the mic, and I would like to——

Mr. SHAYS. You know what the issue is?

Mr. VITKO. Absolutely I know what the issue is.

Mr. SHAYS. Let me just say this to you. We will either spend 10 minutes and figure this out, or we will spend 3 hours figuring it out, but we are not leaving here until we figure it out. And so I would like not, you know, to be having a dialog about—I would like to deal with just the bottom-line basic points, and then fill in all the color.

Mr. VITKO. I will try to, Mr. Chairman. If I miss it, please bring me back on target.

Mr. SHAYS. Sure.

Mr. VITKO. The bottom line is HSPD–10 clearly defines the roles, as you heard——

Mr. SHAYS. No, that is not clearly defined. It clearly does not define.

Mr. VITKO. Oh, I beg to differ, sir.

Mr. SHAYS. Well, tell me. It sounds like everybody has the same responsibility.

Mr. VITKO. No. It says, "The Administrator of EPA, in coordination with . . . is developing . . ." So it clearly establishes who the lead is and what agencies the coordinating is with.

Mr. SHAYS. So you are saying the lead is EPA.

Mr. VITKO. Yes. Yes, sir.

Mr. SHAYS. Well, excuse me for being confused because we had testimony in the last panel that you all had taken on and acknowledged that you have the responsibility. Let me just start out here—and I will let you say what you need to say. Do you disagree with the testimony that was given in the previous panel?

Mr. VITKO. I think they misunderstood the conversation we had. There was never an explicit discussion on May 3rd as to whether or not DHS had the lead responsibility. The discussion on May 3rd dealt with do we embrace the need for a stratified approach to sampling, that is, a combination of targeted and probabilistic sampling. The answer is yes. Do we feel that there is a need for validation? The answer is yes. Do we feel that—and are we taking steps toward that validation strategy? The answer is yes. And that is absolutely true, and that is what occurred on May 3rd.

Mr. SHAYS. Well, what do you think they were saying in the previous panel? What do you think they were saying?

Mr. VITKO. I think they were saying that they had understood, when we agreed to those other terms, that we also agreed that we had the lead in that. That was not discussed, and we did not agree because it is not according to HSPD–10. With that, we have, as evidenced in the testimony, played a significant role jointly with EPA and with the other agencies, just the ones that were said involved in here, in establishing and advancing both sampling strategies and sampling technology, and in doing the validation on it. And I

think you have heard that coordination from the other panel members that testified.

Mr. SHAYS. OK. You know, we will have a lot better dialog if we just talk the way we are talking, and then I can try to figure it out. In other words, Dr. George, the bottom line is the answer to the question I asked it here, we do not agree with what happened in the previous panel, and this is the reason why we do not agree. Is that your statement as well, Dr. George?

Dr. GEORGE. Yes, I agree with what you just said and with what Dr. Vitko just said.

Mr. SHAYS. OK. Dr. Vitko, do you have a card you can give our transcriber?

Mr. VITKO. I don't have a card.

Mr. SHAYS. Then you need to write out your name and full title.

Mr. VITKO. I will write out my name.

Mr. SHAYS. And you were sworn in.

Mr. VITKO. Yes, sir.

Mr. SHAYS. So, Ms. Tulis, it is your responsibility?

Ms. TULIS. When you read HSPD–10, it is particular to decontamination, and decontamination is generally our role. We would not be involved in a lot of the earlier detection and monitoring. We were not provided resources to do that. The other——

Mr. SHAYS. Slow down. So whose responsibility is that?

Ms. TULIS. The various agencies that have developed some of those programs. Most of these efforts——

Mr. SHAYS. You all talk too quickly for someone—[laughter.]

No, no, seriously. You know, I am just trying to understand.

Ms. TULIS. OK. Our focus has been decontamination because sampling analysis, as I mentioned earlier, is critical to be able to accomplish those steps.

Mr. SHAYS. Your responsibility is decontamination.

Do you want to read me what you just read me, Dr. George?

Dr. GEORGE. I beg your pardon? I did not——

Mr. SHAYS. Would you just read me what you read me about——

Ms. TULIS. It is right here.

Dr. GEORGE. Certainly. "The Administrator of the Environmental Protection Agency, in coordination with the Attorney General and the Secretaries of Defense, Agriculture, Labor, Health and Human Services, and Homeland Security, is developing specific standards, protocols, and capabilities to address the risks of contamination following a biological weapons attack and developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities."

Mr. SHAYS. OK. Now, we were talking about the need for a strategy to determine how to validate whether or not this room is clean and so on. So tell me how that relates to this issue. Ms. Tulis——

Dr. GEORGE. Generally we get involved when there is known to be a source of contamination.

Mr. SHAYS. I want to know who takes ownership for having a strategy at this table for developing a protocol so that we can validate whether or not, you know, the Madison Square Garden is not contaminated and that it is clear. Who takes responsibility here? I do not want anyone to speak until someone takes responsibility. Who here takes responsibility?

[No response.]

Mr. SHAYS. Thank you. I think you are proving a point.

Ms. TULIS. If I may, generally, I think our focus, for many of us, is that—at least—but is we would not be monitoring every single building there to see whether or not potential contamination exists.

Mr. SHAYS. No. But the issue is not that you are monitoring it, but that you have a protocol to determine if you actually can verify whether, whatever the standard is, it is a building that is not contaminated, hasn't been compromised.

Do we have GAO still here? Could you all just step up a second? I am not interested in getting into a dog fight here, so that is not my motive. I just want you to help. I plead part of this is my own ignorance. I am not getting it, and you are all very bright people, but what I am not getting is, no one is taking ownership, and that is what I see is the problem.

Dr. George, you read me a document, but that doesn't really address what I think I was hearing GAO say. Now, GAO—excuse me. Mr. Rhodes, if you would just tell me how you would contribute to this. Why don't you sit in the corner? That is great. We are going to sort this out, and we are going to figure it out.

Mr. RHODES. Well, obviously, Mr. Chairman, I don't understand either. I sat before you under oath and swore that on May 3rd we have a conversation where DHS took responsibility. Now, that was for detection as opposed to decontamination. That was our understanding. But if your question——

Mr. SHAYS. Let's even forget the conversation.

Mr. RHODES. OK.

Mr. SHAYS. Tell me, what is the position that GAO holds of who is responsible for developing the basic strategy—strategy is probably not the right word. What is the right word?

Mr. RHODES. Strategic plan?

Mr. SHAYS. Strategic plan. Who in your judgment has the responsibility to develop a strategic plan?

Mr. RHODES. DHS, and that was the recommendation we made last year, and that is what we stand by right now.

Mr. SHAYS. OK.

Mr. RHODES. Now, if DHS doesn't want to take that, so be it.

Mr. SHAYS. Well, OK.

Mr. RHODES. Because they are the Department of Homeland Security. They have the responsibility for the National Response Plan, things like that. And the distinction made in HSPD–10 is about risk assessment and decontamination. That is different than determining if something is actually in this room. EPA cleans it up. EPA doesn't say—EPA didn't walk into Brentwood and say there was a problem.

Mr. SHAYS. Dr. George, kind of react to that.

Dr. GEORGE. DHS does have the responsibility for detection, detection and surveillance, attack warning, and the methodologies that are associated with detection. And we do take leadership on that, and I am happy to elaborate as much as you want.

Mr. SHAYS. Then why was I confusing you then? Because that is kind of what I am interested in.

Dr. GEORGE. I wonder if we are using the term differently. Detection means, in detection and surveillance, it is understanding if we

have been attacked by a particular agent. So in our BioWatch program, we have detection. We also have incident characterization sampling, which we develop methods for in partnership with EPA, DHHS, CDC. We work very closely with these groups, FBI as well. And we develop sampling plans for incident characterization.

Mr. SHAYS. Do we have a strategic plan right now?

Dr. GEORGE. Do we have a strategic plan for R&D effort? Yes.

Mr. SHAYS. R&D effort——

Dr. GEORGE. For surveillance and detection, yes.

Mr. SHAYS. Tell me about that plan.

Dr. GEORGE. Our ultimate capability is our Gen 3 system. That is where we want to be. This system detects approximately 20 agents——

Mr. SHAYS. Could I say something? I think you are speaking too quickly and I think that——

Dr. GEORGE. I am sorry.

Mr. SHAYS. I think you are hurting your own cause, not mine right now.

Dr. GEORGE. I am sorry.

Mr. SHAYS. I am not trying to—I really have no agenda here.

Dr. GEORGE. I want to be clear. I am sorry.

Mr. SHAYS. I don't want you to overstate what you have. If you don't have it, it would be better to acknowledge you don't have it than to suggest that you have it. And what I thought—and tell me if I am wrong—we want to have some kind of strategic plan that gets everyone to be able to agree, it seems to me, on whether a space has been compromised. And it was my judgment that the testimony, intuitively, it would strike me that this would be the Department of Homeland Security's responsibility, working with other agencies.

I am uncomfortable with you saying you have that, and if we are talking about two different things and I am confusing it, then I don't want to keep going on. Let's clarify that.

Mr. Rhodes, what am I trying to sort out? Where are we getting confused?

Mr. RHODES. I think the differences, who is responsible for the beginning of the event, who is responsible at the end of the event? And at the beginning of the event, it is DHS, and according to HSPD–10, at the end of the event—I mean, not to put it into simplistic terms——

Mr. SHAYS. You need to for my benefit, not for them.

Mr. RHODES. But I was just saying I didn't want to simplify it too much. The point is, that at the beginning of the event it should be DHS. DHS should, through surveillance, characterization, determination, say, "Something has occurred. We don't know the extent yet. We don't know exactly what has occurred, but something has occurred at this location where we are right now."

Mr. SHAYS. Is it your testimony that they have not yet done that, that they——

Mr. RHODES. It is our testimony, based on the recent work, that on May 3rd they said that they had taken responsibility——

Mr. SHAYS. That is a different issue. Let's not go there. I don't want to get into that issue right yet.

Mr. RHODES. OK.

Mr. SHAYS. Is it your testimony that this strategic plan has not yet been developed, that we do not have markers and whatever?

Mr. RHODES. I have not seen it. I have not been presented with it.

Mr. SHAYS. Have you asked for it?

Mr. RHODES. What I have been told is that it is in process. It is in the review process, but I do not have a draft in hand——

Mr. SHAYS. Refresh us as to what you found out a year ago?

Mr. RHODES. A year ago there was nothing. A year ago, we were disagreed with. A year ago, DHS didn't acknowledge that they had the responsibility, and a year ago, they didn't acknowledge that there needed to be a plan.

Mr. SHAYS. With all due respect, Dr. George, I think that is true, and if it is not true, I really want you to be very careful in this. This is a point where I don't want you to say something that you would like to be true or you think might be true. I need you to be very, very precise.

Dr. GEORGE. As Mr. Rhodes said, DHS has responsibility for the front end of the problem, which is detection and surveillance, attack warning, and we do the preliminary incident characterization to understand where the spread of contamination is. We then hand off to our colleagues at Health and Human Services, who are responsible for the public health response, and they then followup with the sampling methodologies and the epidemiology surveillance——

Mr. SHAYS. By then we have already determined that it has been compromised.

Dr. GEORGE. Yes, sir.

Mr. SHAYS. Don't even go down there, we are not there yet. We had a report provided last year to which DHS was not even present, which implied to us that they didn't even think they needed to be here at the hearing. I want you to respond to what Mr. Rhodes said about that report.

Dr. GEORGE. I am a little confused. Could you restate your question? Because he is referring to a session that I was not in attendance——

Mr. SHAYS. No, not a session. I am talking about a report done a year ago. I am talking about anthrax detection. "Agencies need to validate staff and activities in order to increase confidence in negative results."

Dr. GEORGE. And your question specifically is?

Mr. SHAYS. My point was that DHS was missing in action, and not there. And the implication was—and I was starting to feel pretty good about it, not that you weren't there, but you accepted—you weren't there, but now you accept responsibility. The implication you are trying to give this committee—it may be true or not—is that you were always there, and we have a plan, and this is dead wrong. Have you read this report?

Dr. GEORGE. Yes, sir, I have.

Mr. SHAYS. What do you disagree with this report?

Dr. GEORGE. I don't disagree with the report, and in fact, in my testimony I said that we have done the recommendations that they have in the back of that report, and that was the opening of my testimony.

Mr. SHAYS. When did you start doing them, before the report or after the report?

Dr. GEORGE. The activities that I referred to in the testimony were done long before the report was written in March 2005.

Mr. SHAYS. Excuse me. You do disagree with the report because you basically say they said it wasn't happening, and you said it was happening. You are confusing the hell out of me, frankly.

Dr. GEORGE. Well, I apologize, and I am a little confused myself. So we have been actively working in that area. For example, the coordination activities, the Subcommittee on Decontamination and Standards and Technology started——

Mr. SHAYS. You know what? We are not going to get anywhere here. We are going to have a special hearing with DHS just on this, because we are getting nowhere.

Dr. GEORGE. OK.

Mr. SHAYS. We are going to have professional staff ask some questions.

Ms. FIORENTINO. The question is for Dr. Parker. Why does CDC recommend the use of anthrax vaccine in conjunction with antibiotics after exposure to aerosolized anthrax, when the vaccine is not FDA approved for post-exposure use to prevent anthrax disease?

Dr. PARKER. There actually is a growing scientific literature and studies and medical consensus that does support the use of an anthrax vaccine to complement and support, not replace, but to complement antibiotic use post exposure prophylaxis. The anthrax vaccine, AVA, is licensed for pre-exposure indication. It is not licensed currently for post-exposure use in combination with antibiotics. But there are publications that make that recommendation in scientific literature, and recommendations by the CDC for use of AVA in a post-exposure prophylaxis mode in combination with antibiotics. That would be an investigational use of AVA in that setting.

We talked a lot about the next general anthrax vaccine and the intent of that development program and acquisition program is to license for both indications, post-exposure and pre-exposure.

Ms. FIORENTINO. How many studies is this based off of? How many studies are out there that share that this works? And, Ms. Embrey, you may know the answer to this as well if you want to step in.

Dr. PARKER. I am going to ask my colleague, Dr. Besser.

Dr. BESSER. If I could just add to that. Thank you for that question. One of the questions with an anthrax exposure is that you are dealing with spores, and spores are very hardy and they can survive for long periods of time in the lung. So the theoretical goal here is that while you are taking your antibiotics you are protected clearly from the infection progressing. Once your antibiotics stop, there is an opportunity for spores to germinate.

Based on some animal data showing symptomatic disease at a very long time after exposure, during the 2001 event, the feeling was that antibiotics would provide additional benefit in that setting. So it's a combination of theoretical—I think very good theoretical hypothesis, and animal data.

Ms. FIORENTINO. Ms. Embrey.

Mr. REED. What he said, seriously.

Ms. EMBREY. I think the idea here is that there were animal studies done to evaluate if you had antibiotics only, particularly if the spores lodged into the lungs. There was some concern that they may not respond to a short-term—they come back after the antibiotics were delivered. And so there was prudent judgment made that a post-exposure vaccine, in combination with the antibiotics would be fully protective. But the animal studies at that time were the only basis for that, and I think that's our going-in position even now.

Ms. FIORENTINO. And just to clarify, was it just one study that was done that showed that? Because that was my understanding. Is there more than one study that showed the use of vaccine with the antibiotics was effective against post-exposure aerosolized anthrax?

Dr. PARKER. We will get you the specific studies that support that from animal model use.

Ms. FIORENTINO. My other question is, are there any steps being taken to obtain FDA licensing for the use of anthrax vaccine to prevent anthrax disease after exposure at this point?

Dr. PARKER. Well, I think we just discussed that the goal of the next generation anthrax vaccine is to develop that and do the requisite animal efficacy studies so we can pursue both a licensure for post-exposure and pre-exposure use.

Ms. FIORENTINO. One question for the panel. What steps have been taken to invest in validation studies of sampling process activities and methods for other biothreat agents besides anthrax?

Ms. EMBREY. I missed the question.

Ms. FIORENTINO. Clarify the question? What steps if any have been done now to invest in validation studies of sampling process activities and methods for other biothreat agents besides anthrax? Are there any being done at this point?

Mr. REED. We will take that for the record.

Mr. SHAYS. What does that mean?

Mr. REED. It means, sir, I don't have the data available at this point.

Mr. SHAYS. Fair enough.

Ms. FIORENTINO. Thank you.

Mr. SHAYS. Did you want to respond to that question?

Dr. GEORGE. Yes, I will be happy to respond to that.

We have done a lot of work with the CDC to develop assays. We then hand those—so we work hand in hand, and we then hand those assays off to CDC, and they run them through a multi-lab validation process, and then they operationalize those assays, both in their LRN, as well as for our BioWatch Program.

Mr. SHAYS. Yes, sir?

Dr. BESSER. Thank you, Mr. Chairman. The next set of studies that CDC is going to be working on on Dugway deal with environmental sampling for Yersinia pestis, so there is additional work going on for sampling.

Mr. SHAYS. Here is what I want to do. I want to resolve this issue with DHS and the GAO tonight. I don't want to add one more thing to the hearing levels that I have. So I am going to say to Defense, we are done with you guys.

Dr. Parker, do you have anything that you would be able to contribute to this dialog, or Dr. Besser, in regards to what we are trying to—I think DHS needs a little help here.

Dr. PARKER. Yes, sir, I will stay here.

Mr. SHAYS. What I am going to ask is, Mr. Rhodes, if you and your colleague would take the seat of Ms. Embrey and Mr. Reed and those spaces. What I am going to do is—we may just agree to disagree, but at least I will know where the disagreement is. I am going to read GAO's statement to us, and I am going to ask you—and Dr. George, I would like you to invite your colleague to join you.

Ms. Tulis, do you have anything that you might be able to——

Ms. TULIS. I doubt it.

Mr. SHAYS. You seem to be heavy in the document that they make reference to though, so I think you better stay.

Ms. TULIS. OK.

Mr. SHAYS. If we could pull up another chair here.

Sometimes what happens in a hearing, I know when I am getting ready to leave for the plane, I try to cut corners with my staff to try to get done what I need to get done, and I end up not expressing myself the way I want to.

So I am going to start over. This is a new process, a new hearing. Everything is just—we are going to start fresh, and we are going to help this committee understand. But I will tell you, I had a dog in a fight eventually with DOD when I felt that we were misusing the anthrax vaccine and requiring people to have it that shouldn't. And it is clear that I was happy to prove a point at those hearings about how wrong I thought it was, and I am happy the program had become discretionary, that people could say no.

I have no doing in this fight, I really don't, except this. I don't think that we have seen the progress we need to, and I would like to get a handle on that. That is the only thing that I think. So I am going to read Mr. Rhodes' statement.

He just said, "We are pleased to be here today"—and I am going to ask for reaction. Anyone who is up at the desk, if you can help the two parties here sort it out, it would be helpful here.

He said, "We are pleased to be here today to discuss the status of our recommendations on two bodies of work that we did at your request: licensed anthrax vaccine and anthrax detection methods." I am just going to focus on the anthrax detection method. That is my words.

In today's testimony I will specifically report on the problems we identified, two, recommendations we made, three, actions taken by Federal agencies and what remains to be done.

Then Mr. Rhodes says: With regard to anthrax detection methods, last year I reported to you that the overall sampling process and the individual activities were not validated. Consequently, Federal agencies could not answer the basic question: is this building contaminated?

Now, that is what he said. I would like to know from DHS if they disagree with that basis statement?

Mr. VITKO. I don't think at that time, or even now, that we have full validation of techniques. I do believe that we have made significant progress.

Mr. SHAYS. Let's get to it. But right now, consequently, Federal agencies could not answer the basic question: is this building contaminated? That part is true. Whether or not—you know, maybe Superman can't do it. That is not my issue. But do you agree with that statement?

Mr. VITKO. We made our best assessment. It needs further validation.

Mr. SHAYS. That is not my point. Do you agree with the statement: Consequently, Federal agencies could not answer the basic question: is this building contaminated? Yes, you agree or no, you don't, and why you don't.

Mr. VITKO. As stated, it is too definitive. There are cases when we can decide whether a building is contaminated. There are levels below which we can't detect.

Mr. SHAYS. That is a helpful answer.

I am sorry to report to you that we are not much further along in being able to answer this question than we were in 2001. Do you agree with that statement?

Mr. VITKO. No. I believe we made significant progress in characterizing the sampling efficiencies of various techniques.

Mr. SHAYS. If this building is contaminated today and tested negative, you would not know for sure whether the negative finding is due to a small number of samples collected or the samples were collected from places where anthrax was simply not present, or in fact, anthrax is not present in this building?

Mr. VITKO. There is always a chance that we could miss it. We use our best strategies.

Mr. SHAYS. What do you mean by always a chance?

Mr. VITKO. What I mean, sir, is that—I want to clarify first what stratified sampling is, and then tell you what I mean by best guess.

Mr. SHAYS. Sure.

Mr. VITKO. Stratified sampling means I do both targeted sampling, which means if you spill a cup of coffee, I am not going to go randomly sample the room for where you might spill it, I am going to look for near where you are. So I am going to do a targeted sampling. And then in addition, I add some probabilistic sampling, which means I may cover, say, 10 percent of the surface area, and if I deduce there is nothing there, I make some confident statement about it is probably not there.

It is possible that I contaminated in one corner where I did not sample the 10 percent and get the coverage. So you can never say with finality that it isn't there, but you could make best estimates.

Mr. SHAYS. Now, let me just go back to that previous sentence. Tell me why you feel that you have made progress since 2001. What has happened that makes you feel you have made progress?

Mr. VITKO. OK. In 2001 we were confronted with an event of an anthrax contamination, a facility, and we had not characterized the efficiencies of different techniques, so whether I take the sample by swab or rubbing it this way, whether the swab is dry or wet, whether I use a wipe, whether I use a so-called HEPA vacuum, we made the quick field determinations of those efficiencies and the right mixes of those to use.

Since then we have done well-characterized laboratory studies on putting a controlled number of spores down on a surface and seeing

how much are picked up by each of those techniques, and quantifying those, and scientifically validating them and getting them peer-reviewed. And we have also moved that into the field. So that is on the actual physical sampling itself.

The second thing that we have made a lot of progress on are the so-called sampling tools, how do you decide where to take samples and how do you log them? One of the testimonies you heard, that we in fact developed a hand-held personal data system that automatically logs where you take a sample, geographically registers it on the building, plots it out for visual inspection, and we develop techniques that help you tell how many samples to take for the probabilistic part, to give you a certain level of confidence.

And we are also testing these things in the field, as you heard, with Dugway and with others, to see that actually holds up with agents on real-world surfaces, because the characterizations so far have been done on clean, smooth, scientific surfaces.

Mr. SHAYS. Let me ask GAO just to react to that, what you have just heard so far. Why don't you slide over a little closer.

Mr. RHODES. The first point I would make is that we do not say anywhere in the report that targeted sampling should not be used. We say that if you do know where the sampling is, where the spill is, just as the description of the cup of coffee, we say that targeting is fine. The question is when you are going to declare a building clean or where you aren't certain that a building has been contaminated, that is the point we would make.

Now, at the heart of our recommendation is the question about validation, and as you have heard, we concur with the point that was made—the methods have not been validated, and we still stand by that. There is no disagreement there.

Mr. SHAYS. Let's keep going a second. This is just a page and a half: We therefore recommended that the Secretary of Homeland Security ensure that appropriate validation studies of the overall process of sampling activities, including methods, are conducted.

So how does DHS react to that point?

Mr. VITKO. DHS believes that it has a role in overall coordination. We believe, as in the words read to you on HSPD–10, that the development of standards, protocols—and I forgot the other word in there—to assess the risk of contamination, EPA has the lead and we are working with them.

Mr. SHAYS. Let me ask EPA. Do you believe that you have the responsibility? I mean has GAO given it to the wrong person? Is it really your responsibility and not DHS's?

Mr. TULIS. I believe our responsibility is associated with sampling for decontamination.

Mr. SHAYS. Which means that what?

Mr. TULIS. Which means once an event has been verified, that's what we go in and decontaminate.

Mr. SHAYS. So you don't take ownership the way DHS is suggesting?

Mr. TULIS. No, we don't.

Mr. SHAYS. OK. So she doesn't take ownership. So we have now a disagreement with GAO on this, and now we have—you have any disagreement with EPA? What is your reaction?

Mr. VITKO. My reaction is to ask additional questions.

Mr. SHAYS. OK.

Mr. VITKO. My reaction is to ask EPA whether they believe that the sampling to determine the extent——

Mr. SHAYS. Talk through the mic. I know you want to be polite.

Mr. VITKO. I am sorry.

Mr. SHAYS. You want to look at the person you are speaking with but you need to talk through the mic.

Mr. VITKO. My apologies, sir.

Mr. SHAYS. That is all right.

Mr. VITKO. So my question is simply one of: EPA, do you believe that the sampling to assess the state of contamination is not an EPA task?

Mr. TULIS. Yes, it is. Sampling for decontamination, that is the parameters I have said.

Mr. VITKO. To assess the extent of contamination as well?

Mr. SHAYS. Wait, hold on a second. They need to be through me, the questions.

Mr. VITKO. I am sorry.

Mr. SHAYS. That is all right. You do not need to apologize.

Mr. SHAYS. So what I am hearing is that EPA is not saying though that their responsibility is to develop a strategic plan. They deal with the consequence. And that is what I think I heard when the President's directive was written.

Let me just keep going on though: Although in the past there has been confusion as to which Federal agency would take the lead, as well as responsibility for ensuring that our recommendations are addressed, I am pleased to report that DHS is now accepting responsibility.

You have already said you disagree with that, that was misunderstood.

On May 3, 2006, DHS told us that DHS recognized that it is the principal agency's responsibility for coordinating the Federal response and would be responsible for ensuring the sampling methods, including the process, are validated. DHS also would work toward developing a probability based sampling strategy.

You obviously disagree with the basic point, but what part of this do you agree with?

Mr. VITKO. Excuse me for a moment, sir, that I could read that passage again.

Mr. SHAYS. Do you have your testimony? If you just hand it over to him. It is on page 2 of it, and it is at the top of the page on—I don't know if his page is the same. It is not the same testimony. What GAO does is they give us a shorter version so they stay close to the 5 minutes.

Mr. VITKO. Where do it start?

Mr. SHAYS. Page 2. And take your time, we are not in a rush.

Mr. VITKO. This is a vaccine page.

Mr. SHAYS. Page 2. I would like you to look at that a second before you have to respond. At the top: On May 3, 2006 DHS told us.

Mr. VITKO. At the top, OK.

Mr. SHAYS. Just look at it a second.

Mr. VITKO. Is this the second paragraph, Mr. Chairman?

Mr. SHAYS. And the first paragraph: On May 3, 2006, DHS told us that DHS recognizes that its principal agency responsibility—yes, that is it.

Mr. VITKO. All right. As you acknowledged in the earlier comments, we did not tell them that we were the principal agency.

Mr. SHAYS. I am acknowledging that you disagree with this.

Mr. VITKO. Right.

Mr. SHAYS. Let me keep going: While actions taken by DHS are steps in the right direction, we recommend that DHS develop a formal strategic plan that includes a road map outlining how individual agency efforts would lead to one, validation of the—and this is the key I think—validation of the overall process of sampling activities including the methods; and two, development of a probability-based sampling strategy that takes into account the complexity of indoor environments. This would allow DHS and the Congress to measure its progress against its stated goal.

How do you react to that?

Mr. VITKO. We are happy to do that, sir.

Mr. SHAYS. Happy to do it is not—I mean I am happy you are happy to do it, and I mean by that, that is good, but do you think you don't have the role? I mean not only are you happy to do it, do you believe that is a responsibility that you—and if you don't do it, who the hell will? That is the problem I am having right now. I mean, when I asked who took ownership, nobody took ownership. And so I thought this was constructive. I thought it was constructive that DHS was going to take ownership, so I wasn't ready to throw rocks at DHS because they didn't take ownership before. I thought, well, I am happy DHS takes ownership because somebody has to.

Mr. VITKO. I am getting a feeling that——

Mr. SHAYS. Dr. George, do you want to make a point. I just want to give you a chance.

Dr. GEORGE. Thank you. As I stated before, DHS is responsible for the characterization part as part of attack warning, as I said earlier. When it comes to decontamination effectiveness and the risks associated with the decontamination process, that is our interpretation of HSPD–10, which is why we didn't stand up and take ownership for that problem. We certainly support EPA as needed in that process, but it clearly defines EPA as having a leadership role.

Mr. SHAYS. With all due respect, I think that was talking about consequence. That is how I read it. I read it that way. What is a little heartbreaking to me is that—well, before I tell you what is heartbreaking, Dr. Parker or Dr. Besser, do you have anything that you might just establish for the record that might be important? And let me just say it is important that your agencies at least give me a sense of who you think has the role. Otherwise, we are even worse off than I think. If it is not you, whose role is it? So I think you all have an obligation to tell us who you think the role is, and I am going to press you both on it, Dr. Parker and Dr. Besser?

Dr. BESSER. Thank you, Mr. Chairman. The CDC has a long history in environmental microbiology, over 50 years, and uses environmental microbiology as part of the public health response. So I

would view CDC as having a very important role during an initial response.

For example, during the recent anthrax event in Pennsylvania, where an individual——

Mr. SHAYS. You don't need to give me a for instance. I understand that. So now what?

Dr. BESSER. So CDC has an important role there. We work on improving assays. And when it comes to the decontamination, we look to EPA as the lead for having the ability to say, "Is this building clean? Can someone go in?"

Mr. SHAYS. So that is helpful. Now what? I want you to address what we have been talking about. You have told me your role, and that is good, and you don't want to give an inch on your role, and that is good, I like that. I wish DHS would take it. But what you are avoiding is the question I am asking. Don't avoid it.

Dr. BESSER. I think it is an important question. I think CDC has an important role at the table in terms of assay validation.

Mr. SHAYS. You already told me. Who has the role to develop the strategic plan, in your judgment?

Dr. BESSER. I think in terms of the GAO report from last year, that role was with DHS.

Mr. SHAYS. Dr. Parker.

Dr. PARKER. I agree with my colleague, Dr.——

Mr. SHAYS. Your mic is not on.

Dr. PARKER. I agree with my colleague, Dr. Besser.

Mr. SHAYS. Let me just tell you what I think. What breaks my heart is that I have been working on terrorist issues since 1998. We knew that—we had three commissions, the Bremer Commission, the Rudman Commission, the Gilmore Commission. They all agreed that there is a terrorist threat. We needed a strategy to deal with the threat. We needed to reorganize our Government to implement that strategy. And the strongest position was to create a Department of Homeland Security. The reaction I got back home from people is, what are we, Great Britain? And then we had September 11th and we had impetus to move forward.

What I am seeing—and there was arguments, don't create a Department of Homeland Security, because, frankly, it would be too big, too bureaucratic, and it would just empower the various groups to do their thing.

In a way I feel like we have created a Department of Homeland Security that is not acting like a Department of Homeland Security, and it is there. But, for instance, with Katrina, where I was involved in the investigation, in Katrina, we basically determined the White House was somewhat in a fog, and then DHS was missing in action, and then we determined that FEMA was negligent. Now, DHS basically said, we want FEMA to be FEMA, and they were, but they were overwhelmed and they were negligent.

But DHS didn't add value, and what we wanted from DHS was for you all to add value, and in some cases, what I envisioned is there would be some potentially gray areas, but that intuitively we would say, "Well, this is the role of DHS because nobody else has the power to do it, and we are kind of like the umbrella." And so even if it didn't specifically say that the whole thrust of the legislation said it was yours, grab it and do it, and then if some other

department said, "No, you're treading on our territory," then I could see a little bit of dialog.

So what you have read to me, Dr. George, to me validates exactly what Ms. Tulis said, that she has the consequence of it. But I think it is overwhelming that if you had that meeting last week, you should have said exactly what you said, that you have ownership, you take ownership, you have done some things to get you there. That is kind of where I am coming down. So I am sorry that there was a misunderstanding there because I think the answer you really had that was right was, "It is our responsibility, we should have been moving ahead more quickly, but we are working on lots of things. We have made progress here." I would have just said, "Terrific." Then I would have been happy, for you to say you would be happy to take on the responsibility. I don't think we need DHS to take that kind of position.

Mr. VITKO. Mr. Chairman, can I speak?

Mr. SHAYS. Sure.

Mr. VITKO. First of all, if we misunderstood and if it is clearly accepted that we have responsibility for this, we accept that responsibility, first of all. Second, I think whether we have that responsibility or not, we believe—and our testimony was to that effect—that we have been playing a leadership role in that. I do want to make that clear and I do want it on the record. We, DHS, have led the interagency process in developing an environmental sampling document and protocols for contaminated areas, to assess contamination following a BioWatch positive. There is a volume of that is work jointly under DHS leadership with HHS, DOJ, EPA, and I am missing one—there are five agencies in that.

Second of all, for the last 3 years we sponsored a so-called restoration, demonstration and applications program at the San Francisco International Airport, that again was an interagency effort that was geared at looking at how do we rapidly characterize and clean up major contaminated transportation hubs? In there, we, in fact, developed sampling protocols. We did the sampling validation that we talked about. We developed the sampling tools. We worked with the EPA to have pre-reviewed processes to speed up that decontamination. The whole purpose of that was to take an end-to-end systems approach to the problem.

Mr. SHAYS. Here is what we are going to do. We are going to let you have the last word. You have taken some hits today. I am happy to have that be your last point, and this is something that we will have dialog privately with all of the particular parties. It has been an interesting hearing for me, and hopefully we have made some progress.

With that, this hearing is adjourned.

[Whereupon, at 5:19 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

Questions for the Record
House Government Reform National Security, Emerging Threats, & International Relations Subcommittee
"Anthrax Protection: Problems or Progress"
May 9, 2006
S&T Director Bio-Countermeasures Dr. John Vitko &
Deputy Director Bio-Countermeasures Dr. Elizabeth George

Question from Representative Chris Shays

The Department of Homeland Security responded to the GAO report by stating: The Environmental Protection Agency has the primary responsibility establishing the strategies, guidelines and plans for recovery from a biological attack, while the Department of Health and Human Services has the lead role for any related public health response guidelines.

After two years, we are still waiting for a strategic plan and a validation of sampling process to determine, for instance, whether Madison Square Garden or even the room we are in sitting in right now is free from anthrax.

1. I want to know who takes ownership for having a strategy at this table for developing a protocol so that we can validate whether or not Madison Square Garden is not contaminated, and that it is clean? Who takes responsibility here?

Response: According to Homeland Security Presidential Directive (HSPD)-5, the Secretary of Homeland Security is the principal Federal official for domestic incident management. Pursuant to the Homeland Security Act of 2002, the Secretary is responsible for coordinating Federal operations within the United States to prepare for, respond to, and recover from terrorist attacks, major disasters, and other emergencies. The Secretary shall coordinate the Federal Government's resources utilized in response to or recovery from terrorist attacks, major disasters, or other emergencies. To that end, the Department of Homeland Security (DHS) has taken ownership for leading the development and validation of a coordinated, interagency strategy and the associated methods that will determine if a facility 'of possible concern' poses a public health risk. Data resulting from the execution of this sampling strategy will then be used by the local lead agency, i.e. local public health, to declare whether a facility is or is not safe to occupy.

However, it is also recognized that a successful response to any incident will involve effective coordination, and one challenging issue for all involved is that of decontamination. Recognizing this, the White House Office of Science Technology and Policy (OSTP), through its Subcommittees on Decontamination Standards and Technology (SDST), and on Standards (SOS), is coordinating the development of science-based guidance for cleanup decisions following biological, chemical, or radiological terrorist incidents. The guidance, outlining specific decisions and actions to be taken by each agency to enable effective cleanup, is being developed by interagency expert working groups.

DHS is providing leadership and coordinating the interagency (Environmental Protection Agency [EPA], Department of Health and Human Services [HHS], Federal Bureau of Investigation [FBI], and Department of Defense [DOD]) environmental sampling activities including:

- Obtaining agreement on a definition of validation
- Validating key steps of the end-to-end sampling process, to include targeted and probability based sampling strategies as appropriate; sample collection; sample transport; sample extraction and sample analysis

Questions for the Record
House Government Reform National Security, Emerging Threats, & International Relations Subcommittee
"Anthrax Protection: Problems or Progress"
May 9, 2006
S&T Director Bio-Countermeasures Dr. John Vitko &
Deputy Director Bio-Countermeasures Dr. Elizabeth George

- Defining key milestones and tracking progress against those milestones
- Defining, identifying, and working with its partners to provide appropriate investments in:
    - Methods development
    - Empirical validation studies
- Focusing on anthrax but keeping in mind extensions to all agents of concern
- Working with its partnering agencies to incorporate the results of these studies in their policies and guidelines

Hearing Date: May 9, 2006
Committee: House Government Reform
Subcommittee on National Security, Emerging Threats and International Relations
Member: Congressman Shays
Witness: Mr. Reed
Question #2

Hearing on "Anthrax Protection: Progress or Problems?"

Question: Mr. Reed, Have detection systems been deployed to other major cities besides Washington DC?

Answer: Yes, the Department of Defense's (DoD's) involvement in deployment of biodetection systems within the Washington DC Metropolitan Area is primarily focused on surveillance of operationally significant areas for the military. Additionally, biodetection systems are deployed at key military installations both in the Continental United States and outside the Continental United States.

The Department of Homeland Security's Science and Technology Directorate (DHS S&T) has the primary mission to deploy biological and chemical surveillance capabilities supporting the monitoring of civilian areas of interest, including major jurisdictions throughout the United States. DoD did provide technology and fielding support for several of the jurisdictions in the initial deployment of DHS' BioWatch program. Information inquiries on DHS S&T's capabilities deployed both within the Washington DC Metropolitan Area and other major jurisdictions should be redirected to the DHS S&T Program Executive Officer, Dr. Jeffrey Stiefel, 202-254-6076, Jeffrey.stiefel@dhs.gov.

The United States Postal Service (USPS) Biological Detection System (BDS) Program has the primary mission to deploy surveillance capabilities supporting the monitoring of the mail, focusing on safety for its personnel. BDS systems are deployed within USPS facilities not only in the Washington DC Metropolitan Area, but in cities throughout the United States. Information inquiries on USPS capabilities deployed both within the Washington DC Metropolitan Area (including the Metro System) and other major cities should be redirected to the BDS Program Manager, Mr. Don Crone, 703-280-7874, don.e.chrone@usps.gov.

Hearing Date: May 9, 2006
Committee: House Government Reform
Subcommittee on National Security, Emerging Threats and International Relations
Member: Congressman Shays
Witness: Mr. Reed
Question #3

Hearing on "Anthrax Protection: Progress or Problems?"

Question: Mr. Reed, What steps if any have been done to invest in validation of studies of sampling process activities and methods for other biothreat agents besides anthrax? Are there any being done at this point?

Answer: The Department of Defense (DoD) is involved with validation studies to support both the sampling and detection processes for environmental and diagnostic samples for other biothreat agents besides anthrax. The DoD was a major contributor to the interagency working group that developed the new American Standards and Testing Method (ASTM), "Standard Practice for Bulk Sample Collection of Visible Powders Suspected of being Biological Agents from Non-Porous Surfaces," and is contributing to additional sampling protocols now in development. The DoD, the Department of Homeland Security (DHS), the Centers for Disease Control and Prevention, the Technical Support Working Group, and the Environmental Protection Agency have organized the Second National Conference on Environmental Sampling and Detection for Bio-Threat Agents to create a forum for first responders from military and civil defense to exchange techniques, ideas, and lessons learned and for leaders to exchange strategies for environmental sampling and detection in the defense of our homeland.

Activities associated with environmental monitoring for other biothreat agents have included interagency collaborations with the DHS through the BioNet Program, which includes a task to evaluate and compare detection assays for Anthrax, Tularensis, Plague, and Smallpox. The key objective of this task is to obtain mutual acceptance of results from assays employed by both DoD and DHS in their respective environmental monitoring systems. In addition, DoD, DHS, Department of Health and Human Services, United States Postal Service, and Department of Justice signed a Memorandum of Understanding on Coordinated Monitoring of Biological Threat Agents. Section 3.c. calls for Biothreat Agent Test Performance Equivalency. This effort is currently underway.

Hearing Date: May 9, 2006
Committee: HGRC
Member: Representative Shays
Witness: Ellen P. Embrey
Question # 94

ANTHRAX PROTECTION: PROGRESS OR PROBLEMS?

Question: Why hasn't "A Review of the Scientific Literature as it Pertains to Gulf War Illnesses: Volume 3-Immunizations" been released and when will it be?

Answer: The review is an undertaking by the RAND Corporation's, National Defense Research Institute. It is one of eight commissioned by the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses in 1997. RAND completed seven of these reviews and published the results. Only the report on immunizations remains.

Previously published reports were:

Volume 1: Infectious Diseases (published in 2001)
Volume 2: Pyridostigmine Bromide (1999)
Volume 4: Stress (2000)
Volume 5: Chemical and Biological Warfare Agents (2000)
Volume 6: Oil Well Fires (1998)
Volume 7: Depleted Uranium (1999)
Volume 8: Pesticides (2000)

RAND provided draft versions of the immunization report in 1999, 2003, and 2005 to the Department of Defense (DoD) for review and comment. DoD sent comments and recommendations to RAND. Such opportunities for review and comment were also afforded to DoD for drafts of the other seven reports as well.

According to RAND representatives, editorial review and changes to the latest draft are still underway. Publication before the end of 2006 is the current projection.

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