

**DEPARTMENT OF HOMELAND SECURITY
APPROPRIATIONS FOR FISCAL YEAR 2006**

THURSDAY, APRIL 28, 2005

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:29 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Judd Gregg (chairman) presiding.

Present: Senators Gregg, Cochran, Stevens, Craig, Allard, Byrd, and Inouye.

DEPARTMENT OF HOMELAND SECURITY

STATEMENT OF DR. PENROSE C. ALBRIGHT, ASSISTANT SECRETARY
FOR SCIENCE AND TECHNOLOGY

OPENING STATEMENT OF SENATOR JUDD GREGG

Senator GREGG. We will convene this hearing.

The purpose of this Homeland Security hearing is to review where we stand relative to defending this Nation from biological or chemical attack, which is in my opinion the biggest threat to our country. If you prioritize threat, which is exactly what we should be doing as a Congress and as a Government, you have to put at the top of the list the concerns weapons of mass destruction used against the American population somewhere here in the United States or overseas obviously.

We, 2 years ago, began the effort to try to aggressively address this issue, recognizing some fundamental flaws within our structure as a country, the biggest flaw being the pharmaceutical industry, which one would presume would naturally pursue ways of being able to respond to a biological attack, was not structured to do so, and the Government was not structured to deal with a chemical or a biological attack.

BIOSHIELD

So we worked very hard, in my prior role as Chairman of the Health Committee, to pass a piece of legislation called BioShield, which was the initiative of the administration. And the purpose of this bill was to reenergize the vaccine industry in this country and to energize the research community within our Nation to pursue ways to respond to various chemical and biological agents which might be used against us.

We understand, obviously, there is no market for a product to respond to these type of agents. These agents are by definition agents

which do not commonly occur, but only occur when we are attacked, although smallpox was a problem, but it has been eradicated. So we needed to create a structure where there would be not only an atmosphere where creative individuals and scientists would step forward to develop responses to attacks involving threats such as anthrax, smallpox, botulism, and plague, but we also had to create a monetary system, a market system which would encourage this from a standpoint of making it a reasonable place to invest your money if you were an investor. And that is what BioShield was all about. It basically put the Government in the business of buying antidotes and vaccines for this list of major threats.

We are now well into this process. Progress has been made in some areas but there is still a long way to go in other areas. The purpose of this hearing is to discuss what we are doing and what we should be doing that will better produce results.

My own personal concern is we have still not stood up a vaccine industry in this country at the level I would like to see it. We still do not have many participants in the production of vaccine, that the research community, especially our academic research community, has not yet embraced this initiative as well as and as aggressively as I would hope, and that there appears to be some incentives in the system which are discouraging research in this area, and the question of how we are purchasing products, to the extent it is being brought on line, whether that is chilling competition or participation of other parties in the research and development of creative new ways to address these types of threats.

It is a complex issue involving the most cutting-edge levels of science, and it does not have a simple solution. If it did, we would have gotten to it much sooner. But we do have a committed effort to do it, and we have got a committed Government to accomplish it, and I think we have got some good witnesses today to find out where we stand and where we should go.

With that, I will yield to the honorable Senator from Virginia, Senator Byrd.

STATEMENT OF SENATOR ROBERT C. BYRD

Senator BYRD. That is West Virginia.
 Senator GREGG. I apologize profusely.

BIOLOGICAL OR CHEMICAL ATTACK

Senator BYRD. Mr. Chairman, first of all, let me thank you for your service. I listened with rapt attention at your remarks. You are well prepared to be the Chairman of this subcommittee and well prepared to probe this very important subject.

I welcome the witnesses on both panels for this hearing, and I applaud you, Mr. Chairman, for calling us together for such an important topic.

Earlier this year during testimony before the Senate Intelligence Committee, CIA Director Porter Goss warned and I quote "It is only a matter of time before Al Qaeda or another terrorist group tries to use chemical, biological, radiological, or nuclear weapons in the United States." Mr. Chairman, I believe that. I believe it is absolutely the case, and I am not sure that we are prepared. I doubt it because we do not know when, we do not know where this mon-

ster will confront us with a bioterror attack, a chemical attack, a nuclear attack, or a radiological attack.

With regard to a biological attack, Congress made a serious commitment by appropriating \$5.6 billion to pursue new vaccines and medications to protect the American public from known biological threats. It is essential the agencies involved in this process be accountable for progress in this area. So, I look forward to discussing this and other homeland security efforts, not only to detect and respond to a bioterror incident, but what efforts are being made to prevent a biological, chemical, also to examine nuclear terror incident.

Thank you, Mr. Chairman.

Senator GREGG. Thank you, Senator Byrd.

We will turn to the panel now. The first panel will be people in our Government who have first-line responsibility for getting us prepared for a biological or chemical attack and being able to respond to it. Our first witness is Dr. Albright who was confirmed as Assistant Secretary of Homeland Security, Plans, Programs, and Budgets on October 3. Our second witness is Mr. Simonson who is the Assistant Secretary for Public Health Emergency Preparedness, United States Department of Health and Human Services. And these two gentlemen have the portfolio and we look forward to hearing how we are doing. So let us start with you, Dr. Albright.

STATEMENT OF DR. PENROSE C. ALBRIGHT

Dr. ALBRIGHT. Good afternoon, Chairman Gregg, Senator Byrd, and distinguished members of the Subcommittee. I am pleased to appear before you today to discuss the progress the Science and Technology Directorate of the Department of Homeland Security is making in the Nation's efforts to prevent, protect against, respond to, and recover from acts of bioterrorism against the American people.

President Bush has made strengthening the Nation's defenses against biological weapons a critical national priority. The President's focus on these issues has resulted in a joint Homeland Security Presidential Directive/National Security Presidential directive entitled Biodefense for the 21st Century that provides a comprehensive framework for our Nation's sustained and focused effort against biological weapons threats.

ACCOMPLISHMENTS IN BIODEFENSE

The Department of Homeland Security and the Science and Technology Directorate have explicit responsibilities in this integrated national effort. In particular, I want to highlight the strategy, planning, and accomplishments to date of the Science and Technology Directorate in the area of biodefense and the essential collaborations with key Federal partners, including those represented here today.

In 2004 and 2005, the Science and Technology Directorate developed a national architecture and plan for the detection of biological attacks, should they occur, and as initial steps, deployed the BioWatch Environmental Sensor System to protect our Nation's cities from the threat and ramifications of such an attack and also

initiated the design of the National Biosurveillance Integration System as part of an interagency process.

We completed the planning and conceptual design of the National Biodefense Analysis and Countermeasures Center. This center will focus on, among other things, creating a scientifically based understanding of the biological threat.

We established the Biodefense Knowledge Center, which is an operational hub for enabling collaboration and communication within the Homeland Security enterprise. We have certified four material threats and have two additional certifications underway. These material threat determinations are required in order to commit BioShield funds.

We have established a National Bioforensic Analysis Center to provide a national capability for conducting forensic analysis of evidence from biocrimes and terrorism to obtain a biological fingerprint to identify perpetrators and determine the origin and method of the attack.

In 2006, our expectations are to complete the deployment of the second generation BioWatch system to the top threat cities and to complete test and evaluation of the laboratory prototypes for the third generation of these detection systems.

We will also complete the first formal risk assessment that is required under HSPD-10 and close many of the key remaining experimental gaps in our knowledge of the classic biological threat agents.

We will continue operations of the Plum Island Animal Disease Center and essential upgrades to the facility and initiate the design of the National Bio and Agrodefense Facility.

We continue to develop bioassays for Foot and Mouth Disease and look-alike animal diseases. We continue to conduct cutting-edge research in academia through our Homeland Security Centers of Excellence. Although each of the four centers we have has a role in addressing bioterrorism, let me highlight two.

One is at Texas A&M and its partners which study foreign animal and zoonotic diseases at the National Center for Foreign Animal and Zoonotic Disease, and they address potential threats to animal agriculture, including Foot and Mouth Disease, Rift Valley fever, Avian influenza, Brucellosis, that sort of thing.

The University of Minnesota and its partners established best practices and attract new researchers to manage and respond to food contamination events.

S&T DIRECTORATE'S INTERAGENCY COLLABORATION

Ensuring that all relevant Federal Departments and agencies coordinate in the area of biodefense is critical to protecting the Nation from biological threats. The Science and Technology Directorate has been and continues to be an active participant in relevant interagency activities. A full list of the S&T Directorate's interagency collaborations is in my statement for the record. Highlights include our integral participation in the creation of HSPD-10. We also participate in the Counterproliferation Technology Coordinating Committee, the National Science and Technology Council's Weapons of Mass Destruction Medical Countermeasures Committee, which is really crucial to our way ahead on BioShield. This

last, which I personally co-chair, provides an interagency forum for discussing and prioritizing the medical countermeasure needs, as I said, that will be pursued under the BioShield program.

We work closely with our colleagues in the Department of Health and Human Services and USDA. Mr. Simonson and I see each other very frequently, and he and I and our staffs interact nearly daily in our respective efforts to protect the Nation from the threats of bioterrorism.

As I hope I have indicated, the Science and Technology Directorate's programs fully support the National Biodefense Program, as stated in HSPD-10. Moreover, they are conducted in an active collaboration with other Federal Departments and agencies, having a role in meeting this national priority and are focused on reducing the threat of a biological attack against the Nation's population and its agricultural and food infrastructures. We also support a science-based forensics and attribution capability.

PREPARED STATEMENT

This concludes my prepared statement. With the subcommittee's permission, I request that my formal statement be submitted for the record. Mr. Chairman, Senator Byrd, members of the subcommittee, I thank you for the opportunity to appear before you and will be happy to answer any questions that you may have.

[The statement follows:]

PREPARED STATEMENT OF DR. PENROSE C. ALBRIGHT

INTRODUCTION

Good afternoon, Chairman Gregg, Senator Byrd and distinguished members of the Subcommittee. I am pleased to appear before you today to discuss the progress the Science and Technology Directorate of the Department of Homeland Security is making in the Nation's efforts to prevent, protect against, respond to, and recover from acts of bioterrorism against the American people.

President Bush has made strengthening the Nation's defenses against biological weapons a critical national priority. Although significant progress has been made to protect America, President Bush instructed Federal departments and agencies to review their efforts and find better ways to secure America from bioattacks.

This review resulted in a Presidential Directive entitled Biodefense for the 21st Century that provides a comprehensive framework for our Nation's biodefense. This directive builds upon past accomplishments, defines specific roles and responsibilities, and integrates the programs and efforts of various communities: national security, medical, public health, intelligence, diplomatic, agricultural and law enforcement into a sustained and focused effort against biological weapons threats.

The Department of Homeland Security (DHS) and the Science and Technology (S&T) Directorate have explicit responsibilities in this integrated national effort. In particular, I want to highlight the strategy, planning and accomplishments to date of the Science and Technology Directorate in the area of biodefense, and the essential collaborations with key Federal partners.

BIODEFENSE

Before I speak directly to the biodefense efforts of the S&T Directorate, I want to briefly address the role of the DHS's Information Analysis and Infrastructure Protection Directorate (IAIP), and how their work is linked to the S&T Directorate. IAIP assesses intelligence and information about threats and vulnerabilities from other agencies and takes preventative and protective action. They are partners in the total interagency efforts to obtain, assess and disseminate information regarding potential threats to America from terrorist actions. These threat and vulnerability assessments are inputs into the strategy and research, development, testing and evaluation (RDT&E) activities of the Science and Technology Directorate. For example, agriculture and food are two of the multiple critical infrastructure sectors iden-

tified by Homeland Security Presidential Directive 7 (HSPD-7). As such, they fall within the domain of the IAIP Directorate; they are also within the domain of concern for biological threats and are considered in HSPD-9 and HSPD-10/National Security Presidential Directive-33 (NSPD-33). In addition, the IAIP Directorate's cooperation with the Science and Technology Directorate is critical to the Department's mission to determine what agents would significantly impact national security if released (Material Threat Determinations).

Mission and Objectives

HSPD-10 outlines four essential pillars of the Nation's biodefense program and provides specific directives to further strengthen the significant gains made in the past 3 years. The four pillars of the program are:

- Threat Awareness.*—Which includes biological weapons-related intelligence, vulnerability assessments, and anticipation of future threats. New initiatives will improve our ability to collect, analyze, and disseminate intelligence on biological weapons and their potential users.
- Prevention and Protection.*—Which includes interdiction and critical infrastructure protection. New initiatives will improve our ability to detect, interdict, and seize weapons technologies and materials to disrupt the proliferation trade, and to pursue proliferators through strengthened law enforcement cooperation.
- Surveillance and Detection.*—Which includes attack warning and attribution. New initiatives will further strengthen the biosurveillance capabilities being put in place in fiscal year 2005.
- Response and Recovery.*—Which includes response planning, mass casualty care, risk communication, medical countermeasures, and decontamination. New initiatives will strengthen our ability to provide mass casualty care and to decontaminate the site of an attack.

The Department of Homeland Security has a role and responsibility in each of these four pillars of the national biodefense program. The S&T Directorate has the responsibility to lead the Department's RDT&E activities to support the national biodefense objectives and the Department's mission.

Achievements and Planned Activities

- In fiscal year 2004 and fiscal year 2005, the Biological Countermeasures portfolio:
- Deployed the BioWatch environmental sensor system to protect our Nation's cities from the threat and ramifications of a bioterrorist attack.
 - Engaged in creating additional near real-time monitoring (Autonomous Pathogen Detection System) of critical infrastructure facilities such as major transportation hubs. New infrastructure protection efforts include shorter response time biological agent detection capabilities for BioWatch. This pilot (second generation Bio Watch) is in the process of being deployed in New York City and will join an expansion of the number of collectors in that city.
 - Initiated the design of the National Biosurveillance Integration System (NBIS) as part of an interagency process. Recently completed in the first quarter of fiscal year 2005, we will work with the Information Analysis and Infrastructure Protection (IAIP) Directorate to implement this system.
 - Conducted preliminary analyses, using the reference scenario approach recommended by Homeland Security Presidential Directive (HSPD)-10 for understanding the requirements of an integrated national biodefense architecture, of four baseline reference cases: a large outdoor release of a non-contagious agent (anthrax); a large indoor release of a contagious agent (smallpox); contamination of a bulk food supply; and two highly virulent agricultural attacks, one on livestock (Foot and Mouth Disease) and the other on crops (soy bean rust).
 - Established the Biodefense Knowledge Center, an operational hub for enabling collaboration and communication within the homeland security complex. The Biodefense Knowledge Center will meet the operational and planning requirements of government decision-makers and program planners, the intelligence community, law enforcement officers, public health practitioners, and scientists. Specific capabilities offered to these end-users include knowledge services, modeling and simulation, situational awareness and a pathway to accelerate research and development.
 - Certified four "material threats" (anthrax, smallpox, botulinum toxin, and radiological/nuclear); will complete the rest of the Category A bioagents (plague, tularemia) by the end of fiscal year 2005.
 - Established the National Bioforensic Analysis Center (NBFAC) to provide a national capability for conducting forensic analyses of evidence from bio-crimes and terrorism to attain a "biological fingerprint" to identify perpetrators and determine the origin and method of attack. The NBFAC was named in HSPD-

10 as the lead Federal facility to conduct and facilitate the technical forensic analysis of materials recovered following a biological attack in support of the appropriate lead Federal agency [in most cases the lead Federal agency will be the Federal Bureau of Investigation (FBI)].

In fiscal year 2006, the Biological Countermeasure portfolio plans to:

- Complete the three high-level architectures initiated in fiscal year 2005, identifying key requirements for each major element, a “report card” on the current and projected status in that area and performing detailed design tradeoffs for those areas in which DHS has execution responsibility.
- Complete the first formal risk assessment required under HSPD–10 and close many of the key remaining experimental gaps in our knowledge of the classical biological threat agents. Near-, mid-, and long-term plans for dealing with engineered agents will be developed, and R&D on addressing the gaps in responding to genetically modified organisms (e.g., antibiotic resistant) initiated.
- Complete the deployment of Generation 2 BioWatch systems to additional cities while continuing to operate and optimize already extant BioWatch systems.
- Complete test and evaluation of laboratory prototypes of the Generation 3 BioWatch detection systems for selection of fieldable prototypes for fiscal year 2007.
- Continue operation of the interim National Bioforensic Analysis Center. International Organization for Standardization (ISO) certification is expected to
- 5 have been achieved, giving the analyses conducted additional credibility and authenticity in both the national and international community and courts of law. R&D will continue on the physical and chemical signatures of the “matrix” materials associated with biological agents so as to develop methods for understanding tell-tale remnants of enrichment media, culture conditions, metabolites, and dispersion technology.
- Continue operation of the Plum Island Animal Disease Center (PIADC) and essential upgrades to the facility and initiate design of the National Bio and Agrodefense Facility (NBAF). R&D will continue on next generation vaccines and antiviral therapeutics for foot and mouth disease (FMD) and other high priority foreign animal diseases.
- Continue to develop bioassays for FMD and look-alike animal diseases. The initial agricultural forensic capability established in fiscal year 2004 at PIADC will be enhanced and epidemiologic capability added. A High Throughput Diagnostics Demonstration will be initiated to work with regional and State laboratories to demonstrate a capability of analyzing thousands of samples per day in support of response to a suspected case or an outbreak. A FMD table top exercise will be conducted, and development of a coupled epidemiological and economic model for FMD will begin. The end-to-end systems study initiated in fiscal year 2004 for Soybean Rust and FMD will be completed, and system studies will be initiated for highly pathogenic avian influenza.

National Bio-Defense Analysis and Countermeasures Center (NBACC)

The NBACC, a key component of the National Strategy for Homeland Security, addresses the need for scientific research to better anticipate, prevent, and mitigate the consequences of biological attacks. The need for the NBACC facility is further defined in HSPD–10, the Nation’s blueprint for future biodefense programs. The NBACC’s mission will support two pillars of this blueprint—threat awareness and surveillance and detection. The NBACC is made up of two centers, the Biological Threat Characterization Center and the National Bioforensic Analysis Center to carry out these missions. Specifically, NBACC’s mission is to:

- Understand current and future biological threats, assess vulnerabilities, and determine potential impacts to guide the research, development, and acquisition of biodefense countermeasures such as detectors, drugs, vaccines and decontamination technologies; and
- Provide a national capability for conducting forensic analysis of evidence from bio-crimes and terrorism to attain a “biological fingerprint” to identify perpetrators and determine the origin and method of attack.

In fiscal year 2004, the Department completed the planning and conceptual design of the NBACC facility. Additionally, the Department has been working through the National Environmental Policy Act (NEPA) process during the year, which culminated in the signing of the Record of Decision in January 2005 of the Final Environmental Impact Statement (EIS) for the construction project and subsequent operations. It was decided to delay the award of any contracts for design and construction until further in the EIS process. As the public concerns are analyzed and considered it is anticipated that contracts will be awarded in fiscal year 2005 to initiate design and construction of the NBACC facility

In fiscal year 2005, the solicitations of contracts for the construction of the NBACC facility are expected to be awarded. The design of the NBACC facility will commence in March 2005. Congress appropriated \$128 million in obligated funds, of which \$35 million was appropriated for award of the construction contract in the fourth quarter of fiscal year 2005. Construction of the facility is planned for completion by the fourth quarter of fiscal year 2008.

University Centers of Excellence

The mission of the University Programs is to stimulate, coordinate, leverage and utilize the unique intellectual capital in the academic community to address current and future homeland security challenges, and to educate and inspire the next generation of scientists and engineers dedicated to homeland security.

Within the University Programs in the S&T Directorate, the Homeland Security (HS) Centers of Excellence provide independent, cutting-edge research in academia for focused areas of homeland security Research and Development. Established centers include: the Homeland Security Center for Risk and Economic Analysis of Terrorism Events, the National Center for Foreign Animal Disease and Zoonotic Defense, and the National Center for Food Protection and Defense. In the next few months, the S&T Directorate expects to establish the Homeland Security Center for Behavioral and Social Aspects of Terrorism and Counter-Terrorism. Each Center is selected on a competitive basis, and each grant is for 3 years. Each Center has a role in addressing bioterrorism and two are specifically aligned with addressing bioterrorism.

DHS awarded funds, over 3 years, to the University of Southern California (USC) and its major partners, University of Wisconsin at Madison, New York University and Structured Decisions Corporation (affiliated with MIT) to establish the Center on Risk and Economic Analysis of Terrorism Events. The mission objectives are to evaluate the risks, costs and consequences of terrorism and to guide economically viable investments in countermeasures. Specifically, the Center will develop risk assessment and economic modeling capabilities that cut across general threats and targets, in application areas such as electrical power, transportation and telecommunications. Additionally, USC and their partners will develop tools for planning responses to emergencies, to minimize the threat to human life and reduce economic impacts of terrorist attacks.

Texas A&M University and its partners from the University of Texas Medical Branch, University of California at Davis, and the University of Southern California expect to receive funds over the course of the next 3 years for the study of foreign animal and zoonotic diseases. The Center, which will be known as the National Center for Foreign Animal and Zoonotic Disease Defense, will work closely with partners in academia, industry and government to address potential threats to animal agriculture including Foot and Mouth Disease, Rift Valley fever, Avian influenza and Brucellosis. The Foot and Mouth Disease research will be conducted in close collaboration with DHS's Plum Island Animal Disease Center.

The Department of Homeland Security will provide the University of Minnesota and its partners, Michigan State University, University of Wisconsin at Madison, North Dakota State University, Georgia Institute of Technology, and the University of Tennessee at Knoxville with funds over the course of the next 3 years to establish best practices and attract new researchers to manage and respond to food contamination events, both intentional and naturally occurring. The University of Minnesota's National Center for Food Protection and Defense, will address agricultural security issues related to postharvest food protection.

Negotiations began January 10, 2005, for a 3-year grant with the University of Maryland for a fourth Center on Behavioral and Social Research on Terrorism and Counter-Terrorism. We expect its mission objectives to be to provide strategies for intervention of terrorists and terrorist organizations and to embolden the resilience of U.S. citizens. Major domestic partners include, the University of California at Los Angeles, University of Colorado, Monterey Institute of International Studies, University of Pennsylvania, and the University of South Carolina.

A broad agency announcement was released in mid-January, 2005 for proposals for a fifth DHS Center of Excellence on the topic of High Consequence Event Preparedness and Response.

In addition to the University Centers of Excellence, the Department of Homeland Security's University Programs and the Environmental Protection Agency's Science to Achieve Results (STAR) Program are reviewing proposals for a research Center of Excellence focused on an area of high priority to both Agencies, Microbial Risk Assessment (MRA) for Category A bio-threat agents.

Interagency Collaboration

Ensuring that all relevant Federal Departments and agencies coordinate in the area of Biodefense is critical to protecting the Nation from biological threats. The previously mentioned HSPD-10, as well as other directives including HSPD-9, Defense of United States Agriculture and Food; HSPD-8, National Preparedness; HSPD-4, National Strategy to Combat Weapons of Mass Destruction; and HSPD-7, Critical Infrastructure Identification, Prioritization, and Protection, identify national objectives and priorities, and departmental and agencies' roles in addressing these national objectives.

The S&T Directorate has been, and continues to be an active participant in these interagency activities as illustrated by our participation in the biodefense program. At the highest level HSPD-10/NSPD-33 laid out the overall strategy, department and agency roles, as well as specific objectives and called for periodic reviews to plan, monitor and revise implementation. This was followed by an interagency review, of specific fiscal year 2006-fiscal year 2010 science and technology needs to support the national biodefense strategy as articulated in HSPD-10.

The National Science and Technology Council's Weapons of Mass Destruction Medical Countermeasures Subcommittee (WMD-MCM), co-chaired by the Assistant Secretary of the S&T Directorate, provides an interagency forum for discussing and prioritizing medical countermeasure needs to be pursued under BioShield. At still the next level of coordination, there are strong bilateral efforts around key elements of the strategy. Examples of this coordination including strong and frequent collaborations on Bioshield (HHS/DHS), the development of coordinated civilian and military surveillance and detection systems (DHS/DOD), the development and execution of a National Strategy for Agricultural Biosecurity (DHS/USDA), and development and assessment of decontamination technologies (DHS/EPA).

In addressing these activities, DHS has a leadership role in several key areas and partners with lead agencies in others. Those areas in which the S&T Directorate provides significant leadership are:

- Providing an overall end-to-end understanding of an integrated biodefense strategy, so as to guide the Secretary and the rest of the Department in its responsibility to coordinate the Nation's efforts to deter, detect, and respond to biological acts of terrorism.
- Providing scientific support to the intelligence community and the IAIP Directorate in prioritizing the bio-threats.
- Developing early warning and detection systems to permit timely response to mitigate the consequence of a biological attack.
- Conducting technical forensics to analyze and interpret materials recovered from an attack to support attribution.
- Operation of the Plum Island Animal Disease Center to support both research and development (R&D) and operational response to foreign animal diseases such as foot and mouth disease.

DHS also supports our partnering departments and agencies with their leads in other key areas of an integrated biodefense: the Department of Health and Human Services (HHS) on medical countermeasures and mass casualty response; the U.S. Department of Agriculture (USDA) on agriculture biosecurity; USDA and HHS on food security and the Environmental Protection Agency (EPA) on decontamination and on water security.

In addition, the Science and Technology Directorate has engaged with other Federal Agencies in the following efforts:

- The S&T Directorate worked with DOS (STAS), USDA, Office of Science and Technology Policy (OSTP), National Science Foundation (NSF) to create and support the U.S.-Japan Safe and Secure Society forum.
- The Directorate and DOS (OES) jointly created and negotiated the US-UK S&T Memorandum of Agreement (MOA). The resulting MOA supports collaboration on Homeland Security research, development, testing, and evaluation between the United States and the UK.
- The S&T Directorate represents DHS as the lead U.S. agency for the US-CA Public Security Technical Program (PSTP) which is the primary cooperative arrangement on S&T for homeland security between the two countries. Other U.S. agencies involved in the PSTP include: FBI, DOE, DOD, USDA, HHS, DOC (NIST), EPA, DOS, NSA and other DHS components.
- Currently leads a partnership with the Center for Disease Control (CDC), EPA, and FBI on the deployment of BioWatch, a bioaerosol detection system deployed to many of this Nation's cities.
- Funds BioNet—Defense Threat Reduction Agency (DTRA) executed pilot program to integrate civilian and military domestic biodetection and consequence management, using San Diego as a pilot city.

- Leading an interagency effort with HHS, DOD, and the United States Postal Service (USPS) to develop a National Integrated Biomonitoring System, part of HSPD-10 responsibility.
- Primary participant in the establishment of the National Interagency Bio-defense Campus being developed at Ft. Detrick.
- The National Bioforensics Analysis Center (NBFAC) is a joint Science and Technology Directorate-FBI program
- In a joint effort with USDA, have developed an integrated national agrodefense strategy, with especial emphasis on foreign animal disease. The Directorate and USDA also conduct joint research and development programs at the Plum Island Animal Disease Center

Presidential Initiatives

Three Presidential Initiatives address the needs of an integrated biodefense strategy and DHS plays a key role in each one. These three initiatives are:

BioShield.—Signed into law July 21, 2004, BioShield is a program coordinated by the Secretary for Homeland Security and the Secretary for Health and Human Services that provides \$5.6 billion over 10 years for the purchase and development of countermeasures to WMD. DHS's S&T Directorate plays a significant role in this in determining which agents constitute "material threats" and in developing scenarios that inform decisions on the quantity of countermeasures required. We have certified four "material threats" (anthrax, smallpox, botulinum toxin, radiological/nuclear, and nerve agents), have two additional underway, (plague and tularemia), and the rest of the Category A bioagents should be completed by fiscal year 2006.

Biosurveillance Initiative.—A program that seeks to enhance systems that monitor the Nation's health (human, animal and plant) and its environment (air, food, water) and to integrate these with intelligence data to provide early detection of an attack and the situational understanding needed to guide an effective response. The S&T Directorate plays a major role in the Biosurveillance Initiative in operating its 1st Generation BioWatch System, in deploying a 2nd Generation system and significantly expanding the number of collectors in the highest threat cities and at key facilities (e.g. transportation systems), and in continuing to develop advanced detection systems to further increase the capabilities. We are also designing the information system that will be used to integrate health and environmental monitoring information from the sector specific agencies with intelligence data from the IAIP Directorate. Implementation of this system will actually be initiated by the IAIP Directorate in fiscal year 2005, but the S&T Directorate will continue to supply subject matter expertise in biological threat and defense.

Food and Agricultural Initiative.—Seeks to enhance the security of our agricultural and food infrastructures. DHS activities in this area are led by the IAIP Directorate—but the S&T Directorate brings significant contributions in end-to-end studies of key agricultural and food threats, through the development of advanced diagnostics, and through R&D conducted jointly with USDA at the Plum Island Animal Disease Center.

CONCLUSION

The Science and Technology Directorate's programs conducted within the Department of Homeland Security fully support the national biodefense program as stated in the presidential directive Biodefense for the 21st Century, and other Homeland Security Presidential Directives. Moreover, they are conducted in an active collaboration with other Federal departments and agencies having a role in meeting this national priority, and are focused on reducing the threat of a biological attack against this Nation's population and its agriculture and food critical agricultural infrastructures, and supports a science-based forensics and attribution capability.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Senator Byrd, and Members of the Subcommittee, I thank you for the opportunity to appear before you and I will be happy to answer any questions that you may have.

Senator GREGG. Thank you, Mr. Albright.

Before we turn to Mr. Simonson, it is the tradition of this subcommittee to recognize the Chairman of the full committee, whenever he arrives, for any statement he wishes to make.

STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, thank you. Let me congratulate you on the success of the legislation which you authored here in the Senate to establish the legal authority to appropriate funds to deal with threats to our food supply and our agriculture infrastructure and our other concerns in the whole general area of bioterrorism. There is nothing more frightening to contemplate than an attack against these resources and assets in our country, and we do have a serious lack of products, drugs, countermeasures to deal with a serious assault on our food supply and our agriculture infrastructure. So it is very appropriate, I think, that you chair this subcommittee now that is in charge of funding the law you helped create and took a leadership role in, and we appreciate those efforts very much.

I am glad to be here with Dr. Albright and Mr. Simonson to congratulate them on their initiatives and hard work in developing a response structure at the Federal level and to provide national leadership in this very important undertaking.

Thank you.

Senator GREGG. Thank you, Mr. Chairman. I would simply note, it is only through your generosity that I chair this subcommittee, and I am very appreciative of that.

Mr. Simonson.

**STATEMENT OF STEWART SIMONSON, J.D., ASSISTANT SECRETARY,
OFFICE OF PUBLIC HEALTH EMERGENCY PREPAREDNESS, U.S.
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Mr. SIMONSON. Good morning, Mr. Chairman, Senator Byrd, Senator Allard, and Senator Craig, and other members of the subcommittee. I am Stewart Simonson, Assistant HHS Secretary for Public Health Emergency Preparedness, and I appreciate the opportunity to share with you information on the progress of implementing the Project BioShield Act of 2004, which was enacted some 9 months ago.

The events of September and October of 2001 made it very clear bioterrorism is a serious threat to our Nation and the world. The Bush administration and Congress responded forcefully to this threat by seeking to strengthen our medical and public health capacities to protect our citizens from future attacks. To encourage the development of new medical countermeasures against threats and to speed their delivery, President Bush in his 2003 State of the Union address proposed and Congress subsequently enacted Project BioShield. The \$5.6 billion 10-year special reserve fund was created to assure developers of medical countermeasures that funds would be available to enable the Government to purchase critical products.

Since enactment, my office has moved aggressively to fill immediate gaps in our reserve of medical countermeasures. A sense of urgency has pervaded our efforts and has defined new ways of doing business. Let me briefly describe to you what we have done to address these gaps beginning with anthrax.

ANTHRAX

Anthrax is a serious public health threat, and although the Strategic National Stockpile contains antibiotics sufficient to treat millions of persons exposed to anthrax, the vaccine has an important place in our preparedness and response strategy. The U.S. Government, relying on interagency expert input, defined the initial vaccine requirement for protecting 25 million persons.

The Institute of Medicine, in a report issued in 2002, urged that a new anthrax vaccine based on modern principles of vaccinology be developed. An assessment of developing technologies was undertaken by HHS, experts in the field, and it was determined there was sufficient scientific basis to support the aggressive development of a new generation of vaccine consisting of recombinant protective antigen, the so-called rPA vaccine. Research spanning more than a decade, conducted in large part by the U.S. Government, permitted us to move the vaccine further along the development pipeline. The National Institutes of Health took the lead in working with the private sector to advance development of this new vaccine.

When HHS felt the technology was mature enough to indicate that the vaccine could be licensed within 8 years, my office launched an initiative to acquire it for the Strategic National Stockpile. Utilizing a stringent evaluation process, we reviewed multiple proposals and finally negotiated a contract with VaxGen of Brisbane, California for 75 million doses of vaccine, anticipating a three-dose regimen. The milestone contract with VaxGen lays out an ambitious program, including delivery of the first 25 million doses of usable vaccine within 2 years of award.

I want to draw your attention to a feature of the contract with VaxGen and, indeed, all BioShield contracts. No payment for vaccine is made until the product is received into the stockpile.

To provide for the stockpile's immediate needs, my office is in the process of completing negotiations for 5 million doses of the currently licensed vaccine and hopefully with an option for an additional 5 million doses. We expect those negotiations to be concluded shortly.

But we are focused on threats beyond anthrax as well. My office has moved quickly to address the need for pediatric liquid formulation of potassium iodide, a drug that protects the thyroid from radioactive iodine. This formulation is aimed at young children who are at the greatest risk from the harmful effects of exposure to radioactive iodine. In March, a contract was awarded under Project BioShield for suspension potassium iodide to protect at least 1.7 million children. Product delivery will begin next month.

In addition to the BioShield contracts that have already been awarded, there are several other BioShield procurement related activities underway. We are reviewing the responses for request for proposals for anthrax therapies and we are continuing to move forward on the acquisition of an antitoxin treatment for botulinum.

To signal our intent to acquire a next generation smallpox vaccine, we will be releasing a draft request for proposal for industry comment within the next few weeks.

Finally, in anticipation of yet-to-be-determined requirements, we actively monitor the state of the medical countermeasure pipeline, both within and outside of the U.S. Government, by evaluating Government research and development portfolios and engaging industry to the publication of requests for information. For example, we have released three RFIs to assess the time line to maturity of medical countermeasures to treat nerve agent exposure, acute radiation syndrome, and additional products that might be available to treat anthrax. These requests are key for HHS to dialogue with industry partners to inform them on the development of a sound acquisition strategy.

Defining priorities and quantifying the size of the threat to the population are key steps in focusing our efforts. In the process, we must be mindful of the realities of the spectrum of efforts needed along the research and development pipeline to produce a usable medical countermeasure. The process of defining required specifications for countermeasures often reveals few, if any, candidates in the pipeline. We have been fortunate that some of our highest priority needs for countermeasures could be addressed using the available advanced development products already in the pipeline. However, basic research and early development efforts, when even robustly funded, often take years before a concept is mature enough for advanced development, and it is only when a product has reached the advanced development stage that Project BioShield provides a meaningful incentive for manufacturers to take the product the rest of the way.

PREPARED STATEMENT

In closing, HHS has a clear mandate from President Bush and Congress to lead the charge in countermeasure development. We have already made important strides to address the public health needs of the Nation, but there is more that needs to be done. Mr. Chairman, I look forward to working with you and Senator Byrd and other members of the committee to address the challenges of bioterrorism and to improve the public health of the Nation.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF STEWART SIMONSON

Good morning, Mr. Chairman, Senator Byrd and Subcommittee members. I am Stewart Simonson, Assistant Secretary for Public Health Emergency Preparedness. I appreciate the opportunity to share with you information on our progress in implementing the Project BioShield Act of 2004, which was enacted some 9 months ago. Biodefense is a top priority for the Bush Administration and having an appropriate armamentarium of medical countermeasures is a critical aspect of the response and recovery component of the President's "21st Century Strategy for Biodefense." The acquisition and ready availability of medical countermeasures, such as antibiotics, monoclonal and polyclonal antibodies against infectious threats, therapies for chemical and radiation-induced diseases, and vaccines to protect against exposure from biological agents will have a substantial impact on our preparedness and response capabilities.

PROTECTING AMERICANS

The events of September and October 2001 made it very clear that terrorism—indeed bioterrorism—is a serious threat to our Nation and the world. The Bush Administration and Congress responded forcefully to this threat by seeking to strengthen our medical and public health capacities to protect our citizens from fu-

ture attacks. The Bioterrorism Act of 2002 substantially increased funding authorization for the Centers for Disease Control and Prevention's Strategic National Stockpile. To encourage the development of new medical countermeasures against biological, chemical, or radiological agents and to speed their delivery and use in the time of an attack, President Bush, in his 2003 State of the Union address proposed and Congress subsequently enacted the Project BioShield Act of 2004. The Special Reserve Fund, pre-appropriated with \$5.6 billion was created to assure developers of medical countermeasures that funds would be available to purchase critical products for use to protect our citizens.

THE STRATEGIC NATIONAL STOCKPILE TODAY

The wake-up call that we received in the fall of 2001 brought clarity to the gaps in our chemical countermeasure armamentarium and we immediately sought to address them. Although there is much work still to be done, we have made significant progress in building our Strategic National Stockpile from that time to what we have on-hand today. For example, our smallpox vaccine stockpile has grown from 90,000 ready-to-use doses in 2001 to enough vaccine to protect every man, woman, and child in America. Major strides have been made in building our chemical countermeasure reserve against anthrax, plague, and tularemia. We are now able to protect and treat millions of Americans in the event of an attack with one of these agents. We have taken the botulism antitoxin program started by the Department of Defense in the early 1990s to completion and we are now building our antitoxin stockpile further. We have also built our stockpile of countermeasures to address the effects of radiation exposure with products such as Prussian Blue and diethylenetriaminepentaacetate, or DTPA. These countermeasures act to block uptake or remove radioactive elements such as cesium, thallium, or americium from the body after they are ingested or inhaled. Potassium iodide, a drug that can protect the thyroid from the harmful effects of radioactive iodine, is also in the Stockpile.

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, namely, smallpox and anthrax. A sense of urgency has pervaded our efforts and has defined new ways of doing business. Our new national security environment demanded accelerated product development timelines and new paradigms of interactions between industry and government with risk-sharing and enhanced intra-governmental collaboration. Using a robust interagency process, that mined intra- and extra-governmental expertise, requirements for medical countermeasures were identified, and options elaborated for addressing immediate and long-term needs. These experts continue to help us define the most expeditious way to traverse the critical pathway to develop and acquire usable countermeasures for the Strategic National Stockpile.

Application of the strategic approach: Anthrax

Although not transmissible from person-to-person, an attack involving the aerosol dissemination of anthrax spores, particularly in an urban setting, was considered by public health experts to have the potential for catastrophic effects similar to smallpox. . . . 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 the Department of Homeland Security determined that anthrax posed a material threat to the Nation. And, because untreated inhalation anthrax is usually fatal, the Secretary of HHS identified anthrax as a significant threat to public health.

The approach to protect citizens against this threat demanded immediate, intermediate and long-term strategies and requirements. First, the existing stockpile of antibiotics in the Strategic National Stockpile was increased. Second, there was a need for a licensed vaccine to be used not only for pre-exposure protection for laboratory and other workers at known risk for anthrax, but for use along with antibiotics after an exposure to potentially decrease the currently recommended 60-day course of antibiotic therapy. Anthrax spores are stable in the environment and would have a profound impact if released in an urban population. Availability of a vaccine is a critical requirement for repopulation and restoration of the functionality of any exposed area.

The limitations inherent in the currently available anthrax vaccine were articulated in a 2002 Institute of Medicine report, "Anthrax Vaccine: Is It Safe? Does it

Work?” The report stated, “. . . a new vaccine, developed according to more modern principles of vaccinology, is urgently needed.” 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). This research, spanning more than a decade from its inception in the early 1990s, was conducted in large part by the United States Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland.

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 Institutes of Health’s National Institute of Allergy and Infectious Diseases 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 and the conduct of Phase 1 and Phase 2 clinical trials. Large-scale manufacturing capacity would be required to support the civilian requirement for this medical countermeasure, which was defined through an interagency process to be the initial protection of up to 25 million persons. Senior officials throughout the United States government evaluated acquisition options to achieve this requirement and, in the fall of 2003, the decision was made to pursue the acquisition of rPA anthrax vaccine.

An evaluation of the status of the NIAID rPA anthrax vaccine development program suggested rPA vaccine could potentially 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 fiscal year 2004 Department of Homeland Security appropriations bill. Utilizing a robust technical and business evaluation process, we reviewed multiple proposals and finally negotiated a contract with VaxGen of Brisbane, California, for 75 million doses of the vaccine, (anticipating a three-dose regimen). Using a milestone and deliverables approach utilized with the ACAM2000 smallpox vaccine development and acquisition program, and the rPA anthrax vaccine development related contracts at NIAID, the VaxGen contract lays out an ambitious program to include the delivery of the first 25 million usable vaccine doses to the Strategic National Stockpile within 2 years of contract award. A unique and critical aspect of the rPA vaccine BioShield acquisition contract is the fact that no payment is made until a usable product is delivered to the Stockpile. While awaiting delivery of this new vaccine to the Stockpile my office will complete negotiations for 5 million doses of the currently licensed anthrax vaccine in the next few days to support immediate requirements. Delivery of the product to the Stockpile will begin very soon after the contract award and will have a direct impact on our preparedness.

Other Needed Countermeasures

In an effort to fill other gaps in the Stockpile, we have made progress in contracting for products that will soon be delivered for use.

Potassium Iodide

In March 2005 a contract was awarded under Project BioShield for a pediatric liquid formulation of potassium iodide, a drug that helps limit risk of damage to the thyroid, from radioactive iodine. This formulation is aimed at young children who cannot take pills and are at the highest risk of harmful effects from exposure to radioactive iodine. This acquisition will provide needed protection for at least 1.7 million children. Product delivery will begin next month.

Ongoing Project BioShield activities

In addition to the Project BioShield acquisition contracts that have been awarded in the last 9 months, there are several other important BioShield procurement-related activities underway. We are reviewing the responses for Requests for Proposals for anthrax therapies, and we are continuing to move forward on the acquisition of an antitoxin treatment for botulism. Furthermore, to signal our intent to acquire a next generation smallpox vaccine, we will be releasing a draft request for proposal for industry comment within the next 2 weeks. Finally, in anticipation of yet to be determined requirements, we actively monitor the state of the medical countermeasure pipeline—both within and outside the government—by evaluating USG research and development portfolios and engaging industry through the publication of Requests for Information (RFIs). For example, we have recently released three RFIs to assess the timeline to maturity of medical countermeasures to treat nerve agent exposure, acute radiation syndrome, and additional products that might be available to treat anthrax. These requests are a key tool for HHS to dialogue

with industry partners and to inform the development of sound USG acquisition strategies.

Priority Setting Beyond Smallpox and Anthrax

The approach taken to rapidly expand our Nation's response capacity to meet the medical and public health impact of either a smallpox or anthrax attack demonstrate our national resolve to address these threats. But, in many ways, anthrax and smallpox represent the "low hanging fruit" for medical countermeasure research, development and acquisition and was enabled by a substantial research base developed by USAMRIID and NIH. There was consensus that these were our highest priorities and we had countermeasures available or relatively far along in the development pipeline to permit acquisition. Given an almost endless list of potential threats with finite resources to address them, prioritization is essential to focus our efforts. We rely heavily upon our interagency partner, the Department of Homeland Security, to provide us with a prioritized list of threats along with material threat assessments that will provide reasonable estimates of population exposure. This information is critical for future strategic decision making regarding how best to focus our National efforts in countermeasure development and acquisition, including whether in the short-term, the so-called "one-bug, one-drug" approach should continue while simultaneously investing in more broad-spectrum prevention and treatment approaches for the longer term.

Challenges to Rapidly Expanding the Strategic National Stockpile

Although defining priorities and quantifying the size of the threat to the population are the key steps to focus our efforts, we must be mindful of the realities of the spectrum of efforts needed along the research and development pipeline to produce a useable medical countermeasure. The process of defining required specifications for a countermeasure often reveals few, if any, candidates in the pipeline. Basic research and early development efforts, even when robustly funded, often take years before a concept is mature enough for advanced development. When a product has reached the advanced development stage, Project BioShield Act of 2004 provides an important incentive for manufacturers to take the product the rest of the way through the pipeline. And, as I have outlined here today, in the 9 months since Project BioShield was enacted, the incentive has sped final development of several products for the Stockpile.

Conclusion

In closing, I must emphasize that the number of threat agents against which we could guard ourselves is endless and new and emerging threats introduced by nature will present continuing challenges. Although we cannot be prepared for every threat, we have the ability to create a strategic approach to identifying and combating the greatest threats. HHS and its agencies including NIH, CDC, and FDA, have a clear mandate from President Bush and Congress 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 bioterrorism preparedness and its impact on public health.

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

Senator GREGG. Thank you, gentlemen.

Let me start by saying I think there has been significant progress made. We started at zero, but I do not think we should underestimate how far we still have to go. We will start off by saying you have done a good job getting to where you are going, but the context of this hearing may ask questions about where do we have to go and how do we get there and why are we not there yet.

Let us begin. You, Mr. Simonson, talked about anthrax, and that is probably a good case study to look at because if you order the pathogens which are our biggest threat, smallpox is number one, followed by anthrax, and you have botulism. Then you actually drop down a level in my opinion and you hit botulism and hemorrhagic fever and a number of other things that are much more controllable than either anthrax or smallpox.

SYSTEM WEAKNESSES

But we have also seen three instances of what I would call real-life case studies as to how we react. We have got the SARS situation. We have got the avian flu situation, and we have just the simple flu vaccine situation. In each one of those instances, we saw weaknesses and we saw strengths of our system. I wanted to focus a little bit on the weaknesses because the strengths are good. Let me congratulate you for them, but I am concerned about the weaknesses.

The weaknesses, as I see it, are this. In the flu vaccination situation, we found ourselves with an “all the eggs in one basket” philosophy, and the provider of the vaccine turned out to be incapable of maintaining the supply. And thus, people were unable to get the vaccine. Are we creating the same problem again with anthrax, for example, where we essentially committed to a single supplier where the situation is that the supplier has not even gotten through clinical trials yet. Should we be approaching this by throwing the net wider and trying to energize more input to get more participation from more players?

We have one approved vaccine out there, which you mentioned you are buying 5 million doses from. It is a much more complex vaccine procedure than the one being proposed, but the one being proposed has not been approved, whereas the one that exists is approved. And so I guess my question is, why are we not splitting up at least into a couple baskets here rather than going full bore with one basket? That is the first question.

The second question is, are we energizing the minds out there that might have even more creative answers? Again, I will use anthrax as an example. I hate to be anecdotal because this should be more systematic than anecdotal. But I was up at Dartmouth where they have a very fine research facility, and the researchers up there said they were having great success with a proposal which basically addressed not only pre-prevention, but also if you were actually exposed to anthrax, had almost 100 percent recovery from anthrax. It was just at the mice level but they thought they were making great progress. But their attitude was they could not break into the system.

How many other people are out there? Are there people at Baylor? Are there people at Duke? Are there people out in Minnesota who basically have not figured out how to break into the system but might have the ideas? Are we energizing the research community first to come up with ideas and are we giving them a clear pathway that gets those ideas into the process, or are we shutting them out by simply choosing a winner here and saying this is the vaccine we are going to use, everybody else is off the table for the next 5 years because all the money is committed to this vaccine?

So it is two levels of questions. Have we made technically the right decision by choosing one vaccine to basically put all our eggs in one basket in light of the flu experience? And secondly, in doing that, have we also shut down the creativity in this area of anthrax because everybody now says, well, the anthrax is off the table because they have chosen this vaccine? So people at Dartmouth, peo-

ple at Baylor, people at Duke are going to move on to something else.

Mr. SIMONSON. I think, Senator, the influenza situation and other situations where we have put all of our eggs in one basket is distinguishable from what we are doing on anthrax. Utilizing what we sometimes call the push-pull, you push scientific development along the way using NIH and other instrumentalities to the point where it is far enough along that a Government contract can incentivize a maker to pull it. That is a very delicate balance in the negotiations with these companies. We found in our negotiations with the contractor that got the award that the \$75 million was about what we needed to pull it and—

Senator GREGG. How much does that constitute in dollar value?

Mr. SIMONSON. \$877 million.

That was the pull needed to get there. Cutting it in half would have really limited our ability to take advantage of the economies of scale and so forth as you ramp up.

But I think our interest in acquiring more AVA BioPort vaccine shows we are seeking not to put all of our eggs in one basket. Hopefully, we will be finishing the 5 million dose contract very soon. There is an option in there for another 5 million doses. It keeps the door open and allows us to continue a dialogue with BioPort so we can, where appropriate, adjust our stockpiles there.

Plus, we are doing some other things that are related. We have enormous quantities of antibiotics effective against anthrax.

We are trying to develop a good anthrax therapeutic, and this procurement I think especially speaks to the situation you mentioned earlier about people feeling locked out. What we have said is in order to keep our acquisition in sort of the state of the art, we are going to engage in essentially a three-stage acquisition, acquire the first round of anthrax therapeutics, but keep RFPs open for the next 2 years so products that were not able to compete in the first round could compete in the second round so that we have a diverse portfolio of anthrax therapeutics. So it was specifically designed for the purpose of not locking out someone who was on the verge of a breakthrough but had not quite gotten to the point where he could meaningfully compete for a BioShield contract. So we are sensitive to that.

I am not sure we are doing it the right way. I am not saying we are fully satisfied with the experience, but I think we are learning as we go and we are trying to be good stewards and to not over-commit where we do not see a need to. But we are sensitive to the need to keep the scientific community energized and interested in breakthroughs.

Senator GREGG. Senator Byrd.

CHEMICAL AND BIOLOGICAL AGENTS

Senator BYRD. The Gilmore Commission in its December 15, 2003, report stated that a single biological or nuclear attack could realistically kill tens of thousands of people. The report went on to say that to meet today's threats, we need technological breakthroughs such as the development of sensors to detect deadly chemicals or biological agents.

I believe that is your area, Dr. Albright. What are you doing to prevent these deadly agents from crossing our borders, coming into our ports, or arriving by plane?

When Secretary Ridge testified before the subcommittee last year, he said if a passenger wanted to board a plane with a biological or chemical weapon, we do not have the capacity to detect it. Is that still the situation? Does your budget request address this issue?

Dr. ALBRIGHT. So there were a couple questions. To answer the second question, the answer is no, we do not have a good way of detecting someone trying to bring a vial of pathogen across the border. That would be an extraordinarily difficult technical problem to address. If you think about the amount, for example, of anthrax or of smallpox needed to be brought across the border in order to either affect a large number of people or to act as seed stock for a domestic capability, you do not really need very much. The amount of the actual anthrax you would need would be about the size of a quarter. You would need very little smallpox to start culturing seed stock.

So the approach we have taken is rather than trying to solve what appears to be an intractable problem at the borders, let me stop and say there is another side to this, and that is when people and cargo do cross our borders, to the extent that we are able to target suspicious individuals or suspicious cargo and then inspect them manually and thoroughly, that would certainly provide a venue, just as it would provide a venue for detecting almost anything else they would bring across the border. But looking for, as I said, a vial of anthrax, the technical obstacles to that are just extraordinary.

So the approach we have taken instead is rather to detect an attack when it occurs because, in a sense, one of the real dangers or terrors associated with these kinds of pathogens is if they are deployed covertly, they start to infect people before anybody really knows what has happened. And by the time you start to see symptoms, it is usually too late to do much about it. So the trick here is to detect the attack before people become symptomatic, and when we have an opportunity, deploy the stockpile and treat the individuals concerned and save them.

BUDGET REQUEST

Senator BYRD. Would you touch upon the other question I asked? Does your budget request address this issue?

Dr. ALBRIGHT. Yes, sir. Our budget request I believe is approximately \$80-odd million for the next generation of the BioWatch. These are the urban detection systems. We have also got about \$100 million in our budget, roughly that is operations in support for the current system and actually there is another generation being deployed as we speak.

CHEMICAL DETECTORS

Senator BYRD. The Department is spending over \$100 million on the system of sensors known as BioWatch. The budget request for fiscal year 2006 proposes over \$225 million for a new office called the Domestic Nuclear Detection Office.

Less clear are the Department's efforts to prevent a chemical attack. After 9/11, the Senate approved \$15 million for the D.C. Metro system to deploy chemical detectors in the D.C. subway system. Now, that is an excellent system. It gives Metro the capacity to immediately determine if the subway has been exposed to a chemical agent so it can effectively respond.

This funding was included at Congress' initiative. It was not requested by the President. In fact, the White House specifically objected to the funding, describing it as excessive.

Last year, Under Secretary McQueary listed the D.C. Metro project as an accomplishment.

Is there any funding in the President's budget to take advantage of the lessons learned from this pilot program to deploy the chemical detectors in other large subway systems or urban areas around the country?

Dr. ALBRIGHT. The short answer is yes. Let me explain to you how it works.

First, it is called the PROTECT System, the system we have in the Washington Metro system. We see it as a significant success. In fact, the Department of Homeland Security is no longer really involved with it. We turned it over to the Washington Metropolitan Area Transit Authority. They operate it to the extent they need technical assistance, which is almost never, we supply it for them, but this is something that has been completely transitioned.

I will also add that during both the Republican and Democratic national conventions, we deployed this system also to the subway systems in Boston and in New York, and in fact, at the specific request of the New York Transit Authority police, we have kept the system deployed at certain sites in the New York subway system.

The way it works, though, is that from our perspective, the technology development is finished. So now the question here is one of transition. How does one do that? In particular, how does one transition these technologies to transit authorities which are local government entities?

So what we have been doing is working very closely with the Office of Domestic Preparedness, with ODP, to create grant guidance that will allow and focus grants to be deployed in local metro systems. There are something like over 30 metro systems around the country. They would then basically take the system and install it. It is really very inexpensive. It is only a few million dollars per metro system that is needed to do this. So that work is underway, but that would be embedded within our overall grant budget.

Senator BYRD. My time is up. Thank you, Mr. Secretary.

Senator GREGG. Thank you. Again, I recognize the chairman of the full committee.

NEW PRODUCTS TO PROTECT AGAINST BIOTERRORISM ACTS

Senator COCHRAN. Mr. Chairman, I just have a couple of questions. One is to focus attention on how we are developing incentives for researchers to discover and develop new products to protect the general public against bioterrorism acts. Dr. Albright, what are we doing and what is in the budget to try to help reach that goal?

Dr. ALBRIGHT. In terms of fundamental research for medical countermeasures, sits within the realm of my colleague here, Mr.

Simonson, and the Department of Health and Human Services. I will point out they have well over \$1 billion devoted to research and development activities within NIAID to invoke intramural and extramural contracts, and by that, I mean to researchers within NIAID, as well as to universities to develop the scientific basis for countering these threats across the entire list of category A and even B and C agents.

Senator COCHRAN. Mr. Simonson, do you have a response?

Mr. SIMONSON. That is absolutely right. We have about \$1.7 billion assigned to the biodefense research portfolio at NIH. It is a very aggressive agenda there to move advancement forward.

Senator COCHRAN. Will this utilize expertise that we have at academic health science centers, specifically the drug discovery efforts of schools of pharmacy?

Mr. SIMONSON. The extramural program does leverage academic health centers. I will check this for certain, but I would be shocked if discoveries in schools of pharmacology did not leverage some of this money.

SYSTEMS THAT MONITOR SUPPLY OF PHARMACEUTICAL PRODUCTS

Senator COCHRAN. I know there are efforts underway at the Centers for Disease Control and other agencies to develop systems that monitor the supply of pharmaceutical products besides those already in the strategic stockpile that could be needed in the event of widespread bioterrorism attack. Mr. Simonson, can you comment on such systems?

Mr. SIMONSON. Yes. CDC, through the Strategic National Stockpile, has a monitoring function where we are looking for availability in the both reverse distribution and distribution system, in case something happens where we would have to leverage what is already out in the field.

The FDA has a drug shortage function where they are tracking vulnerabilities in the pharmaceutical industry, how much of a particular product is out there and could be used in an emergency.

The difference is FDA has access to very closely held proprietary data that CDC often does not have access to. So we work it together.

Senator COCHRAN. Is there a sufficient amount of money in the budget request to get us started, Dr. Albright, to develop the infrastructure, the facilities for continued research in an aggressive way to meet this challenge?

Dr. ALBRIGHT. I think certainly in our fiscal year 2006 budget request, the answer is yes. There are multiple aspects to your question. Certainly in the research side, again that would be in DHHS, but there have been funds actually appropriated in 2004, for example, for the development of the laboratory infrastructure, the capitalization, for example, of biosafety level 4 research facilities across the country, and it is my understanding is well underway.

There are other issues, though. One of the things that Mr. Simonson and I have been working closely with is some of the capitalization needs associated with the developmental process. There are some unique issues associated with putting some of these bioterror pathogens through clinical trials, or the equivalent of clinical trials, because obviously we do not infect human beings with these

diseases in order to test them, that we are actively discussing at the moment.

Senator COCHRAN. Thank you, Mr. Chairman.

Senator GREGG. Thank you.

Senator Craig.

SHELF SENSITIVE VACCINES

Senator CRAIG. Mr. Chairman, thank you very much.

You touched upon a subject I want to pursue with our panel, and gentlemen, you are the professionals here. You tell me if this is an area that does not pertain to this particular area.

In the last several years, I chaired the Select Committee on Aging and a week before Chiron announced its Liverpool plant had been shut down, they were before us telling us they were going to meet the necessary 100 million doses, or whatever the number was, for the flu season. They did not meet it. We got through that season.

But it exposed to us the vulnerability of that particular vaccine industry, and it was a product, in part, because of what had transpired over a course of years. Here you have a mutating virus, I believe, and it changes annually, and you cannot stockpile, and so you have to predict and produce. If you mispredict, you end up with a lot more doses and it bankrupts your company and you go away. And you find out it is much too expensive to play in that field of health care, if you will, unless it is incentivized by government.

Of course, that technology is an egg-driven culture technology, and we are not into cell technology yet. We are trying to get money there.

The bottom line is we made it through this last season. I do not know that a flu virus could be brought to this country effectively and spread to create a pandemic by a terrorist organization. You are the ones who would have to be able to tell us that, whether it was a doable proposition.

But if it were, we would be so unprepared at this time to deal with it by all situations, and in certain segments of our country, certain demographics, the elderly, flu can be lethal, as we know, losing thousands and thousands of them in a normal flu season.

We are trying to correct that problem, but we are not quite there yet. Government is simply going to have to help these companies and buy off the surplus at the end of the season to allow them to produce.

Senator COCHRAN. How many of these kinds of vaccines or treatments are we preparing that are shelf-sensitive, that have to be rotated on an annual basis, that have to be sensitized to the mutating viruses all the time to be good and usable?

Mr. SIMONSON. Flu is the only vaccine that has to be made in this campaign process.

Senator CRAIG. Is it transportable and can it be used as a weapon?

Mr. SIMONSON. Influenza?

Senator CRAIG. Yes.

Mr. SIMONSON. One would think so, yes.

Senator CRAIG. Would you agree we are totally unprepared if it were ever used in that situation?

Mr. SIMONSON. I am not sure I would say we are totally unprepared, but it presents an enormous challenge to us and it is something we have been mindful of and worried about I think since the President took office.

Senator CRAIG. We are proceeding into the next flu season with how many producers of flu vaccine? Two?

Mr. SIMONSON. There are two producers of the killed vaccine, one producer of the live attenuated vaccine, and a third on the horizon. There is still regulatory work occurring with respect to the third.

CELL TECHNOLOGY VERSUS CULTURE TECHNOLOGY

Senator CRAIG. How much investment are we making in the new cell technology versus, if you will, the culture technology of eggs?

Mr. SIMONSON. We entered into a \$97 million contract for tissue culture, cell culture technology, which has enormous benefits over the embryonated hen's egg approach.

Senator CRAIG. And that benefit is to be able to speed up a process ultimately to produce a vaccine more quickly. Is that not correct?

Mr. SIMONSON. More quickly and it is less vulnerable to the things chickens are vulnerable to. We have hundreds of thousands of chickens who lay eggs for our vaccine every year. A high path influenza virus, avian influenza virus—

Senator CRAIG. Clean chickens.

Mr. SIMONSON. Yes, but they are still susceptible to disease. So it has worked out so far, but it is a fragile infrastructure.

We have also developed over the last 6 months some contingencies for our chicken flocks. We are building up flocks so if we have a problem in one, we can supplement with another, and we can also produce year around.

Senator CRAIG. But you have a tremendous time spread in that technology compared to tissue. Is that not correct?

Mr. SIMONSON. That is right.

Senator CRAIG. Well, I hope you are putting money into that new technology. We lucked out this year. We made it through the season with a lot of cooperation and, frankly, a lot of good coordination on the part of NIH and others and a lot of communities of interest. But I was absolutely amazed at our vulnerability in that area and the unwillingness, at least of Congress to date, to recognize it and incentivize it so we can keep industries functioning in those areas, not just in influenza but in other childhood areas. There is the liability issue, along with a lot of other things, that have just simply caused them to leave the market.

Mr. SIMONSON. Even before 9/11, this was a very clear priority of the Bush administration. There was work going forward even before 9/11 on this. There is so much more to be done, but we have made a very good start I think. But it was, for decades, neglected as a seasonal nuisance, the flu, and the flu is not a seasonal nuisance. The flu is, in some ways, a very, very unique threat to us if you look back at 1918 and what that did to this country, and we have to prepare for that and we are.

Senator CRAIG. Thank you.

Senator GREGG. Senator Stevens.

ADVANCE APPROPRIATION

Senator STEVENS. Thank you very much, Mr. Chairman.

I was pleased to join you in introducing this basic bill on Bio-Shield, Senator Gregg. We gave an advance appropriation of \$5,593,000,000. How much of that has been allocated to you for 2005? That was for the years 2004 to 2013. I just wondered how much has been released to you.

Mr. SIMONSON. Well, \$2.5 billion has been released to us.

DEMONSTRATION OF IDEAS BY PEOPLE

Senator STEVENS. We had a sense of urgency in terms of your mission. Part of it came from the fact that I was chairman of appropriations. Senator Cochran is now, and he is going to have this delightful experience. But people came to me to demonstrate some of the things they said they had prepared. One gentleman told me he had a substance which, if it was injected into the leg of an individual, would guarantee protection against all substances for a period of 48 hours. Now, I sent them to see you. What do you do with people like that when they come in?

Mr. SIMONSON. Well, there are a number of these people.

Senator STEVENS. There are a great number of people, but somewhere there might be one who knows what he is doing. That is what I want to know. What do you do with them?

Mr. SIMONSON. I hold out that hope as well. So what we do is we gather the research and development types, the physicians and scientists, in my office who have the capability of seeing maybe a gem in the rough and we go through it. In fact, we do this, I would say, in the regular course of business. We are going to be doing it again next week with a provider, a stem to stern review of what they say will protect against, in this case, irradiation exposure.

But it does happen often. We do it, and if we think there is any hope for it, we bring in our colleagues from NIH. We are looking all the time for more. Sometimes they are stacked up a little bit, but we do get to the people who come forward with these ideas.

Senator STEVENS. Is Dr. Franz still out there?

Senator GREGG. He has not testified yet.

Senator STEVENS. He has not testified yet. Can I ask him a question?

Senator GREGG. You can, sure.

NONGOVERNMENTAL SCREENING GROUP

Senator STEVENS. Do you think there should be a nongovernmental screening group that people will know exists that could review suggestions like this coming from individual scientists?

Dr. FRANZ. I'm sorry, sir. A nongovernmental screening group?

Senator STEVENS. Yes. Should we have provided for such an entity in the bill that we passed, a nongovernmental screening entity to review these suggestions so it would be quickly reviewed?

Dr. FRANZ. I think it depends on the resources. My own experience was as the Commander of the USAMRIID, we used to receive a lot of these things, and for the most part, as Mr. Simonson has said, I believe it is possible to look at the data presented, and oftentimes it is scanty. And to sit down with some smart people with

both basic research and clinical experience and make a decision to do a very careful screening, using good laboratory practices and so on, of each of these products would be very, very expensive. So I think it is important there be some kind of careful look outside the laboratory by some smart people before we send them to the laboratory.

Senator STEVENS. Thank you.

Mr. Simonson, my only comment is it just sounds to me there are a great many people in our national community who are thinking about these threats and some of them have capability and others do not. But I do hope we find some way to have an identification of where these people can take their suggestions. I am sure Senator Cochran will appreciate this because they still keep coming to us for money and we do not know one single thing about what they are talking about. So I do think there ought to be some identifiable place where people with capability and ingenuity to try to help solve some of these problems could go and know who they are talking to and we could know who to send them to.

Mr. SIMONSON. There is one other mechanism we use, as I indicated earlier. This request for information. We will take a look at what is missing and having looked through the Government pipeline, seeing nothing, we will send out a request for information, sources sought. Do you have work in this area that might be useful to the Government? And that produces a fair amount of really reliable data that we can then move forward on. So we are trying to do that.

I think there is no question, Senator, that when it comes to security countermeasures, people coming forward and saying we have got these ideas and we need a place to go, ours is the place to go. We want to have an open door for those sorts of inquiries.

Senator STEVENS. Thank you very much. My only comment would be if I let someone study how many permits the Wright brothers would have had to proceed with the demonstrations down at Kill Devil Hills, it would amaze you how many they would have had. I am sure similar things apply in this area. There is just an overwhelming number of permits necessary for anyone to even proceed with this independently. So I do hope we find some way to accommodate the knowledge of some people who may have the ingenuity to think a lot better than we thought they could.

Senator GREGG. Senator Allard.

Senator ALLARD. Thank you, Mr. Chairman.

BIOTERRORISM AND COOPERATIVE EFFORTS

I would like to make an inquiry as to how your efforts against bioterrorism are being coordinated with the Department of Defense, as well as the CDC lab? They are all deeply involved in biological threats to this country either through an epidemic, what we naturally have occurring in this country, which may be introduced or could be used by other nations as far as a bioweapon is concerned. I wonder if you might comment about your cooperative efforts, if you would, please.

Mr. SIMONSON. We have a structure in place that Dr. Albright and I, Dr. Winkenwerder, Assistant Secretary for Health Affairs at the Department of Defense, and Dr. Kline, who is Assistant to Sec-

retary Rumsfeld for chemical and radiological and nuclear matters. The four of us chair an interagency group that works through these countermeasure issues, set requirements, and make sure the right hand knows what the left is doing because there is a fair amount going on outside of HHS laboratories. Parny may have something to add to this, but I think that really is where all the coordination is occurring right now on the countermeasure development front.

Senator ALLARD. Are you communicating with the Department of Agriculture's plant and animal infectious diseases also? That is anthrax and potentially plague and zoonotic diseases. I assume you are also communicating with them.

Mr. SIMONSON. Yes. They participate in this group.

INTRODUCTION OF DISEASES FROM OTHER COUNTRIES

Senator ALLARD. Now, I understand the chairman had some questions he raised about flu. I was not sure whether he was talking about just the regular variety of flu that affects humans or he was talking about the avian influenza, which does not occur in this country but causing some deaths in Asia and apparently is pretty virulent and is a disease that is of serious concern to get introduced in this country.

When you have those kind of reports, what kind of action do you take?

Mr. SIMONSON. The first thing we do is to ensure that we are getting reliable data out of the region.

Senator ALLARD. So we send scientists down there to confirm the diagnosis.

Mr. SIMONSON. We do send people there. We also bring material back to the CDC or other laboratories to make sure the sample is being properly evaluated and that we are watching for antigenic drift, changes in the characteristics of the disease.

We fund, directly through the World Health Organization (WHO) or through bilateral agreements, ways to improve surveillance in these countries that have minimal infrastructure.

The United Kingdom and the United States fund a transport fund to actually pay for isolates to be shipped out of these countries that cannot afford to ship them, believe it or not. It is a very expensive proposition.

So that is the first thing we do. We trim that up. We send doctors into the field working with the WHO.

I think the second thing we do, this is something Secretary Levitt has been very committed to doing, is work diplomatically with his counterparts, health ministers and so forth to underscore the importance of transparency because without transparency, none of this is going to do us any good. We are trying to back up that transparency with funding.

Senator ALLARD. Well, the importation of material that is infected or potentially infected is a very volatile issue. We have a research laboratory off the shores of this country so we can make a claim that the disease does not occur in this country. I would hope that when you are bringing in those types of materials some consultation be made that in this particular case we happen to be talking about animal diseases, and it is important on our trade agreements that we never and we can always make the claim the dis-

ease does not occur in the United States. And avian influenza can have a dramatic impact, for example, in the poultry industry if we cannot make that claim as far as import and international trade and everything.

So I would encourage you, if you are not, to work closely with those various agencies because we are trying to do what is necessary to protect our population. We need to study. We need to be prepared for them, but yet we have to be careful in what way we set up our studies and how we handle that kind of material. It can be very complicated and it could be very controversial.

Mr. SIMONSON. I just want to follow up on something I said a moment ago. When we bring material back into this country, it is done in a very high level of bio-security so that we do not have to worry about it getting out, much like when other agents are brought back—

Senator ALLARD. Very, very important. Thank you.

Thank you, Mr. Chairman.

Senator GREGG. Thank you. I want to thank the panel.

I think Senator Stevens' point that we need to formalize the point of access where people of ideas can go is a pretty valid one because I know I hear it too. I have people come to me and say I have got a solution to this problem, and I refer them. It would be nice, I think, if we could pick a central Government place where we could send all these people who have those good ideas. I guess yours is the shop. I am not sure how we make it more visible in that area, but I think that might be useful.

But we do appreciate your work and we thank you for your time this morning and appreciate your testifying.

We are going to now move on to the second panel which is folks who are outside the Government right now and who have expertise as to whether or not we are doing a good job as a Government and who have a lot of experience, beginning of course with Dr. Franz, who has already been drawn into the discussion here, which we very much appreciate. Hopefully we can get the electronics here to work well so we do not end up with a lot of interference. Dr. Franz we know well because he was head of the U.S. Army Medical Research and Materiel Command for 23 years. He is now active in a number of other activities.

We have Dr. Leighton Read, who has joined the Alloy Ventures as a general partner in October 2001. He has 14 years as a biotechnical entrepreneur and investor, and he is going to give us his thoughts as to how you get into this business and whether or not the Government is making it easy.

And we have Mr. John Clerici who is an expert in liability issues. He was Judge Advocate in the United States Air Force where he spent a considerable amount of time advising the Air Force research laboratories on how to procure technologies.

So we appreciate all of you taking the time to be with us today. What we are interested in hearing about is how you think the Government is doing in instituting the goals of BioShield, which have certainly been outlined rather thoroughly this morning, to prepare ourselves to deal with a biological/chemical attack and to anticipate what the problems would be and be ready to deal with them. So we want to hear your thoughts on this.

We will start with you. Why do we not start with Dr. Franz and make sure we have got this thing working so that he is up and running. Dr. Franz is in Boston, which is obvious because there is a Red Sox symbol in front of him, probably curing Red Sox fever. If you could give us a test, Dr. Franz, that would be good.

Dr. FRANZ. Good morning, sir. Can you hear me?

Senator GREGG. Yes, we can. Thank you. Why do you not proceed?

**STATEMENT OF DR. DAVID FRANZ, CHIEF BIOLOGICAL SCIENTIST,
THE MIDWEST RESEARCH INSTITUTE**

Dr. FRANZ. Mr. Chairman, distinguished members, it is an honor to appear before you to address issues related to the procurement of medical countermeasures to protect the American population from bioterrorist agents and emerging infectious disease. I am currently Senior Biological Scientist at the Midwest Research Institute in Kansas City. I believe you have my resume.

This committee has asked that I provide some broad perspective on the medical aspects of biological defense in the context of a world in which intentional release of biological agents is of significant concern and natural introduction of disease is a reality. I will make seven brief points that encapsulate my written statement and then summarize my thoughts regarding the implications of these points for the challenges at hand.

First, regarding the threat, I believe the most significant barriers to biological terrorism today is the intention to commit the crime. This is especially true for contagious viruses. In the future, technology will draw on the options for both protection and for abuse.

Second, we are extremely vulnerable to bioterrorist attack in this free society, but for many technical and behavioral reasons measuring actual risk to any segment of the American population or its agriculture will continue to be extremely difficult.

Third, biology is characterized by great diversity. Microbes like our own immune systems can be either strong or weak. We can rank microbial capabilities that cause disease and even their utility for terrorist exploitations, but without solid intelligence, we can never know for sure which specific biological agent we might face or when. Many of us agree, however, as was mentioned earlier, there are outliers among the diverse microbial population. These include organisms that cause smallpox, anthrax, and foot and mouth disease.

Fourth, biology is neither as crisp nor are the rules of play as well defined as they are for physics and chemistry. Therefore, there are many opinions regarding the way ahead for bioterrorism defense.

Fifth, just trying to decide how to organize to protect ourselves is challenging. Secretary Richard Danzig has proposed a handful of select scenarios to be used "as an anvil against which to hammer our ideas." A compatible approach, which I have often discussed, is to prepare for the outliers and then broadly enhance our public health system as if we were expecting an unknown emerging infectious disease.

Sixth, regarding future threats, we should assume that almost anything is or will be possible, but we must not forget just because

it is theoretically possible it is almost always harder for us to manipulate biology either for good or for ill than we predicted.

And finally, seventh, we can do many things to protect ourselves but our preparation can never be perfect. I believe it is critically important that we carefully craft our concept of use and application of various biodefense measures are being developed so we address the greatest risks and vulnerabilities and ensure the maximum benefit for our investments. It will be costly, but the cost of failure in this area is potentially enormous. So how can we apply these principles?

First for vaccines. It is relatively easy to justify the acquisition of vaccines for anthrax and smallpox for the population. It is important, however, we thoroughly understand our concepts of use as we attempt to develop traditional agent-specific vaccines for the civilian population. In the short term, we should exploit next generation, flexible vaccine platforms. We were working on these in USAMRIID in the mid-1990's already, which will allow us relatively quickly to produce a licensed product, counter an outbreak of either epidemic or even pandemic. The basic platform might be licensed for use in humans now, allowing us to simply add a genetic cassette when a new vaccine is needed, greatly shortening the time for use. Our current system of vaccine research, development, and approval is simply not flexible enough to respond to terrorist attack or emerging disease.

For drugs, it is difficult to argue against spending as much as we can afford on antivirals and new classes of antibiotics and exploiting the genomic revolution to develop new categories of anti-infectives. All of these will improve the lives of Americans with or without a bioterrorist attack.

And regarding the future, attempting to protect our population from the unknown threat of today and especially of tomorrow with specific countermeasures like traditional vaccines will likely be extremely costly and inefficient. Significantly boosting the immune system to give us broad, multi-agent protection is now slightly more than a great idea I believe. I will not be surprised if it will be 15 or 20 years before we can do this in domestic animals effectively and maybe 30 years before we can really make a difference in the broad population of humans. But I believe we must be doing the necessary research right now. We probably do not yet know how much difference attempts to turn up the gain on our own immune systems will make. It is likely that for prophylactic use in a broad population where side effects may be totally unacceptable, the value could be minimal. However, in select populations or the already exposed or ill, where non-life-threatening side effects are accepted, this class of countermeasures may be significantly more effective. We actually have examples of use in individual patients with cancer and hepatitis today, but our tools are still very, very crude.

Finally, regarding market drivers for medical countermeasures, my experience is second-hand and limited. I believe specific countermeasures for most bioterrorism agents and probably for briefly emerging infectious diseases will, for the most part, require Government funding. For those countermeasures that have broader application, a significant portion of the research will still probably be

funded by the Government. However, advanced development and even production will be of interest to industry, I am sure. Even there, incentives may be helpful or necessary in driving development and production of certain compounds.

PREPARED STATEMENT

Again, I appreciate the opportunity to present this information before the committee. I worked hard to keep our leading national laboratory for the development of medical countermeasures for the force solvent through the 1990's. I know it is not easy to convince someone that medical countermeasures for a poorly understood threat of unknown risk are really important. The field of the vaccine and antiviral drugs requires both science and imagination, a phenomenal personal dedication by scientists and shepherding over enormous regulatory hurdles. And when it is completed, you cannot paint on the national colors and sail it around the world or even fly it over the Super Bowl at half-time. When it is finally licensed, the administration of that vaccine is often dreaded by the healthy recipient whose very life you want to save.

Thank you for your important work and for this opportunity. I'd be happy to answer any questions.

[The statement follows:]

PREPARED STATEMENT OF DR. DAVID FRANZ

Medical Countermeasures to Biological Threats—and Emerging Infectious Disease

Mr. Chairman, distinguished Members, it is an honor to appear before you to address issues related to the research, development and procurement of medical countermeasures to protect the American population from bioterrorist agents and emerging disease. I am currently the Senior Biological Scientist at the Midwest Research Institute in Kansas City. I served on active duty in the U.S. Army from 1971 to 1998, with 24 of those years in the U.S. Army Medical Research and Materiel Command. I served for 11 years at the U.S. Army Medical Research Institute of Infectious Disease, which I commanded before my retirement. I currently serve on a number of senior S&T advisory panels for the Department of Defense and Department of Homeland Security.

This committee has asked that I provide some broad perspective on the medical aspects of biological defense in the context of a world in which intentional release of biological threat agents is of significant concern and natural introduction of disease is a reality. I have attempted to provide my views on a number of these issues below.

What is the nature of the bioterrorist threat?

Biological terrorism is a unique threat to our society, our economy and our freedom. Like the biological warfare threat of a decade ago, dual-use facilities and technologies may be exploited to make terrorist weapons. Although we have improved our defensive capability, we can still not yet, geographically or temporally, warn our citizens of an attack in time to take evasive or protective action. Unlike biological warfare, the production facility' and the weapon of the bioterrorist may be very small indeed. Finally, as we have learned since October 2001, attribution of a small scale attack can be very difficult or impossible. Furthermore, the microbes are generally widespread in nature and the technological tools are rapidly improving in capability and availability worldwide. Neither the microbes nor the tools to manipulate them can be outlawed, the former because of their ubiquity and the latter because of their value to society. Therefore, it is possible to easily hide a biological terrorist program. With proper agent selection there could be minimal technical hurdles. The most significant barrier to the biological terrorist today—and for the foreseeable future—is the intention to commit the crime.

Can we measure the risk?

We know that our human and livestock populations are extremely vulnerable; this is a function of our free society and our well-developed livestock industry. We know

that the impact of an intentional attack with microbes could be enormous, measured in human lives or dollars lost. We know there are groups and individuals who threaten us and we have some sense of their abilities with things biological. Our understanding of the all-important factors of intent and motivation is much less clear. Therefore, risk—where all these variables come together—is only poorly understood. The president’s directive “Biodefense for the 21st Century” specifically calls for a biological risk assessment to be performed every two years, so that our national response to the threats, vulnerabilities and consequences of bioterrorism can be improved. This risk assessment presents technical challenges that are being addressed by the Department of Homeland Security.

Are some agents to be feared more than others?

Biology is characterized by great diversity. Microbes of a given genus or family may be strong or weak. Species, subspecies or strains within a genus or family may be stronger or weaker than their near relatives. We call variola virus (the agent of smallpox), *Bacillus anthracis* bacterium, the foot and mouth disease virus and maybe even the toxin, botulinum, “outliers” because they can cause severe disease in humans or impact animal populations. Even that is an oversimplification. Botulinum isn’t botulinum and anthrax isn’t anthrax. All of these organisms, or the toxins they produce, live on a spectrum with regard to the pathology they can cause in humans or animals: some weaker; some stronger. To be an agent of concern the bug need not only be able to cause disease in humans or animals, but must also have the right combination of a series of important characteristics, for example: stability, transmissibility, easy producibility and/or the ability to overcome countermeasures. With regard to catastrophic bioterrorism, we may be truly concerned about less than 1 percent of those microbes found in nature. Yet, that’s enough! The lesson for us is that we can—at least to some degree—prioritize the agents for which we use our resources to develop countermeasures. However, without solid intelligence, we can never know for sure which one we will face.

What is the impact of all this variability in biology?

If we were able to plot all known microbes in the world on a graph with their name stacked up on the vertical (Y) axis and their relative ability to hurt us spread across on the horizontal (X) axis, we would get some kind of a curve. Let’s assume the curve would be roughly bell-shaped with a small number of microbes having very low ability to cause disease, most of them with moderate ability to cause disease and few which can cause severe disease. We could do the same thing with stability, transmissibility and the ease with which they can be produced. If that isn’t enough, we could plot all Americans on a similar curve, describing the relative ability of their natural immune systems to combat disease of various kinds. Some of us are strong and some are weak, but most of us are average in ability to withstand exposure to disease. More than half of us might survive exposure to smallpox, without any medical help, but maybe only a few percent of us would survive inhalational anthrax. To complicate the picture even further, the outcome of some exposures is dose-dependant. This is especially true of the toxins, which don’t replicate within out bodies, but act more like chemicals. Biology is just not as crisp and clean as physics or even chemistry; this is one reason we have heard so many opinions about protecting our citizens from biological terrorism.

How can we decide what to protect ourselves against?

The short answer is, “We can’t”. However, certain bugs are much better suited as weapons than others: *B. anthracis*, because of its ability to survive in a spore form for many years; variola virus, because of its ability to spread from person to person and foot and mouth disease virus because of the way it can sweep through an agricultural economy so quickly that its point of introduction may be difficult to discern. We have recognized those and either have dealt with the outliers or are in the process of dealing with them specifically—as we should.

Richard Danzig has proposed another scheme in his excellent document entitled, “Catastrophic Bioterrorism: What is to be done?” His approach involves a short set of specific agent release or introduction scenarios, which if prepared for properly will likely give us many of the tools and capabilities to deal with most other agents which have characteristics similar to those we specifically prepared for. Several of our government departments and agencies responsible have implemented Secretary Danzig’s approach.

Another model which I, and others, have put forward—after taking anthrax and smallpox off the table with specific countermeasures—is to think about the unknown as emerging infectious disease and take general steps such as establishing surveillance systems, upgrading diagnostics capabilities and educating healthcare providers regarding outbreak response. Eliminating vulnerabilities in our public

health system is not difficult to justify, and has a beneficial “dual use”. I have characterized this way of thinking about preparation by the simple equation, Bioterrorism—Emerging Infectious Disease + Intent. We don’t know when we will face a bioterrorist attack, but history tells us that we should expect emergence and re-emergence of “exotic” diseases every few years in the United States. If we prepare our public health system to deal with these types of occurrences, we will be far better prepared to deal with a bioterrorist attack.

What about future threats?

We believe that multiple-drug-resistant bacteria were produced by the Soviets before the genomic era. We know that foreign genes can be added to both bacteria and viruses, making avirulent agents virulent, or conferring additional properties of virulence or pathogenicity. We know that the tropism—the virion’s preference regarding the body’s cells it infects—can be changed. We know that nature can change an animal pathogen so that it infects humans. In the biology of microbes, we should assume that almost anything is possible. That does not mean that it will be done by a human—but we are entering an era in which all these manipulations and more will become easier.

Can we place a value on classes of countermeasures?

We can do many things to protect ourselves from a bioterrorist and his bugs; they range from political and behavioral actions to change intention in those who might harm us, or to undermine their support where they live, to medical solutions like vaccines and drugs, physical devices such as protective masks that filter microbes out of the air we breath, or monitoring systems to detect an attack on high population densities. All have a place in our integrated national defense, but not all are equally suitable for all populations we must protect—or deter—OR for every agent we wish to protect against. The Nunn-Lugar Cooperative Threat Reduction program has had a very significant positive result among the now-aging weaponeers of the FSU, but we would not expect the same model to work with Al Qaeda. A protective mask will be of much greater utility to a soldier on the battlefield than a businessman in Boston, because we don’t have, and probably can’t afford, the capability to tell the business man when to don it. A vaccine against plague will more likely be useful to a Marine than a housewife, for behavioral and cost reasons. A currently-available antibiotic may be of great utility after an anthrax attack and useless after the release of highly-pathogenic avian flu virus that has been adapted to infect humans. We need to carefully craft our concept of use and application of the various biodefense measures that are being developed so that we address the greatest risks and ensure the maximum benefit of our investments.

Can we place a value on individual countermeasures within a class?

Vaccines are the most agent specific of medical countermeasures; therefore, for agents which are rarely seen in the clinic, they have very limited application. Stockpiling vaccines for civilians makes sense for anthrax and smallpox for two reasons. For these two agents, unlike most others, vaccines can be used—in different ways—after an attack. For most other agents, efficacy of post-exposure vaccination just hasn’t been demonstrated. The one instance in which, let’s say a plague vaccine or an Ebola vaccine if we had one, might have utility is during a bioterrorist campaign; a series of sequential attacks (the term “reload” was coined by Secretary Danzig). Here, an individual or group attacks one U.S. city and then announces that another city will be targeted unless we capitulate. I will leave it to epidemiologists and statisticians to decide if we could respond effectively in such a situation, assuming we had the right vaccine licensed and in stock. In attempting to place a value on such a vaccine, we must consider actual cost to develop, produce and license, the shelf life, as well as the biology and the psychology involved. The behavioral and legal issues surrounding the prophylactic use of vaccines in the general population, without significant evidence of risk, can be difficult, as has been seen with both anthrax and smallpox vaccine programs in the recent past.

Antibiotics are considered a general countermeasure and, therefore, will likely have dual-utility. They can and are typically given post-exposure. This makes them ideally suited for protecting a civilian population after an attack. The issues to be considered include, first, sensitivity of the specific bacteria to a given antibiotic, then availability of the drug and its timely distribution to the affected population, if that population can be determined. Secondary issues, post attack, include possible allergy or other reactions to the drug, but the psychological and public relations issues may be slightly different after an attack than before. We currently have licensed antibiotics which are effective against most bacterial agents likely to be used by a terrorist. For some there would be issues of availability and, possibly, surge production. We believe that the Soviet Union developed antibiotic resistant strains

in the past. Resistant strains have also developed naturally' throughout the world in recent years. Although, I am not expert regarding recent submissions to the FDA, it is my understanding that there are few, if any, new classes of antibiotics moving forward for licensure. This trend should be of concern to all of us, even if there were no potential for bioterrorist attack on our population.

Anti-viral preparations can, for this purpose, be considered to have the general use characteristics of antibiotics, but are for use against viruses. They would have wide application if we never have a bioterrorist attack. For a number of reasons related to the way viruses live and function in our bodies, it is more difficult to develop antivirals that both stop the microbe and are safe for human use than it is to develop antibacterials. A very few antiviral drugs have been developed in the past 20–30 years. Now, with the availability of genomic and proteomic information, we are probably in a better position regarding the discovery or design of new classes of antiviral compounds, at least for certain families of viruses. As is with antibiotics, it is my understanding that market dynamics within the pharmaceutical industry have not, in recent years, been favorable for the development of antiviral drugs.

Antibody preparations which provide passive immune protection without vaccination, whether produced in animals, or by modern synthesis methods, have a place in our medical tool kit. They, like vaccines, are specific in that they typically are only effective against the agent they were developed for. Unlike vaccines, they can be used immediately before exposure, immediately after and in some cases in the face of disease. They are typically less effective than vaccines, even if given before exposure; an exception to this generality is the antibody preparation for botulinum toxins, which, if given before clinical signs of disease, is amazingly effective in laboratory animals. Logistically, however, antibody preparations are cumbersome in that they must be administered either intramuscularly or intravenously.

Vaccines protect by stimulating the body to produce a specific antibody which identifies and deals with the microbe when it enters the body. Antibiotics and antiviral drugs generally attack the microbe directly. There is a fourth possibility that we haven't fully exploited, primarily because we don't yet understand our immune systems well enough. This method is called non-specific immunity. Our bodies normally produce a variety of cells and chemical substances that attack microbes and help keep us healthy. These cells and chemicals deal with both bacteria and viruses. This part of our immune system is tightly integrated into our entire being and might be what we are describing when we say one person is generally "healthy" and another is not. The "innate" immune system is generally stronger when we have had a good night's sleep, when we are fit, when our nutritional and hydration status is within normal limits and when we are "happy". This protective system breaks down when we are jet-lagged or stressed. The beauty of the innate immune system is that it can protect us from many different agents and it's always on board. The limitation is that it can be easily overwhelmed. Some scientists believe that, if we could increase the "strength" of the innate immune system, we might be able to actually shift each of us toward "healthy" on the population bell curve. Today we understand this system only well enough to use very crude tools to treat some cancers and viral infections like hepatitis C. Even when we gain greater precision, it is likely that turning up the power of the innate immune system won't work for everyone. Just as a vaccine might only work for 90 percent of a given population, this method might work for 40 or 60 percent—and until we get really good, there will be significant side effects. As we learn more and more about this system, we will be better able to control it and protect humans and animals from infectious diseases. This method of protecting our citizens from biological terrorist attack—or emerging infections—may be available in 15 years—or maybe 30. It is critical that we do the basic research now to make the most of the innate immune system. This investment will pay enormous dividends even outside the world of infectious disease.

Principles regarding development of medical countermeasures for biodefense:

- Vaccines are probably the best solution, but they are good for only one microbe and must generally be given long before onset of illness. Their concept of use is more consistent with military deployment than with homeland security, with some specific exceptions.
- Antibiotics have more general application, but they are good only for bacteria.
- Antivirals that are safe and effective have been difficult to discover, but we have some new tools and should exploit them.
- Our innate immune system, if manipulated appropriately, holds promise, but we have a lot to learn before we can exploit it, especially in the healthy population.

What principles might we consider regarding acquisition of medical countermeasures?

Vaccines.—It is relatively easy to justify the acquisition of vaccines for anthrax and smallpox. Reactogenicity, cost, shelf-life, animal efficacy and licensure are all being considered. It is important that we thoroughly understand our concepts of use as we develop additional agent-specific vaccines. We should be developing next-generation flexible vaccine platforms which will allow us to relatively quickly produce and license a vaccine to counter an outbreak that subsequently becomes epidemic or pandemic. The basic platform might be licensed for use in humans, allowing us to simply add a genetic cassette when a new vaccine is needed, to greatly shorten the time to use. Our current system of vaccine research, development and approval is simply not responsive enough to respond to terrorist attack or emerging disease.

Drugs.—It is difficult to argue against spending as much as we can afford on antivirals, new classes of antibiotics and exploiting the genomic revolution to develop new categories of anti-infectives. All of these will improve the lives of Americans with or without a bioterrorist attack.

Non-Specific Therapies.—We have a long way to go to achieve broad application of what is little more than a hypothesis, but we should be doing the necessary research now. Attempting to protect our population from the unknown threat of today, and tomorrow, with specific countermeasures, will likely be extremely costly and inefficient. We probably don't yet know how much difference these preparations will make; it is likely that, for use prophylactically in the broad population where side-effects may be totally unacceptable, the value will also be minimal. In select populations or the already exposed or ill, where non-life threatening side effects are accepted, this class of drugs may be significantly more effective.

Market issues:

My experience regarding market drivers for medical countermeasures is second-hand and limited. I believe that specific countermeasures for most bioterrorism agents—and probably for emerging infectious disease—will remain in the category of orphan drugs. Research, development and production will be dependent on funding by the U.S. Government and the debate regarding licensure or investigational use will be handled for each preparation. For those countermeasures that have broader application, a significant proportion of the research will be funded by the government; however, advanced development and even production will be of interest to industry. Tax- or intellectual property-related incentives may be helpful or necessary in driving development and production, especially where the market is large enough to interest the pharmaceutical industry.

Again, I appreciate the opportunity to present this information before the Committee. I shall be happy to answer your questions.

Senator GREGG. Thank you, Dr. Franz. The last few comments there are well taken and very much appreciated. We appreciate your service to the Nation. Clearly you should have a flag painted over your front door and the appreciation should be there for all you have done in the area of protecting our soldiers, sailors, and airmen.

Dr. Read.

STATEMENT OF J. LEIGHTON READ, M.D., GENERAL PARTNER, ALLOY VENTURES

Dr. READ. Mr. Chairman and members, thank you for the opportunity to testify about BioShield and our Nation's strategy. Your interest in stopping to consider the overall approach is timely and appropriate here.

I am commenting today as an individual who has been building and financing biotechnology companies in Silicon Valley for about 17 years now. Before that I was an internal medicine doctor, and my academic career was studying costs, risks, and benefits of new medicines and vaccines.

When I received your invitation just a little a while ago, I looked up my testimony on biodefense for the Senate Governmental Affairs Committee in 2002 and then in 2003 for the Subcommittees

of the House Energy and Commerce Committee. Re-reading that testimony, I have to say I had concerns and recommendations that I voiced then that are just as relevant today as they were when the Department of Homeland Security and Project BioShield were still on the drawing board. So there is clearly still some work to do.

This problem requires long-term thinking. I agree with statements made earlier by your colleagues that there is no potential threat to us. I would like to focus particularly on our economy and our lifestyle. If an easy-to-deploy, transmissible bioweapon were deployed, even with a very small loss of life, the impact on our economy would be unbelievable because the necessary steps to interrupt the chain of transmission would interfere with travel and commerce of all kinds, even potentially food and medical supply distribution. Most importantly, I am really concerned about the impact of this on the freedom of people to meet during a time of stress and worry and political consequence. Nothing would test our trust in Government authority more than a quarantine separating loved ones. So, the stakes are very high.

One of the companies I built was in the influenza vaccine business, and I agree it would be a very realistic proposition that someone could smuggle a dangerous strain of influenza into the United States. That deserves serious attention.

Now, a great deal of positive work has been done. It is hard to describe how big a step forward the BioShield legislation was and some of the implementation that has followed that at the same time as talking about how much is still to be done, but we need to do that. Much remains to be done to educate the public and strengthen our traditional public health systems, our first responders.

I was very heartened by some of the responses to the presidential directives in Mr. Albright's testimony. Many of those problems or challenges can be dealt with in just a few years of sustained effort, and one of my key points is that is not the case for our longest lead time countermeasures, drugs and vaccines, that have not even been invented yet to counter these threats. As you know, drugs typically take 5 to 10 years from the first commitment to do something to the delivery of something for patients; vaccines, more like 10 to 20 years.

This company I founded in 1992 licensed a very promising influenza vaccine, nasal influenza vaccine technology from the University of Michigan in 1995. This technology had already undergone 20 years of clinical trials under NIH support, and yet it was 2003, 8 years later, and after the expenditure of \$1 billion by three different companies of private capital before this product was approved by the FDA. This is a product known as FluMist which is now of growing importance as part of our influenza protection armamentarium.

My second point is we clearly need the private sector to be involved and BioShield represented a very strong and clear recognition that this was the case, that we needed to get the incentives right. There are many reasons why we need the private sector, but basically all of the drugs and vaccines we use today for everything outside the field of biodefense come from the private sector, admit-

tedly and with great respect for the huge national investment in the basic science made these discoveries possible.

Start-ups and smaller companies play a very important role. I invest in these companies as a full-time venture capitalist. They take on higher-risk projects. They can demonstrate proof of principle.

But I would like to underscore today the importance of the larger, more capable companies. They often acquire technology by acquiring these smaller companies that we invest in or by carrying out licensing deals with them. But there are skills for the downstream development of pharmaceuticals and vaccines that are very hard to come by outside a relatively small number of very large pharmaceutical and biotechnology companies. The real test of whether BioShield is working is whether it engages the capabilities of these companies in the development of countermeasures. I would say we are not there yet.

A biodefense procurement strategy that relies on companies that have not even launched a commercial product is likely to incur extra delays and other down-side surprises. So this is really a point for attention.

What I think is a key missing ingredient is, we need markets for these products which mimic the size and the predictability of markets for treatment and prevention of other diseases. That is really the goal. The current BioShield law was, as I said, a step in the right direction, but it fails to adequately signal the Government's intention to purchase successful countermeasures. We need much more transparency on what the priority list is so the companies can begin to think about these things in advance. We need much more clarity about who are the people who have both the knowledge to comment and the authority to make decisions.

There are lessons to be learned from some of the ideas being aggressively explored to stimulate private sector investment in vaccines for global health problems, such as AIDS, malaria, and TB. This notion of advanced purchase contracts deserves study as a model for your continued refinement and enhancement of BioShield. The notion there is a strong connection between the benefits of investing in infectious disease research for other diseases or even broadly and defense against biodefense is a very valid concept that is completely appropriate.

BioShield misses in important respects with respect to providing indemnification from product liability. Basically it is a test of confidence. If a company tells you they are not really concerned about that in a conversation about working with the Government in biodefense, it is just because they have not grown up to understand how critical it is for their shareholders.

We need to streamline procurement. It is not clear that any of the work so far by our great public servants who are carrying out the legislation of BioShield have taken advantage of the full ability to streamline the procurement process and take advantage of those special provisions. I think that is going to be important.

I would like to come back to emphasize the point raised by Senator Stevens that we need a way to screen. As a venture capitalist, we get a very large number of proposals for investments, and only a tiny, tiny percentage are actually companies that receive investment. We have worked out screening processes, and I do not know

that it is a model but it makes me sympathetic to the problem of a public servant who gets calls from people who think they have a good idea but the science is not really there and the person who gets lost in that crowd really does have the right idea. I can think of a number of ways we could use some of the new technologies, web-based technologies, table top exercises and maybe even a private sector intermediary to help with some of the filtering.

We are in a biological arms race with our future attackers, and there are specific targets we should be going after. I completely agree with the priority for anthrax and smallpox. That makes sense to me. I must say it is pretty hard for people outside the Government to figure out what the priority list is below that. We have the long list of 20 or 30 agents, but the Government's own thinking about the rank order of what comes after smallpox and anthrax for civilians in particular is obscure. And it seems to me while it might require some defense of that ranking and that might be a little bit difficult, that it should be transparent so the private sector can set priorities.

Sooner or later, despite our efforts to make good specific counter-measures, a clever or lucky perpetrator may deploy an agent for which we have not made specific preparations. And this calls for the notion of some kind of broader approach. We may need broad spectrum antimicrobials or vaccines, as has been mentioned. We may need to harness the nonspecific defenses already working in human biology like innate immunity. We may need to build systems, still very speculative, that you could move from obtaining the pathogen to having a drug in a very short time period. And all of those are worth stimulating some kind of prize or novel recognition and financial reward for some of these more speculative approaches. It might be very useful. I compare it to the X-prize for manned space flight that was successfully competed for and won in the last year.

If we want to think about this broadly and in the long time frame which is really appropriate, a 2030, maybe even longer time horizon, we should be looking broadly. One idea I would like to suggest as an example, it should be studied before moving forward, would be to think about a survey of the microbial world on a scale that has not been attempted. Just as we carry out ambitious projects to systematically catalog the sky within reach of our light and radio telescopes, maybe it is time to carry out a planetary scale survey of humans and the microorganisms with which we frequently interact. We might want to begin by focusing on the respiratory tract.

PREPARED STATEMENT

There is technology available. I cite a remarkable experiment by Craig Venter's group in which they obtained sequences for over a million new genes by looking at 1,500 liters of Atlantic seawater. A company called Affy Metrix has gene chips that have been used to study which organisms are present in nasal swabs taken from approximately 10,000 subjects in studies. So it is possible now with some of the technology to think about such a broad survey. Not only could it provide us a baseline for measurement of new emerging infections by intent or by nature, but the basic science that

would be enabled by this survey could provide more fundamental understandings to help us deal with the general problem.

Thank you very much, Mr. Chairman.
[The statement follows:]

PREPARED STATEMENT OF J. LEIGHTON READ, M.D.

Mr. Chairman and Members of the Committee, thank you for the opportunity to testify today regarding BioShield and our Nation's strategy for confronting bioterrorism. Your interest in stopping to consider our overall approach is timely and appropriate.

I am commenting today as an individual who has been building and financing biotechnology companies in Silicon Valley for over 17 years. Before that, I was an internal medicine doctor doing research on the cost, risk and benefits of new medicines and vaccines. On receiving your invitation to appear here, I looked up my testimony on biodefense for the Senate Governmental Affairs Committee¹ in 2002 and for Subcommittees of the House Energy and Commerce Committee² in 2003.

Unfortunately, the concerns and recommendations voiced then are as just as relevant today as they were when the Department of Homeland Security and Project BioShield were still on the drawing board. Since those remarks are available on the internet, I will only restate the main points here before turning to new thoughts.

Long Term Thinking

Biodefense is a gigantic, long-term problem. There is no potential threat to our economy or lifestyle that would be as easy to deploy or costly to contain as the release of a transmissible bioweapon. We should be clear that deliberate introduction of an agent that spreads from person to person is a completely different category of risk than an attack with dangerous organisms that do not spread. This is because our reasonable efforts to interrupt the chain of transmission would interfere with travel and commerce of all kinds, including distribution of food and medical supplies, and importantly, the freedom for people to meet each other in a time of grave worry and political consequence. Effective quarantine separating loved ones will profoundly test our trust in government authority.

Despite a great deal of positive work, we are not yet organized to deal with this threat. Much remains to be done in educating the public and strengthening traditional public health systems and our first responders. Fortunately, much of this kind of work can be accomplished in only a few years of sustained effort. That is not the case for the longest lead-time components of our readiness: medicines, vaccines and other biomedical technologies needed to protect our population and that of our trading partners. For drugs against viruses or bacteria, it takes 5–10 years from commitment to delivery of medicine for patients. The process for vaccines typically takes 10–20 years. In 1995, a company I founded, named Aviron, licensed a promising intranasal influenza vaccine from the University of Michigan that had already undergone 20 years of clinical testing by the NIH. It took nine more years and over \$1 billion in private investment by three companies before the product known as FluMist™ was approved by the FDA. Despite these timelines and costs, some pathogens are such natural candidates for potential abuse well into the foreseeable future that we must begin work now. It is important to seize this opportunity because infectious diseases represent some of our greatest triumphs in discovering, preventing and treating disease.

Larger, More Capable Companies must be Involved

This work will require enthusiastic and committed engagement by our country's most capable pharmaceutical and biotechnology companies. All of the drugs and vaccines in use in the United States come from the private sector, often after substantial public investment in government and university laboratories. Start-ups and smaller companies play an essential role in taking on many higher-risk projects and demonstrating proof of principle. Larger players gain access to these technologies through licensing deals or purchase of the smaller companies. Several hundred million dollars of private capital and down-stream development skills rarely found outside of larger companies are usually required to finish the job for each important innovation. When R&D is successful, this investment makes sense because innovative products that address substantial medical need are reimbursed at the high value they represent to patients and healthcare payers.

¹ http://www.bens.org/highlights_testimony_read.html.

² <http://www.bio.org/healthcare/biodefense/20030327.asp>.

The experience factor is so important that a biodefense procurement strategy that relies on companies with scant experience in launching commercial products is likely to incur extra delays and other down-side surprises. Yet this appears to be exactly where we are heading with BioShield because the market incentives are not yet in place to attract the most capable innovators.

The missing ingredients for biodefense countermeasures are markets which mimic the size and predictability of markets for treatment and prevention of other serious diseases. The current BioShield law provided an important step in the right direction, but it fails to adequately signal the Government's intention to purchase successful countermeasures that are still years away from completion. There is much to be learned from progress in defining Advanced Purchase Contracts and related "pull" mechanisms for stimulating vaccine R&D against global health targets such as malaria, tuberculosis and HIV. Restoration of patent term lost during regulatory review will be helpful. Important gaps still remain in the details and degree of indemnification from product liability. Larger, more capable companies will not participate unless these problems are addressed in future legislation.

Streamline Procurement and Improve the Dialogue With Industry

It is time to finish the job of re-inventing procurement of biodefense countermeasures. The bureaucratic tangle of approvals and sign-offs involving multiple agencies and departments (even including the President) prescribed in BioShield must be streamlined. Spending authority should be concentrated in the hands of someone close to the intelligence analysis which helps set priorities.

It is essential that much more frequent and transparent conversation occur between companies and those setting the priorities for countermeasures. The formal process of RFPs and related acronyms cannot substitute for frequent, informal contact. Novel formats for meetings, including more table-top exercises web-based interactions should be encouraged. Antitrust relief may be required if these concerns are inhibiting valuable multiparty conversations.

BioShield did not adequately address the need for more centralization of authority for setting priorities, funding solutions, and managing incentives. There is a recurring theme in my conversations with executives interested in making a contribution to biodefense: they can't find the right person in the government who knows the issues AND can make a decision. This more centralized authority should also have enhanced ability to adjust FDA influence processes and safety standards in preparing for high-risk threats.

A Biological Arms Race

One can identify the highest risk agents for the near and intermediate time frame, based on the biology of the microbes, the technical challenges faced by our potential attackers and intelligence data. These agents are presumably at the top of the priority list for BioShield, although it is hard to get clarity about which of a dozen potential threats rank most highly after anthrax and smallpox. There are at least a dozen agents that deserve serious countermeasure investment.

Sooner or later, however, a clever or lucky perpetrator may deploy an agent for which we have not made specific preparations. It may have been derived from nature, cultivated in the laboratory, or engineered to have novel drug resistance or host range. There are several paths to get ready for this event. One is to seek broader spectrum antimicrobial drugs or vaccines. While there are examples of such agents discovered by accident, the rational design of broad spectrum countermeasures is largely beyond our current capabilities. Another path is to harness and enhance the non-specific defenses already available in human biology. We are still early in our understanding of how to manipulate innate immunity and the role of cellular factors such as interferon. Finally, highly speculative processes have been proposed by which one could move from knowledge of a new pathogen to a new treatment in a month, or a week, or a day. Technologies such as antisense agents and interfering RNAs may hold promise for such a goal.

Our biodefense strategy must include a mix of disease-specific countermeasures and new technologies which offer more general treatment or prevention. I am concerned that getting the right mix depends on the quality of the dialogue among companies and the diverse government agencies that are involved. A high level of transparency on priorities and authority will be essential before the parties can effectively explore technical risk and financial incentives needed to get the job done. For some of the more aggressive goals, serious prizes, such as the X-prize for manned space flight may be the most appropriate way to focus innovator's attention.

The Basic Science of Biodefense

Our country has made and continues to make a large national investment in the underlying science of infectious disease and host defense. This effort is serving us

well in many current biodefense efforts. In many cases, adequate financial rewards for the final product will provide incentives to develop new research tools along the way. In other cases, and particularly, animal models it is more efficient to have centralized research tools that can be shared by many innovators. When the government has the keys to scarce resources needed to carry out research, such as higher level biocontainment facilities, or access to dangerous strains, it is essential that access be facilitated for all who need them in pursuit of sanctioned goals.

It may be time to consider an even bolder investment in basic understanding of the relationship between humans and microbes. Research is giving us a growing appreciation of the interdependency of genetics and environment, with particular emphasis on the environmental interaction of unrelated, but physically proximal organisms. Technology is now available to conduct a broad survey of microorganism diversity, genetics and metabolism. A few projects have demonstrated the feasibility of collecting and analyzing data on a very large number of organisms. One example is Craig Venter's report on a rapid genetic sequencing technique that found evidence of 1.2 million new genes in 1,500 liters of Atlantic seawater. Another comes from a company called Affymetrix whose gene chips have been used to identify which organisms are present in nasal swabs taken from thousands of study subjects.

Just as we have carried out ambitious projects to systematically catalogue all of the heavenly bodies within reach of our telescopes, it may be time to carry out a planetary-scale survey of humans and the microorganisms with which they frequently interact. A focus on agents which colonize or infect the respiratory track might be the best place to begin. Data from such a survey could serve as a baseline for detecting introduction of novel threats. More importantly, analysis of the data could lead to more fundamental understanding of how to create robust protection against such threats.

Mr. Chairman, I know that you have recently introduced legislation that would address many of the concerns mentioned here. Thank you for your leadership on this issue and your persistence in asking whether we are doing enough of the right things at the right time. I would be happy to provide further comment if you have questions.

Senator GREGG. Thank you.

I have to recess. I have got to make a quick phone call. I will be right back. It should not take more than 5 minutes.

Thank you for your courtesy. I apologize for the interruption.

Mr. Clerici.

STATEMENT OF JOHN M. CLERICI, ESQ., PARTNER, McKENNA, LONG & ALDRIDGE, LLP

Mr. CLERICI. Thank you, Mr. Chairman. Mr. Chairman, members of this subcommittee, it is an honor to testify before you regarding my views of where we are with Project BioShield and biodefense in general. I applaud the leadership of you, Mr. Chairman Gregg, in your work on the Health Committee and being the lead sponsor on BioShield I, and also applaud the bipartisan leadership of Senator Lieberman and Senator Hatch, and Senator Kennedy, obviously, took a great leadership role in that effort and continue to be leaders on the issue of biodefense.

Over the last few years, I have had the chance to personally work with the Department of Health and Human Services on behalf of a number of clients and entities not only in the area of biodefense, but also emerging infectious disease. We have negotiated contracts, some of which Assistant Secretary Simonson referred to, for SARS, avian flu, pandemic influenza planning, and other issues.

Based upon that experience, it is clear to me that HHS does need additional tools beyond what was provided in BioShield to get the goals accomplished that the legislation meant to accomplish. Primary and first among those goals, as Dr. Read has pointed out, is to address the issue of liability.

As we have begun to purchase these countermeasures slowly and there have been a couple contracts let to date, as Assistant Secretary Simonson said, and a few more on the way shortly, the primary obstacle at the end of the day to getting these deals done is addressing how liability concerns will be addressed. Certainly, as Dr. Read just pointed out, the liability concerns of a public company with shareholders and large assets are much different than a small biotech which has the ability to bet the company without worrying about liability. And I am not sure those are the types of companies we want necessarily participating or leading the way in this effort to bring these countermeasures to market.

Today, there are two primary ways liability can be addressed. Public Law 85-804 has been on the books since the first Wars Powers Act during World War II, and it allows the Government to indemnify contractors after award, only after award, for risks that are deemed in the national security interest. It is an indemnity contract. Therefore, the public is at risk, and I know in your role as budget chairman is of great concern to you as well, Senator. But unfortunately, it provides no predictability because you do not know whether you are going to get liability protection until after you bid on the proposal, negotiated a contract, and are prepared to deliver. It provides no certainty to industry and no transparency to industry to plan.

The second mechanism has been pointed to is the SAFETY Act, and I am very familiar with the operations of the SAFETY Act. It is a piece of landmark legislation to address the tort concerns of providers of Homeland Security goods and services in general. It does not work particularly well for countermeasures for two primary reasons.

First, the SAFETY Act has a gap in it that does not protect vaccine manufacturers because the liabilities removed by the SAFETY Act are only those that occur following an act of terrorism. Most of the liability concerns of a vaccine manufacturer are, of course, before anything has happened. It is in the administration of the vaccine itself.

Second, much like with Public Law 85-804, it is an application process, and there is lack of predictability involved with the SAFETY Act. And currently there are less than 20 companies that have been certified under the Act and no biodefense measures or pharmaceutical companies are among those.

The SAFETY Act also requires a company to litigate all over the country to exert what amounts to an affirmative defense to get out of litigation. Therefore, there are still substantial uncertainty subject to the judicial system in America, which is obviously not something that anyone wants to be their company on sometimes.

I note in your bill, Senator, in Senate bill 3, you have done an excellent job of addressing, in my view, the liability concerns for biodefense manufacturers, and you also attempt to address the liability concerns of pandemic flu manufacturers. As we heard during the previous panel, the threat facing the country from a pandemic flu is much greater in my mind than the threat facing the country in bioterrorism, and that threat is enormous, as you know. The 1918 influenza pandemic, Spanish flu pandemic, killed millions of Americans, and unless we are prepared for that pandemic,

we will be facing those same sort of liabilities both in terms of lives and in dollars if another influenza pandemic occurs again.

The reason why pandemic influenza should be treated off line in my view is the sense of urgency. No amount of detection, no amount of intervention, and we can have the biggest armies and navies in the world, are going to prevent mother nature from affecting us. And this is urgent. We are past the time when this country and this world should be facing a pandemic based on statistics.

The threat of pandemic liability is much like the threat of smallpox in the sense that if there is a pandemic, you will need to vaccinate the entire Nation. And your previous committee, the Health Committee, and through the Homeland Security Act, addressed the liability for smallpox vaccine manufacturers particularly by providing them immunity. We need to provide at least the same sense of liability protection to providers of pandemic flu vaccine because the threat from liability is identical, if not greater than the threat of liability from a smallpox vaccine manufacturer.

Your staff has also asked me, Senator, to address some of the challenges in the implementation of the procurement provisions of BioShield, aside from liability, and liability is certainly first among them again.

As Dr. Read has mentioned, the Department, in implementing Project BioShield, has not taken full advantage of all of the authorities that Project BioShield gave them back in 2004 when the legislation was signed. They have the ability at HHS to conduct these procurements under simplified acquisition rules. They have not exercised that authority to date. What has transpired through these negotiations is nongovernmental contractors, commercial entities, that are not used to doing business with the Federal Government are subject to the same amount of Federal acquisition regulation that our large defense contractors are subject to in providing these goods and services. That causes them both delay, uncertainty, a lack of transparency in what they are signing up to, and the delays resulted have been definitely inhibiting our ability to bring these countermeasures into the market as quickly as possible.

We have discussed already there have been two awards to date, primarily big awards. There is a third smaller award addressing irradiation treatment for children, but two large awards using the special reserve fund under Project BioShield, one large award and one RFP pending, one award pending.

The first award went to VaxGen which has already been discussed. Although that is often labeled as the first BioShield procurement, I would disagree with that characterization. It is the first procurement using BioShield funding, but the mechanisms to procure that countermeasure was done the same traditional way the Government would normally procure things. It was a multi-stage procurement, taxpayer-funded research and development resulting in, at the end of the day, a contract that as Secretary Simonson says, will not be paid until substantial delivery but, nevertheless, is a multi-stage, prolonged procurement. We did not set a market or set someone to guarantee it. Rather we had them chase the market just as if they would traditionally.

The next award up in Project BioShield will most likely be for anthrax therapeutic, and Secretary Simonson mentioned that as well. Now, that will be the very first BioShield procurement, but again, HHS has not made use, in the solicitation at least, of the simplified acquisition procedures allowed to make use of it during that process.

As a result, those contractors, whoever will get this award, face the possibility of very powerful and strong regulatory burdens upon them, including certified cost and pricing data and other burdens that have led this award to take over a year at this point from award. The request for information for anthrax therapeutics was issued on April 1, 2004, and I believe we are at least 2 months away from award for that contract. So these pharmaceuticals and these vaccines are not entering the stockpile at the rate I think Congress intended.

PREPARED STATEMENTS

Going forward, we can certainly do oversight to make sure that HHS and DHS work closely together to make better use of the authorities that BioShield I provided them. We can also, through BioShield II or other legislation such as Senate bill S. 3, provide additional tools such as liability reform and encouragement to make clear these contracts are not to be burden by over-regulation.

I look forward to your questions. Thank you very much.

[The statements follow:]

PREPARED STATEMENT OF JOHN M. CLERICI

Chairman Gregg, Senator Byrd, and Members of the Committee, it is an honor for me to testify before you today regarding my views on the Project Bioshield Act of 2004 and whether we are meeting the biodefense needs of the United States.

I appear before you today as someone who has worked with industries helping to supply the United States with critical biodefense, chemical, radiological, and nuclear countermeasures since even before the attacks of 2001. During this time, I have worked with a number of large pharmaceutical companies, mid and small size biotechs, and companies that provide detection equipment and other ancillary services to help protect the Nation from the threat of biological, chemical, nuclear, or radiological weapons. I also have had the opportunity to work with Congress and the Administration to help formulate policies to stimulate the creation of a thriving bio-defense industry in America. I and other members of our firm have provided testimony to both the House and Senate regarding the Project Bioshield Act of 2004 and we continue to work closely with your staff, Mr. Chairman, and the staff of other leaders in this area, including Senator Lieberman, Senator Kennedy, Senator Burr, and Senator Enzi, to ensure the best possible policies are in place to promote the deployment of the best possible countermeasures in this critical area.

During the last 3 years, I have been personally involved with a number of direct negotiations with the Department of Health and Human Services (HHS) for a number of critical biodefense countermeasures, as well as negotiations for contracts for critical vaccines for emerging infectious disease such as SARS, Avian influenza, and pandemic influenza. That said, it is my view, and I believe the view of many others in this industry, that HHS should be given additional tools to maximize participation of the entities that are best suited to provide critical countermeasures.

First among these additional tools must be expanded authority to address the issue of unmitigated liability associated with undertaking Bioshield contracts.

Liability Must be Addressed to Have a Successful Bio-Defense Industry

Industry concerns over the massive cost of product liability lawsuits are preventing critical countermeasures from being developed for the Strategic National Stockpile (SNS). The liability concerns of a company engaged in day-to-day drug development are clearly different from the liability concerns of a company participating in Project Bioshield. Manufacturers of countermeasures produced under Project Bioshield risk exposure to devastating product liability lawsuits to a far

greater degree than typical drug companies. Safety and efficacy data must be derived, for the most part, from animal trials since healthy humans cannot be exposed to toxic agents during testing. Thus, these critical countermeasures must be developed and are likely to be deployed without the full battery of testing typical of other drugs. Without liability protections, responsible companies will remain on the sidelines for fear of risking corporate assets to defend lawsuits brought as a result of producing a countermeasure that generally has a much lower profit margin than a typical pharmaceutical product.

Even as the Federal Government has begun to purchase Bioshield countermeasures, it has no current way to resolve issues of liability with any degree of certainty. As a result, needed countermeasures are not being developed and deployed, thereby exposing the economy, and the Nation as a whole, to far greater potential liability due to the lack of available effective countermeasures in the event of attack. Either way, the Federal Government is likely to bear both the human and financial cost of such an attack as it did on September 11th. By failing to account for these costs before an attack, countermeasures will not be developed and the Nation will be more exposed to attack.

Senate Bill 3 attempts to address these liability concerns for not only terrorism, but also countermeasures developed and deployed to protect the United States against naturally occurring epidemics such as SARS and pandemics such as Avian influenza. These epidemics and pandemics have the potential to be even more costly in terms of lives and dollars than even the worst terrorist attack. By addressing the issue of liability before an event occurs, we are not only assuring that needed countermeasures are developed, but also, being fiscally responsible by mitigating at the least economic cost of such a tragedy and reducing the cost of needless litigation.

While the similarities between the public health threats of bio-defense and infectious disease are obvious, I would strongly urge Congress to consider—and act upon—liability protections that are necessary to bring a pandemic influenza vaccine to market as quickly as possible. The dangers of a pandemic are real and immediate. Should the Nation face a pandemic similar to the one it faced in 1918 and 1919 with the Spanish flu, millions of American are certain to die. While I do believe Senate Bill 3 provides adequate protections to stimulate the creation of a bio-defense industry, it is inadequate to protect providers of pandemic vaccine given that the response to such an event would be to quickly vaccinate nearly 300 million Americans. Thus, the response to a pandemic is similar to—and perhaps, far broader than—the response to a potential outbreak of smallpox. For this reason, the liability protections provided for a pandemic influenza vaccine provider must be at least as strong as those protections given to providers of smallpox vaccine under the Homeland Security Act of 2002.

Under the Homeland Security Act of 2002, manufacturers, suppliers and administrators of smallpox vaccine are immune from any and all liability resulting from the administration of the vaccine during a declared emergency. These protections provide the certainty necessary to ensure the Nation has an adequate supply of smallpox vaccine in the event of an attack. While there are several improvements that should be made to this legislation to ensure health care workers are properly compensated, these same types of protections must be extended to providers of pandemic influenza vaccine.

Available Liability Mitigation Tools are Inadequate

Under current law, there are currently only two legal authorities that allow the Federal Government to mitigate the liability concerns for providers of countermeasures other than smallpox vaccine—through Federal indemnification under Public Law 85–804 and through designation/certification under the SAFETY Act. Both measures are inadequate to address the practical realities of potential litigation facing the providers of countermeasures and the fiscal realities facing the Federal Government.

Public Law 85–804 grants the President an extremely broad authority to allow a Federal Government contractor to obtain financial or other forms of relief under certain circumstances, even when the government may have no express legal obligation to grant such relief, or when there are express prohibitions against such relief contained in other statutes, regulations, or common law. Under this authority, the heads of designated departments or agencies have the discretionary power to provide contractors with government indemnity when they are engaged in “unusually hazardous” activities and when it is in the interest of the national defense to provide such indemnity.

Indemnification under Public Law 85–804 relies upon the American tort system and places the Federal Government in the position of an insurer—where payments are made only after all claims have been adjudicated in the court system and judg-

ments have been rendered. This rather lengthy process does not result in compensation to victims being paid in a timely manner nor does it place any effective limits on the Federal Government's potential payments to victims when it acts in this capacity.

Although this authority has been invoked by the Department of Health and Human Services (which was first granted the authority in October 2001 following the anthrax attacks) in agreements involving the donation of smallpox vaccine by Wyeth and Aventis Pasteur to the Federal Government in 2001, HHS will only address the issue of indemnification prior to the award of a contract for a countermeasure. As a result, potential providers of countermeasures must expend scarce resources to prepare and submit a proposal that may result in a contract that cannot be accepted due to the lack of liability protections should HHS ultimately refuse to provide indemnification. More often, companies simply refuse to bid at all due to the lack of certainty on the issue of liability. This has resulted in the largest, and far more experienced, drug companies with the necessary expertise to address this threat being left on the sidelines.

Moreover, HHS and OMB have taken the position that indemnification under Public Law 85-804 cannot be granted to protect suppliers of pandemic influenza vaccine since there is not an immediate connection to national security. This extremely narrow view of what constitutes "national security" ignores the implications that our troops stationed in Southwest Asia (which is currently facing a potential Avian Flu epidemic), it also ignores the national security implications of having millions of America perish in a pandemic. Thus, Congress must address this issue immediately to ensure the Nation is fully prepared.

Congress did attempt to address the issue of liability associated with antiterrorism goods and services with the passage of the SAFETY Act in November 2002. The SAFETY Act does, in fact, provide significant protections to providers of countermeasures that receive certification under the Act. However, to date, no such certifications have been granted for bio-defense countermeasures. In addition, there are specific limitations upon the effectiveness of the SAFETY Act for providers of countermeasures under Project Bioshield.

Section 865(1) of the SAFETY Act notes that qualified anti-terrorism technologies may include technologies deployed for the purpose of "limiting the harm such acts [of terrorism] might otherwise cause." The "harm" that may be caused by an act of terrorism clearly goes beyond the immediate effects of the Act itself. An act of terrorism such as the attacks of September 11th or the October 2001 anthrax attacks trigger a number of immediate remedial and emergency responses to limit the resulting harm and deter follow-on attacks.

While the SAFETY Act can provide significant protections to a company, its application in the context of countermeasures is extremely limited. Most significantly, the potential liability of a provider of anti-terrorist technologies that may allegedly cause injury PRIOR to a terrorist attack, such as a vaccine, are not currently addressed by the SAFETY Act. This limitation of the SAFETY Act leaves providers of anti-terrorist vaccines without any adequate protections aside from the possibility of Federal indemnification.

Moreover, SAFETY Act certification is most inadequate to provide the type of protections required for large companies to enter the market for countermeasures. Holders of SAFETY Act certification are still faced with the possibility of hundreds of lawsuits brought against them throughout the country, albeit in Federal court. Since the SAFETY Act protections must be asserted as an affirmative defense to any lawsuit, the unpredictability of the American judicial system still places providers of countermeasures with a large degree of uncertainty regarding potential liability. This uncertainty, coupled with the "gap" in the SAFETY Act for vaccine providers and the cumbersome nature of the application process to receive SAFETY Act certification makes it an inadequate protection for providers of countermeasures under Project Bioshield.

For all of these reasons, Congress should equip HHS with the adequate tools to address liability concerns that are inhibiting the development and deployment of critical countermeasures as soon as possible. More over, it is in the best interests of the United States that Congress act immediately to extend the same types of protections afforded to providers of smallpox vaccine to providers of pandemic influenza vaccine to ensure an adequate response to the certain public health crisis an influenza pandemic will cause the United States unless we are adequately prepared.

Additional Regulatory Relief for Providers of Countermeasures is Needed

The Project Bioshield Act of 2004 makes great strides to reduce many of the regulatory burdens that are obstacles to allowing companies that do not traditionally sell the Federal Government to participate in the development of needed counter-

measures. Based upon the experience of industry during the first procurements conducted Bioshield, more can be done to reduce the amount unnecessarily burdensome regulations. To date, industry reaction to Bioshield has been muted, partly because of initial implementation challenges and partly because the scope and incentives of Bioshield are too limited to attract serious attention from investors, including venture capitalists, institutional investors, or manufacturers that are needed to grow the biodefense industry.

It is important to examine the first actions HHS has taken under the Project Bioshield to understand the challenges in implementing the statute, as well as the need for additional procurement reforms.

On October 26, 2004, HHS received the first proposals to provide therapeutic products for treatment of inhalational anthrax disease in response to Solicitation No. 2004-N-01385 (the “Anthrax Therapeutics Solicitation”) under what was the first, true, Project Bioshield procurement. Just over 2 weeks later, on November 4, 2004, VaxGen, Inc. (“VaxGen”) received an award of a large contract to produce an experimental recombinant protective antigen anthrax vaccine (“rPA”).

While this award to VaxGen was the first countermeasure contract funded from Bioshield’s Special Reserve Fund, this was not a true Bioshield procurement. In fact, all of the research and development for this countermeasure was funded at the taxpayer’s expense through the National Institute for Allergy and Infectious Disease under two earlier awards totaling over \$200 million. Unlike the goals of Bioshield to create a market to encourage private investment, the first award funded by Bioshield was a very typical, multi-stage, Federal procurement fully funded at the taxpayer’s expense, without utilizing any of the unique authorities Congress provided to HHS under Project Bioshield.

The first Bioshield procurement for Anthrax therapeutics solicitation is for the acquisition and maintenance within the SNS of therapeutic products to treat U.S. civilians who have inhalational anthrax disease. The Anthrax therapeutics solicitation contemplates that the awarded contract(s) will be for 10 grams of an investigational new drug (“IND”) for use in testing. The actual manufacture of anthrax therapeutic product is an optional contract line item, which the government may decide to exercise within 12 months from the date of contract award and after the government reviews and approves the test sample. However, while this procurement could have utilized the streamlined procurement provisions provided under Project Bioshield, the solicitation includes numerous provisions of the Federal Acquisition Regulation (“FAR”) and other detailed requirements for bidders, including detailed rules governing the methods of preparing pricing for the proposal.

This initial Bioshield solicitation was curious in three ways. First, the way the solicitation structures the options in the contract fall short of the Congressional intent of the Act to provide for a commitment to recommend funding for production for the SNS as contemplated by Project Bioshield. Contrary to the intent of the Act, HHS has not committed to recommend exercise of the options for production quantities of the countermeasure upon successful development of the countermeasure. Such a commitment would help to advance the Act’s purpose of promoting the development of a biodefense industry by informing the markets that there is some certainty that there will be a government market for the product. Second, as noted above, the solicitation failed to use the simplified acquisition authorities that Bioshield makes available to the government, which would have permitted far fewer bidding requirements. Third, the solicitation makes IND status an absolute criteria for award of the contract. This has been criticized as unduly—restricting the ability of companies with promising technologies that have not yet reached IND, FDP status from competing.

Unlike the Anthrax therapeutics solicitation, the VaxGen solicitation did not suffer from a lack of commitment to production quantities. The scope of work for the rPA contract requires VaxGen to manufacture and deliver to the SNS 75 million doses of experimental (and non-FDA approved) rPA vaccine in pre-filled syringes along with safety needles (with a minimum of 25 million doses delivered within two years of contract award). The contract also requires a variety of ancillary commitments by VaxGen related to testing and licensing.

The VaxGen contract is valued at \$877.5 million, representing approximately 15 percent of the amounts appropriated for Project Bioshield for the next 10 years. The contract provides for payments to VaxGen of \$754 million in advance of the following milestones: (1) approval of a Biologics License Application (“BLA”) for general use prophylaxis, (2) approval of a BLA for post exposure prophylaxis; and (3) demonstration of 18 months of real time stability in pre-filled syringes. When and if these milestones are accomplished, VaxGen will receive specified per dose price supplements.

There are three main criticisms of the VaxGen contract. First, it appears that, as with the Anthrax therapeutics solicitation, HHS elected not to use simplified acquisition procedures in awarding the contract. Second, despite the availability of an FDA licensed competing vaccine technology, HHS restricted the competition for the contract to firms that produced rPA-based vaccines, which have not been advanced beyond early testing in the regulatory approval process. This has made the government and the Nation's security against anthrax attacks highly dependent on an early stage, unproven technology. Third, the government awarded the contract to a single vendor, thereby making the Nation's security against such attacks dependent on this single vendor.

Proposed Implementation Improvements

HHS can take several steps to implement Bioshield to increase industry participation. To fully realize the legislative intent of the law, HHS should enact regulations required under the Project Bioshield Act that take into account the following issues:

- Specify that Project Bioshield Act procurements include only those FAR clauses specifically required by FAR Part 13, Simplified Acquisition Procedures;
- Fully describe how HHS and DHS will make a determination of a material threat and the other determinations required by the Project Bioshield Act;
- Provide for determinations of the order in which the government plans to procure countermeasures;
- Require HHS to specify a firm number of doses or courses of treatment in the call for countermeasures stage;
- Provide for industry participation in market surveys undertaken during the assessment of the availability and appropriateness of countermeasures stage;
- Provide critical suppliers of needed medical countermeasures annual “warm base” funding to ensure that the U.S. Government will have continued access to those products following any procurement contract;
- Provide that multiple products manufactured by multiple suppliers using multiple technologies be procured where practicable to avoid undue dependence on any single supplier or single technology;
- Provide that countermeasures that are already licensed by the Food and Drug Administration should where possible be purchased under Project Bioshield; and
- Provide for the appropriate use of HHS’ “Other Transaction” Authority in procurements under Sections 2 and 3 of the Project Bioshield Act, in accordance with the authority provided to HHS by Title XVI of the fiscal year 2004 Defense Authorization Act.

Also, as required by Section 319F-2(c)(4)(C)(ii) of the Public Health Act, HHS should, in a call for bio-terrorism countermeasures, provide industry with an estimate of the quantities of a countermeasure (in the form of number of doses or number of effective courses of treatment) that HHS intends to procure upon development of a countermeasure that meets the statutory criteria. Providing industry with wide ranges of potential requirements for a countermeasure, as HHS did in the Anthrax therapeutics solicitation, does not serve the statutory purpose of promoting the development of a biodefense industry because it introduces additional uncertainty about the size of the government market for the countermeasure.

HHS and the Department of Homeland Security (“DHS”) should provide industry with information concerning the implementation of the Project Bioshield Act. For example, HHS and DHS should provide industry and the public with a status report concerning the governmental processes required by Section 319F-2(c)(2)-(6) of the Public Health Act. HHS should also publish the report on the adequacy of bio-containment facilities required by Sec. 5(c) of the Project Bioshield Act. This report was due in January, and yet, has not been completed or provided to industry.

Perhaps most important, DHS should inform industry of the progress and priority of the required threat assessments so that companies can make proper business decisions in their planning process. Project Bioshield requires that the DHS, in conjunction with the HHS, conduct a threat assessment to “assess current and emerging threats of chemical, biological radiological, and nuclear agents; and determine which of such agents present a material threat against the United States population sufficient to affect national security” and for which a countermeasure is needed. As implemented, this threat assessment must be conducted prior to any decision to purchase a needed countermeasure under the Project Bioshield.

It is my understanding that, to date, no such assessment has been conducted to determine the threat of cyanide to the American people. Aside from cyanide's historical use as a battlefield weapon in World War I, this country has already suffered from terrorist attacks and plots using cyanide: in the 1980s, with the tampering of Tylenol; in 2003, with the discovery of a cyanide bomb in the possession of a white

supremacist in Texas that held enough cyanide to fatally gas everyone in a 30,000 sq ft facility; and, in early 2004, with the discovery by U.S. troops in Baghdad of a 7-pound block of cyanide salt. Moreover, soon after our successful liberation of Afghanistan in 2002, our forces discovered Al Qaeda training videos using cyanide to poison dogs and other animals.

I note that in the legislative history of the Project Bioshield, a potential treatment for cyanide poisoning, hydroxocobalamin is specifically identified in the reports filed by the House Committees on Government Reform and Energy and Commerce. Thus, providers of this countermeasure are "on hold" pending completion of this threat assessment. Providing this information to industry will aid industrial base planning efforts and thereby promote the Project Bioshield Act's objective of fostering the development of a biodefense industry.

In addition to the specific recommendations above that should be taken into account during regulatory process and in order to carry forth the initiative's legislative intent, we have several policy suggestions that should be considered in implementing Project Bioshield: HHS should keep in mind that the government's use of multiple countermeasure suppliers and technologies would be in the overall interests of public health and homeland security. As evidenced by the recent influenza vaccine shortage, having a diverse "portfolio" of countermeasures in the strategic national stockpile will facilitate flexibility in responding to bioterrorism threats and attacks.

First and foremost, HHS should make clear that the statute does not require contractors to comply with burdensome government procurement requirements, including the requirement for certified cost and pricing data, in order to stimulate the maximum interest possible by commercial companies. Similarly, HHS should avoid the use of cost-type contracts or contract line items (thus, eliminating the need for a proposed contractor to adopt non-GAAP accounting practices) wherever possible.

HHS should structure Bioshield contracts to avoid a "staged" procurement approach such as that announced in the recent Anthrax therapeutic request for proposal, wherever possible. While we recognize the need for staged procurements under certain circumstances, using this method where HHS has conducted proper market research will avoid unnecessary delays and unpredictable results, thereby stimulating far greater private sector interest.

Maximizing the use of these authorities, as well as enactment of the additional streamlined authorities identified above, will go a long way to ensuring the greatest possible participation in Bioshield. Moreover, as we have already seen in how slow the contracting process has been to date with Bioshield, failure to act on these procurement reforms will cost the Nation something that no amount of money or any act of Congress can ever make up for time.

I very much appreciate the opportunity to offer testimony on this very important public health and anti-terrorism issue. Achieving the objectives of the Project Bioshield Act of 2004 and Senate Bill 3 are of the utmost importance to ensuring homeland and national security. Again, I applaud your efforts, and the efforts of President Bush and his Administration, and look forward to continuing our work with Congress and the Administration in this critical area.

I am happy to respond to any questions you may have.

PREPARED STATEMENT OF THE SARNOFF CORPORATION

Chairman Gregg, Ranking member Byrd, Sarnoff Corporation appreciates the opportunity to offer testimony on "BioShield and Bioterrorism." Sarnoff Corporation (www.sarnoff.com) produces innovations in information, biomedical, and electronic technology that generate successful new products and services for clients worldwide. Founded in 1942 as RCA Laboratories, Sarnoff has been serving both the public and private sectors to develop breakthroughs in integrated circuits, lasers, and imagers; drug discovery and development; digital TV, video for security, surveillance and entertainment; high-performance networking; and wireless communications. Our history includes the development of color TV, liquid-crystal display, and the disposable hearing aid, as well as a leadership role in creating the U.S. digital television standard. With the Rosettex Technologies and Ventures Group (a joint venture with SRI), Sarnoff has demonstrated a unique ability to bring a broad range of private sector organizations together to accelerate technology development in the interest of the national security. As discussed below, we believe that these skills are vital to the Nation's ability to meet the bioterror threat.

As a science and technology leader, Sarnoff recognizes the serious danger posed by bioterrorism and emerging infectious diseases to the United States. In addition to the many infectious agents already recognized as threats, new agents, like the

SARS coronavirus and the avian flu continue to emerge. Moreover, the bioterrorist threat includes the growing potential to use biotechnology to create new, genetically engineered pathogens against which existing countermeasures are ineffective.

To effectively secure our Nation against the threat of bioterrorism, in addition to developing countermeasures for all existing threats, it will be necessary to rapidly develop, manufacture, and distribute new countermeasures to treat illness and prevent further infections in the population for those agents we cannot predict. However, today it takes an average of 10 years to develop a countermeasure for a new agent. Clearly, this process must be accelerated if the entire spectrum of the bioterrorist threat, not just the set of currently recognized agents, is to be defeated.

Sarnoff believes that the countermeasure development process can be significantly shortened with a focused effort. For this reason, we are highly supportive of the inclusion of the concept of "research tools" in S. 3 and other legislative efforts seeking to improve the Nation's biodefense. Research tools are integral to the drug and vaccine development process, and thus an essential focus of all efforts to accelerate this process. The concept of research tools includes not only animal models and in vitro tests, but also technologies that reside outside the laboratory or in computers, such as bioinformatics and toxicological databases and drug and disease modeling systems. In addition, the use of new technology and methods in the clinical setting and during manufacturing will have crucial roles to play in accelerating development. While new animal models are essential for approval of needed countermeasures under FDA's current Animal Rule, ultimately research tools will help us move beyond the existing regulatory system by enabling much faster, less expensive, but highly reliable routes to new countermeasures. The FDA's 2004 report, *Innovation or Stagnation? The Critical Path to New Medical Products* lays out a vision of faster translational research and improved product development, and calls for better research tools for determining safety and efficacy and new manufacturing processes.

Determining what research tools are necessary to shorten the countermeasure development process is a significant challenge. Drug and vaccine development is extremely complicated, highly diverse, and multidisciplinary, involving hundreds of different types of technology and areas of scientific expertise. Along the pathway, roadblocks and time-consuming steps, often referred to as "bottlenecks," are multiple and interconnected. We believe a systems approach is required to address what is essentially a complex systems problem. Research tools must be integrated into end-to-end systems in order to move from the local acceleration of the development process that is current practice to substantial, overall reductions in the drug development cycle.

The development of research tools and research tool systems requires more than just scientific and technological advancements. It requires a well coordinated and tightly orchestrated national strategy designed to encourage and support creation of these systems. That coordinated national strategy is not yet in place.

Further, Sarnoff believes an unprecedented public-private partnership will be required not only to bring new research tools and research tool systems into use, but also to enable their application to rapid development of production of life-saving countermeasures in the event they are needed in a national public health emergency.

In summary, the Sarnoff Corporation thanks you, Mr. Chairman, and the Committee for the opportunity to submit this statement for the record of this important and very timely hearing. We look forward to working with you and your colleagues in ensuring that the threat bioterrorism and infectious disease pose to national security and the public health is adequately addressed, mitigated, and, ultimately, eliminated.

THREATS IN ORDER OF PRIORITY

Senator GREGG. Thank you and thank all members of the panel for what were very informative presentations. Hopefully there is somebody here from HHS and Homeland Security listening to it besides just those of us in Congress who try to get their attention. I think some excellent points were made.

Dr. Franz, you essentially seem to be attracted to the second approach here, which you outlined, which is to pick off the major threats and try to come up with ways to address those rather than a more global approach. You mentioned smallpox and anthrax as being obvious areas to start with and where we do appear to have

started and made progress. Dr. Read said, but what is next, and the market does not know what is next.

Is it possible, with your years of experience in the Government, to get an agreement as to what the threats are in order of priority for, say, the top 10 potential pathogens so people could predictably start to look at those, if they are in the scientific community, as places where they might want to put some resources to develop responses?

Dr. FRANZ. Senator, I believe as I mentioned, there are clearly outliers. The two that we all agree on are well above many of the others in my opinion, and that is based on the characteristics of the organisms. I really do not know anything about the likelihood of their being used, but we would have enormous vulnerabilities to those and likewise, as the last speaker mentioned, influenza. I think we would have enormous vulnerabilities there as well.

Senator GREGG. So should we go beyond those pathogens? Should we just do those three then and get ready for those?

Dr. FRANZ. I think if you start into plague and tularemia and Q fever and even botulinum—most of my lab work was done back at the bench at USAMRIID before I moved into the front office with bot. I do not put that up as high as these others, and it is because of the characteristics of the organisms, how difficult they are to grow, how easy they are to treat, how stable they are in the environment and so on.

So I think it becomes so hard and so expensive to produce specific countermeasures for those we do not consider outliers that I prefer a broad, general approach to public health for those, after we have dealt with the outliers. That should include good diagnostics, good disease surveillance, good epidemiology, and the same kinds of things, good education for our health care providers and for our citizens, the same kinds of things that help us in any emerging outbreak.

So I am a believer in very specific countermeasures for those that are really tough to deal with and then very broad preparedness for those which are easier to deal with and harder to pick as potential threats.

Senator GREGG. That sounds like a rational approach, and it is sort of the approach we are taking. Is it not?

Dr. FRANZ. I think it is, and I am happy with that. In that regard, I am actually involved at the S&T review for DHS programs for Secretary McQueary's program here today, and about 6 weeks ago, I was in Galveston to review the RCE meeting which is the Fauci \$1.5 billion or \$1.8 billion basic R&D program. Academe is heavily involved in both of these, and I have really been quite pleased with the fundamental research going on out there. We have some of our best scientists in the country stepping forward as the Nation needs them to contribute.

As the other speakers have said and as I learned in the military, the hard part is transitioning that good basic research into the arms or into the airwaves of our citizens to protect them, and that is where we need the most help I think.

INDEMNIFICATION

Senator GREGG. Well, the first part is good news, and the second part is Dr. Read's job since he is the investment guy here.

You listed a whole series of points, Dr. Read, as to how we could create a better climate for getting people to pursue these and move them to commercialization, if that is the right term. Probably not, but at least to being used.

Would you put indemnification at the top of that list?

Dr. READ. Maybe because it is a non-starter without. So there are many important things needed to be done to enhance BioShield in order for it to meet the test of drawing in our most capable innovators into this fight. So dealing with product liability and indemnification is clearly going to be necessary to have large, capable companies join the fray.

Senator GREGG. And next on the list would be what? The need to know what the targets are, targets of opportunity, so to say?

Dr. READ. Well, it is nice put next because it is clear and somehow we ought to be able to do it. I do not understand why the private sector should have to guess what the Government is thinking about these priorities. So I would put it second for clarity and because we ought to be able to check that box off.

I think one of the best ways it can be signaled is through the economic incentives that our public servants can send using the legislation and the funds available through BioShield and whatever improvements you are working on. The clear economic signals about a market, a reward at the end is by far the most compelling way to communicate those priorities, as opposed to a list. So if we knew the reward that had been created by the Government because it cared so much about, just for example, pick an agent on that list, tularemia or ebola or something, was twice the size of the financial incentive to succeed with a vaccine against another one, that would be about as clear a way to send those priorities as possible. And it would be incredibly useful not only if the reward were big enough and product liability were dealt with. I sincerely believe our largest and most capable companies would engage.

The truth is the market signals are used all the time to make portfolio decisions inside large companies and small ones. And if the large companies are there, the small ones will be there, the companies I invest in, because the small companies often make the key early-stage contributions that enable the larger companies to finish the job.

RISK OF LIABILITY

Senator GREGG. Which brings us to Mr. Clerici's point, which is that the big companies are not in there and the reason we have lost our vaccine industry in this country is the liability and the fact that the risk of liability so far exceeds the risk of return that there is no way to get people to put capital into this market.

Do you think we need to go beyond what we have in S. 3 or do we have enough in there on this liability? I mean, we know this whole liability fight is an uphill fight in the Senate, period.

Mr. CLERICI. Right. The approach that you take in S. 3, whereby a winner of a BioShield contract is automatically protected from li-

ability, so it is based on the same theories as the SAFETY Act, but without the same hurdles, I think would provide the necessary incentives for manufacturers to get into the biodefense market, large and small, because there at least would be some certainty that, assuming that you deliver, this liability protection is forthcoming automatically. I will put aside the political challenges of a system such as that which amounts to, more or less, tort reform rather than an indemnification scheme such as present with smallpox or under Public Law 85-804.

ADDITIONAL COMMITTEE QUESTIONS

For pandemic flu, I am not sure it is going to be enough because the providers of that vaccine know at the end of the day their vaccine is going into the arms of 300 million people. Even under the legislation proposed in S. 3, you are still going to be in Federal court defending those lawsuits throughout the country. So the predictability of what a Federal judge may do with the legislation and the fact that the plaintiffs could certainly file litigation in every jurisdiction throughout the land would be problematic to those companies. And the companies that are primarily going to supply the pandemic flu vaccine are the largest of the vaccine manufacturers and therefore have the most shareholders and the most concerns, being a large public company.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED TO DR. PENROSE C. ALBRIGHT

QUESTIONS SUBMITTED BY SENATOR JUDD GREGG

Question. Which Federal agency determines the bioterrorism threat and the Federal response to that threat?

Answer. Homeland Security Presidential Directive 10 (HSPD-10), Biodefense for the 21st Century, identifies the Department of Homeland Security as the lead Federal agency for “conducting threat periodic assessments of the evolving biological weapons threat” and for “developing comprehensive plans that provide for seamless, coordinated Federal, State, local, and international responses to a biological attack.”

Question. Under what authority is the Department of Homeland Security (DHS) involved in responding to bioterrorist threats?

Answer. DHS authority to respond to bioterrorist threats traces originally through Section 502 of the Homeland Security Act of 2002 which states that “The Secretary, acting through the Under Secretary for Emergency Preparedness and Response, shall include . . . (3) providing the Federal Government’s response to terrorist attacks and major disasters” and has been reaffirmed specifically for biological attacks in the HSPD-10 as cited previously. This role is one of providing overall coordination with the individual Sector Specific Agencies executing their legislated responsibilities, e.g. the Department of Health and Human Services is responsible for public health and the Environmental Protection Agency for decontamination.

Question. How is a biological threat addressed once the threat has been determined and what avenue does DHS use to respond to that threat?

Answer. Once a biological threat has been determined, it becomes a potential or actual Incident of National Significance and DHS becomes responsible for the overall coordination of the response. This is done under the framework of the National Incident Management System (NIMS) using the National Response Plan (NRP). The NRP provides the coordinating structure and mechanisms for national level policy and operational Federal support to state, local and tribal incident managers. The Homeland Security Operations Center (HSOC) serves as the primary national-level multi-agency situational awareness and coordination center. Other key coordinating mechanisms include: the Interagency Incident Management Group (IIMG), a senior level interagency group who provide strategic advice to the Secretary of DHS; a

Joint Field Office (JFO), a temporary Federal facility established locally to provide a central point for Federal, State, local and tribal representatives responsible for incident support and coordination; and a Principal Federal Officer (PFO), designated by the Secretary of DHS to work in conjunction with other Federal officials to coordinate overall Federal incident management efforts. The Federal response to actual or potential Incidents of National Significance is typically provided through the full or partial activation of the Emergency Support Functions (ESF). The NRP applies a functional approach that groups the capabilities of Federal departments and agencies, as well as the American Red Cross, into ESFs to provide the planning, support, resources, program implementation, and emergency services that are most likely to be needed during an Incident of National Significance. Each ESF is composed of primary and support agencies, based on their authorities, resources, and capabilities.

The NRP also includes a Biological Incident Annex, which outlines the actions, roles, and responsibilities associated with response to a disease outbreak of known or unknown origin requiring Federal assistance. The annex outlines biological incident response actions, including threat assessment notification procedures, laboratory testing, joint investigative/response procedures, and activities related to recovery. Because of its authorities, capabilities, and resources, the Department of Health and Human Services is the lead agency for the Biological Incident Annex.

Question. What role does DHS' Science and Technology (S&T) Directorate play regarding research into bioterrorist threats?

Answer. The S&T Directorate plays a major role in research into bioterrorist threats. The S&T Directorate is the national lead for the periodic assessments required by HSPD-10 under its Threat Awareness Pillar. These assessments include formal Risk Assessments every 2 years, with the first due in January of 2006, and Net Assessments every 4 years, with the first due in 2008. Under the BioShield Act of 2004, DHS is also responsible for making the Material Threat Determinations (MTDs) that inform the Department of Health and Human Services as to which agents are of especial concern as to warrant pursuit of medical countermeasures utilizing BioShield funding. To support and inform its assessment roles, the S&T Directorate also conducts research to improve the Nation's understanding of critical agent properties that might have a significant impact on its defense and response, e.g. the infectivity of agents at low doses or how long an agent survives in air, food or water.

SCIENCE & TECHNOLOGY DIRECTORATE AND INTEGRATED BIOSURVEILLANCE

Question. Can you provide the Committee an update on the status of Integrated Biosurveillance?

Answer. The Information Analysis and Infrastructure Protection Directorate (IAIP) of DHS is implementing the National Biosurveillance Integration System (NBIS) to integrate biosurveillance information with the objective of identifying and characterizing a biological attack on the Nation. The NBIS implementation is closely aligned with the NBIS design effort that was led by the S&T Directorate in 2004, with the full participation of the interagency partners. Currently, IAIP is in the procurement process for the NBIS system.

DEPARTMENT OF HOMELAND SECURITY AND BIOSHIELD

Question. How does the National Biodefense Analysis and Countermeasures Center, or NBACC, fit into the Department's role in defending against a bioterrorist threat?

Answer. The National Biodefense Analysis and Countermeasures Center (NBACC) is one of the Department's and the Nation's key tools in defending against bioterrorism. NBACC consists of two centers: the BioThreat Characterization Center (BTCC) and the National BioForensics Analysis Center (NBFAC). The BTCC is responsible for the threat characterization activities described previously, i.e. for conducting the periodic Risk Assessments required under HSPD-10 and for the scientific research to inform these threat assessments and support intelligence activities. The NBFAC, as designated under HSPD-10, is the lead national facility for conducting technical analysis of forensic materials to support attribution by the appropriate Departments and agencies. As such, the NBFAC is operated in close coordination with the Department of Justice's Federal Bureau of Investigation and with portions of the Intelligence Community.

Question. Since its inception, the NBACC has received \$130 million in Federal appropriations from various sources, beginning with work conducted by the Department of Defense (DOD). Given the current research conducted by the Army at Fort

Detrick, is there any duplication of effort between what the Army does and what is proposed for the NBACC facility?

Answer. The Department of Homeland Security (DHS) National Biodefense Analysis and Countermeasures Center (NBACC) and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) fulfill complementary but distinct missions at the Fort Detrick National Interagency Biodefense Campus (NIBC), where Congress has identified the need for Federal agencies to work collaboratively to address the threat of bioterrorism.

NBACC conducts research to protect the American public by enhancing our scientific understanding of biological threats. This complements, not duplicates, USAMRIID biodefense research and development and test and evaluation to provide medical protections such as vaccines, drugs, diagnostics, and information for military service members. Unlike USAMRIID, NBACC does not perform research to develop medical countermeasures.

NBACC threat characterization research provides a scientific basis to understand current and future biological threats, to assess vulnerabilities, and to determine potential impacts. Moreover, NBACC threat characterization supports DHS material threat assessment responsibilities under the BioShield Act.

NBACC bioforensic research provides a national capability to conduct forensic analysis of bio-crimes and terrorism to attain a “biological fingerprint” to identify perpetrators and determine the origin and method of a terrorist attack. HSPD-10 designates NBACC’s National Bioforensic Analysis Center to be the lead Federal facility to conduct and facilitate forensic analysis of biological terrorism.

Question. How does the Department address its responsibilities for dealing with a biological threat to our agricultural infrastructure?

Answer. As specified in HSPD-7 (Critical Infrastructure Identification, Prioritization and Protection), the DHS Information Analysis and Infrastructure Protection Directorate (IAIP) has the lead DHS role for vulnerability assessments and protection of the Nation’s critical infrastructure, and has led the inter-agency effort to develop a National Infrastructure Protection Plan (NIPP; sector-specific plans for agriculture and food are now in preparation). IAIP also has the DHS lead role for outreach to the private sector, including the development of a Food and Agriculture Sector Coordinating Council (F&ASCC) to facilitate information sharing between government and the private sector, and a Government Coordinating Council (GCC) to facilitate coordination across government and between government and the sectors. A “food and agriculture portal” has been created for the Homeland Security Information Network (HSIN) to provide a platform for the secure sharing of information (e.g., alerts, warnings, incident reporting, event tracking, etc.), and a Protected Critical Infrastructure Information (PCII) classification for the protection and special handling of proprietary industry information (e.g., vulnerabilities, threats).

And, as specified in HSPD-9 (Defense of United States Agriculture and Food), the S&T Directorate has responsibility for the overall inter-agency coordination to “accelerate and expand development of current and new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases.” Since June of 2003, the S&T Directorate has been responsible for the operation and management of Plum Island Animal Disease Center (PIADC) and has developed a joint research and diagnostic strategy with USDA (Animal Research Service and the Animal and Plant Health Inspection Service) for foreign animal diseases (FAD). Together with USDA and HHS, we have also begun the conceptual design of the next generation National Bio and Agro-defense Facility (NBAF) needed to replace the aging PIADC. Other major S&T Directorate agricultural thrusts include: systems studies, coupled disease and economic models, and table top exercises to better understand outbreak control options and inform policy and decision makers; demonstration of high throughput detection to better control and respond to outbreaks of foreign animal disease; detection systems for monitoring critical food nodes in the processing and distribution of selected food products; and two University Centers—one on foreign animal and zoonotic diseases and the other on food protection—to provide longer term research and train the next generation of agro-defense researchers and practitioners.

As specified in HSPD-5 (Management of Domestic Incidents), DHS has developed a framework for overall national coordination. This framework is established in the National Response Plan (NRP) and National Incident Management System (NIMS). The NRP includes Emergency Support Functions (ESF) to organize and provide Federal resources during responses (e.g., ESF-8, “Health & Medical Services”, DHHS lead; and ESF-11, “Agriculture and Natural Resources”, USDA lead) and Support Annexes to insure efficient and effective incident management (e.g., “Science and Technology”, DHS Science and Technology Directorate (S&T) lead).

Question. Who determines which vaccines are placed in the National Stockpile and what's the Department's role in that decision, given its responsibility for determining the bioterrorism threat?

Answer. The process to determine which vaccines are placed in the National Stockpile is determined by the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS). Recommendations for advance development of chemical, biological, radiological, and nuclear (CBRN) countermeasures utilize the Weapons of Mass Destruction Medical Countermeasures (WMD MCM) Subcommittee. This is an interdepartmental subcommittee initially chartered by the National Science and Technology Council (NSTC) and co-chaired by senior government officials from the Department of Homeland Security (DHS), the Department of Health and Human Services (HHS) and the Department of Defense (DOD). The material threat assessments (MTA) developed by the DHS based on a plausible attack scenario informs the sizing of the requirement. The HHS then evaluates the availability of current countermeasures and the possibility of development of new countermeasures. The WMD MC subcommittee deliberates on the nature of the medical consequence and the availability of appropriate countermeasures to develop a recommendation for the acquisition of a specific countermeasure. The HHS can issue a Request for Information (RFI) to determine the market availability and to alert industry to the U.S. Government interests. A Request for Proposals (RFP) announcing the specific requirements will then follow, once a U.S. Government requirement for a particular new medical countermeasure has been established by the WMD MC subcommittee, and approved by the Office of Management and Budget (OMB). The HHS implements the acquisition process.

Question. Explain the steps in developing and putting into the stockpile new medical countermeasures. Who has the lead at each step? I understand the role of the National Institutes of Health (NIH) in basic research, but how is that science translated into product?

Answer. The science and research to develop a new medical countermeasure will most likely have been supported by the National Institutes of Health (NIH) or the U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID); however many industrial initiatives are launched independently to develop a new product. In order to translate a basic science advancement into a viable product, certain applied research and advanced development is required. This process will focus on establishing a "formulation" for the product and a scalable manufacturing process utilizing a Good Manufacturing Processes (GMP) validated process conducted under appropriate Quality Assurance and Quality Control activities. In addition the appropriate animal studies and human safety studies need to be conducted in accordance with FDA regulations to assure that the results can be applied to regulatory decisions. The ability to manufacture a consistent and stable product is also evaluated. Please consult HHS for a more complete description.

Question. Does BioShield sufficiently incentivize industry to develop countermeasures to the bioterrorism threat?

Answer. This question is perhaps best answered by industry. However, Project BioShield is a good first step and has sent a message to industry that the U.S. Government is committed to obtaining appropriate countermeasures for the Strategic National Stockpile (SNS). The establishment of a 10 year special reserve fund of \$5.6 billion provides confidence to industry that acquisition funds are available in the long-term. Ten months after the enactment of the Project BioShield Act, the U.S. Government awarded three contracts totaling over \$1 billion for SNS acquisitions. Negotiations are in progress for two other contracts. In addition, two RFIs and one draft RFP have been recently published.

Question. What is the appropriate Federal role regarding research and development of countermeasures for the National Stockpile?

Answer. The role of the U.S. Government regarding research and development for countermeasures has traditionally been through the support of basic research. Both NIH and DOD (USAMRIID, USAMRICD, and AFRRI) have excellent records in this regard. The U.S. Government can further target and facilitate research and development (R&D) efforts by setting clear requirements and specifications for medical countermeasures; facilitating partnerships as needed between government and industry or between differing industries; and providing critical resources such as facilities (e.g. biocontainment labs), animals (for testing), reagents and assays.

Question. How does the Department address the development of countermeasures as it relates to industry disparities regarding large and small companies and their available capital for research and development?

Answer. Human medical countermeasures development is done through HHS and DOD and not through the Department of Homeland Security, so we will defer to them on the medical portions of this answer. For non-medical countermeasures, the

S&T Directorate does not require nor expect cost sharing in our R&D programs. A company's available capital to co-fund R&D is not an issue. Our competitive solicitations for all kinds of countermeasures research and development have offered multiple opportunities for both large and small businesses. Competitive solicitation results show that for research and development in highly technical fields, small companies can successfully compete outright, and this is especially true when they partner with larger or other small businesses.

Question. From your perspective, how has BioShield helped DHS respond to the bioterror threat? Is it working as intended, and what would BioShield II do for DHS and S&T specifically?

Answer. BioShield is helping DHS respond to bioterror threats by stimulating the development of needed medical countermeasures, by providing for emergency use authorization of these and other countermeasures if needed, and by streamlining the review process for research related to future generations of medical countermeasures for these threats. Procurements are now in progress for botulinum antitoxin, the current generation anthrax vaccine (AVA), the next generation anthrax vaccine (rPA) and for a pediatric formulation of potassium iodide—a therapeutic for certain kinds of radiation exposure. A Request for Information has recently been issued for a third generation smallpox vaccine (MVA) which would further minimize any side effects. Also, earlier this month, the National Institute of Allergies and Infectious Diseases (NIAID) made its first series of research awards using its new BioShield authorities.

Question. Please provide a list of administrative, regulatory and legislative proposals needed to invigorate scientific research relevant to the development of needed countermeasures and products to counter natural pandemics and epidemics.

Answer. The Nation has a strong program in basic scientific research related to the development of medical countermeasures. There are broad activities in understanding the genomics and proteomics of microorganisms. In addition many research programs are focused on the understanding and control of the immune system. Advanced research and development however falters after the proof of principle stage when applied product development activities are required. Additional attention is needed in areas critical to mid-stage development of medical countermeasures such as animal studies, clinical studies, regulatory issues and the need to establish and validate a GMP (Good Manufacturing Processes) production process.

Question. I understand that you are the lead DHS representative for an inter-agency working group on bioterrorism and bioterrorism countermeasures. I also understand that the U.S. Department of Health and Human Services (HHS) and DOD participate in this working group. Can you tell me who else is involved in the working group, how often you meet, and what the basic function of the group is?

Answer. Recommendations for advance development of CBRN countermeasures utilize the Weapons of Mass Destruction Medical Countermeasures (WMD MCM) Subcommittee. This is an interdepartmental subcommittee initially chartered by the National Science and Technology Council (NSTC) and co-chaired by senior government officials from the Department of Homeland Security (DHS), the Department of Health and Human Services (HHS) and the Department of Defense (DOD). The material threat assessments (MTA) developed by the DHS based on a plausible attack scenario informs the sizing of the requirement. The HHS then evaluates the availability of current countermeasures and the possibility of development of new countermeasures. The WMD MC subcommittee deliberates on the nature of the medical consequence and the availability of appropriate countermeasures to develop a recommendation for the acquisition of a specific countermeasure.

DEPARTMENT OF HOMELAND SECURITY, BIOWATCH, AND DETECTION OF EVENTS

Question. How does DHS respond to recent criticism in the press that BioWatch is not effective?

Answer. BioWatch has been deployed to over 30 cities and provides these cities with protection against biological threat agents. At the request of the stakeholders, additional assets currently are being installed to provide increased coverage to include high trafficked facilities and other venues that attract large numbers of the population. DHS believes that BioWatch is an effective system which will be further improved by enhanced coverage while maintaining the no system false positives to date after conducting over two million assays.

Question. What kind of measures are in place to assist the Department in its coordination role regarding BioWatch?

Answer. Formal BioWatch coordination is done officially through a Memorandum of Understanding with the DHS, HHS/CDC, and EPA. Roles and responsibilities are

articulated and budgetary aspects addressed. Additionally, the BioWatch Office works closely with CDC and EPA regarding day to day operations, enhancement of the current program, and future capabilities, thus ensuring success through close ties with the partners. Supported by a HSC Biodefense Memorandum of Understanding, the S&T Directorate also is actively engaged with USPS, DOD, HHS, and DoJ to discuss technology R&D programs and interoperability, concept of operations to include notification, and the development of a national architecture.

DEPARTMENT OF HOMELAND SECURITY'S ROLE IN DETECTION EQUIPMENT

Question. Given the overarching responsibility the Department has regarding biodefense, what is the Science and Technology Directorate's role in the development and evaluation of biological threat detection equipment?

Answer. The S&T Directorate's role in the development and evaluation of biological threat detection equipment is to enhance current systems capabilities while developing the next generation of detection systems to provide early detection of attacks on outdoor and indoor areas and on our agricultural and food infrastructures. Currently, S&T Directorate efforts include: detection systems to enable the next generation of BioWatch, our urban monitoring program; the development of rapid (in minutes) identifiers for protection of high valued facilities and special events, and the development of detection systems for food distribution systems. Additionally, the S&T Directorate has a robust bio-assay development program which both supports our current biomonitoring systems such as BioWatch and is also integrated with the Directorate's detection technology development programs. The S&T Directorate, working through the Association of Analytical Chemists (AOAC), has also taken the lead in testing and evaluating hand-held assays for screening of so called "white powder" events.

The S&T Directorate participates routinely on interagency working groups through the Homeland Security Council (HSC) and Office of Science Technology Policy (OSTP) to help establish and coordinate biodefense detection strategies and requirements. A major recent accomplishment in this area is the signing of a Memorandum of Understanding for Coordinated Monitoring of Biological Threat Agents Amongst the Department of Homeland Security, the Department of Health and Human Services, the Department of Defense, the Department of Justice and the United States Postal System. The S&T Directorate also interacts regularly with the detection development, test and evaluation programs in the DOD and the EPA (e.g. the Environmental Testing and Verification Program), including mutual participation in each others program reviews. S&T Directorate staff members routinely monitors literature, attend technology conferences, and host members from industries, academia, and non-profit organizations which present their current efforts and findings in technology development.

Question. How does the Directorate foster the growth in bioterror detection equipment, and how do you respond to a rapidly changing industry?

Answer. The S&T Directorate fosters the growth in bio-threat detection equipment through two key steps (1) a clear formulation and communication of our needs and requirements; and (2) an active, multi-pronged, outreach to the broad R&D community for the best way to meet these requirements in a timely fashion. Through systems studies and scientific and interagency committees, we have focused on three classes of detection systems that are critical to an integrated national biodefense: advanced detection for monitoring urban areas; rapid (minutes) identification for protecting key facilities and special events; and detection systems for protecting our agricultural and food infrastructures. Detailed performance and cost requirements have been formulated to inform industry, academia and the national and Federal laboratories of our needs and have been published on the S&T Directorate's Homeland Security Advance Projects Research Agency (HSARPA) website. The S&T Directorate has had broad solicitations in each of these areas, typically involving an open, national level workshop conveying the needs and asking for inputs and refinements from the participants, a formal Request for Information (RFI), and then a formal proposal solicitation. Hundreds of proposals have been received and evaluated, with some fifteen proposals already funded and others in the works. The focus is on applied research with a goal of fielding technology as rapidly as possible, typically within 3 to 5 years. A phased development approach is used. The technology developers are evaluated and down selected by rigorous testing during each phase (Preliminary Design Review, Critical Design Review, etc.). Each technology does receive feedback during the testing at each phase with an opportunity for adjustments and re-evaluation. However, candidate technologies will be terminated if they fail to show reasonable progress. The S&T Directorate will also consider testing technologies funded through other programs (from other organiza-

tions) against the goals set forth by the S&T Directorate. In parallel, the S&T Directorate participates in a range of technical conferences and discussions with developers of detection systems to stay abreast of any developments that might change how it thinks about the realm of the possible' in both near- and longer-term bio-detection system. The S&T Directorate believes the strategy outlined above provides both the guidance and the flexibility to foster growth and responsiveness in a rapidly changing industry.

Question. What role do the national labs play in this arena?

Answer. The national laboratories have played a key role in BioWatch sensor development and deployment and provide expertise on siting of detection systems. They continue to be a vital part of the S&T Directorate's strategy to develop and pilot advanced biothreat detection systems, with research and development activities in the following areas:

- Development of specific instrumentation (Biobriefcase, Enhanced BioAerosol Detector): Lawrence Livermore National Laboratory (LLNL) and Sandia National Laboratory (SNL).
- Development of new nucleic acid- and protein-based assays of recognized biothreat agents to be used in biodetection instruments: LLNL, Los Alamos National Laboratory (LANL), Pacific Northwest National Laboratory (PNNL), and SNL.
- Identification of next-generation signatures that reflect either (a) the host-pathogen interaction or (b) virulence characteristics or antibiotic resistance of recognized or emerging biothreat agents and using these signatures to develop new assays for biothreat detection: LLNL and PNNL.
- Provision of informatics support to enable the discovery of new targets for assays and to develop new reporting tools for detection instruments: LLNL, LANL, Lawrence Berkeley National Laboratory (LBNL), PNNL, and Oak Ridge National Laboratory.

Question. Without getting into classified information, please tell us how we are doing in the deployment of surveillance and detection equipment.

Answer. In January and February 2003, BioWatch was deployed to approximately 30 U.S. cities. At that time, a limited number of collectors were strategically placed in each city to provide for maximum population protection. At the request of the BioWatch cities, a Generation (Gen) 2 BioWatch was developed to provide increased temporal and spatial coverage and was piloted in New York City in fiscal year 2004 and early fiscal year 2005. Gen 2 increases the number of collectors two to fourfold, including coverage of key priorities identified by the cities, such as transportation hubs and other indoor venues that are highly trafficked. Gen 2 is in the process of being deployed to the top threat cities in fiscal year 2005 and fiscal year 2006. Additional samplers will be placed in each BioWatch city to be used at special events and/or at the cities' discretion. New technology is now under development that will enable a "Gen 3" BioWatch which reduces the sampling and analysis time to four hours on site and will be wirelessly networked to a local public health interface for further confirmation and so that positive samples can be retrieved for further analysis. This technology will provide for the high sensitivity and extremely low false positive rate consistent with the current system.

We are also developing other detection systems. High throughput diagnostics for agricultural testing will be piloted in fiscal year 2006 and food sensors for specific applications will be developed by fiscal year 2007. R&D is also on-going on detect-to-warn' sensors that can detect biological agents in a less than five minutes and hence be used to provide warning of releases in high value building, facilities, and special events.

Question. Have you done any evaluation or testing of surveillance and detection equipment once it's been deployed and is in use?

Answer. Yes, there is active evaluation and testing of the BioWatch system. The BioWatch Exercise and Evaluation Program (BWEEP) is an annual proficiency test for BioWatch laboratory and field operations and is designed to insure protocols and procedures continue to meet or exceed prescribed standards. If there are no deficiencies, they will not be revisited until the next annual cycle. If there are minor deficiencies, on-the-spot corrections or additional training will be administered and they will be re-inspected in approximately 6 months. If there are major deficiencies and/or safety violations, immediate remedial actions will be taken.

Question. What collaborative process does the Department use to gain the input from industry, researchers, and responders in the development of new technology? Does the process include peer review?

Answer. The Science and Technology Directorate uses an open and competitive solicitation process for research and development with the private sector.

Before the official solicitation is issued, the S&T Directorate may publish a draft Statement of Work for public comment, giving industry the opportunity to provide advice and recommendations. In appropriate cases, full scale technical workshops are held to assess the state-of-the-art, inform all potential bidders of current developments in the field, and sharpen the technical focus of the solicitation. In most cases, after each solicitation is published, a public Bidders' Conference is held to explain the solicitation in detail and answer questions that may have arisen in the minds of potential bidders. Each solicitation has an open Frequently Asked Questions (FAQ) section on the website where individual bidders' questions are answered and published for the benefit of all. In a typical solicitation procedure, the S&T Directorate uses the first bidder submission—the white paper—as a vehicle for discussion with private sector bidders. In addition, industry representatives are free to request direct interviews with S&T Directorate Program Managers to describe or discuss their concepts, ideas, and ongoing developments for new technologies.

The criteria by which white papers and proposals are evaluated by DHS technical experts are listed fully in the public solicitation so that bidders understand how their submissions will be judged. The S&T Directorate uses a technical merit review instead of peer review. Technical solutions to DHS needs and requirements often involve complex engineering, proprietary information, and other information of economic value to competitors. To perform technical review, the S&T Directorate organizes a panel of Federal Government experts, including S&T Directorate staff, other DHS technical and operational staff, and experts from other Federal agencies. The evaluation panel may be supplemented by outside advisors if there is a need for specialized expertise the government evaluators do not have. These outside advisors must agree that neither they nor their home institutions may bid against that particular solicitation. The S&T Directorate has found that providing review by government personnel, rather than a panel of peers, allows bidders to be more open about proprietary information supporting their proposed project.

Additionally, DHS and national laboratories are consulted frequently by the S&T Directorate to formulate the strategic direction of research, development, technology and evaluation (RDT&E) programs.

The science and technology needs of emergency responders are represented in the S&T Directorate by the Portfolio Managers. Other methods for collecting salient inputs include the annual Science and Technology Requirements Council, an annual joint conference with the Department of Justice, an annual conference to forecast S&T Directorate opportunities and major program direction to the industrial community, an intense 6 week effort each year involving the identification of responders' needs for rapid prototypes, and face-to-face contact with customers while working on current R&D projects.

Question. What types of detection equipment are most difficult to develop, and how is the industry responding to the demands of the requirements? For example, the drug/vaccine industry indicates that decades of research are required before a drug/vaccine becomes available in the market. Is that same time and financial investment required by other industries?

Answer. In general, any development program that deals directly with human health can take years of research, development, testing and evaluation prior to becoming available to the market because of extensive safety regulations. Instrumentation, including detectors for biological, chemical, and explosive threats, also has a difficult development schedule. Initial systems can be developed and deployed within the next few years, but it may take upwards of a decade to develop and deploy cost effective instruments with all the desired capabilities. The main reason is the requirement to achieve a high probability of detection and a extremely low probability of false alarms in instruments that are of sufficiently low cost that they can be widely deployed and used for continuous monitoring. This will require development of completely novel technologies or complex engineering projects.

SCIENCE & TECHNOLOGY DIRECTORATE AND STANDARDS

Question. Given that Science and Technology (S&T) Directorate's 2004 guidelines and standards for biological countermeasures have been in place for a year, please give us an assessment of the effectiveness and relevance to the standards issued by the S&T Directorate regarding bioterror agents? How has industry responded to them?

Answer. The S&T Directorate has a role and responsibility to ensure the effectiveness of biological countermeasures tools developed for and used by the homeland security community. By setting consistent and verifiable measures of effectiveness for basic functionality, minimum performance, interoperability, efficiency, sustainability, and appropriateness and adequacy for the task, standards improve the qual-

ity of homeland security systems and technologies. The S&T Directorate's Standards Program strives to enable the homeland security community to make informed equipment purchases by establishing minimum performance standards which can be linked to Federal grants programs so that equipment purchases comply with these minimum performance standards.

In 2004, the primary focus for Standards for Biological countermeasures revolved around developing minimum performance criteria for biological screening devices (specifically lateral flow immunoassays) used by first responders. In fiscal year 2004 and early fiscal year 2005, an interagency task force was formed to address the effectiveness and use of lateral flow immunoassays for the detection of *Bacillus anthracis* (anthrax) by emergency responders. The task force agreed upon and published accepted performance criteria associated with the hand held assays (HHAs). The HHAs were tested and evaluated against the accepted criteria and those results were also published. An effort was also initiated with the Center for Domestic Preparedness to develop a standard Bio-Protocol for first responders to use to guide their response to a suspicious powder incident.

The relevance and effectiveness of this important effort to develop and implement standards for biological field screening devices are clear. In the past these devices were procured in great numbers and often used incorrectly in the field by first responders to assess the biological threat associated with suspicious powders. Numerous false alarms were raised based on the results of these devices. Before these devices can be used in the field, first responders must understand their limitations, have a clear concept of how they are to be used, and be trained to use them properly. The S&T Directorate's effort to develop standards for the detection of anthrax using HHAs has given the homeland security community access to reliable information on how these devices perform and which devices met the performance standards. These standards are just a first step in ensuring confidence in the Nation's response to biological threats. There are numerous other types of biological countermeasures technologies to be evaluated against the range of biological agents. In addition, standard sampling protocols and standardized training must be developed and implemented.

Industry was heavily involved from the onset with the process of developing these standards. Manufacturers voluntarily attended the interagency task force meetings, provided technical feedback on the study design and testing protocols, and provided instruments for testing. The entire standards development process relied upon working in an open atmosphere and gaining consensus of the majority of the stakeholders. Results of the testing were supplied to the manufacturers in a clear and timely manner. Unfortunately not all of the devices met the published acceptance criteria and hence some manufacturers were disappointed with the outcome. However, most manufacturers have indicated a desire to improve their devices and enter into a second round of testing.

Question. How does S&T respond to the Department's Office of State and Local Government Coordination finding that its existing standards are inadequate?

Answer. The S&T Directorate acknowledges that the existing biological countermeasures standards only address the performance of one type of detection equipment to one type of biological agent. The S&T Directorate's Standards Program is building a long-term plan and process for the development of standards to ensure the effectiveness and performance of all critical biological countermeasures technologies for a number of biological agents. However, the standards development process relies on consensus building, an activity that is often time-consuming and costly. Therefore, standards development activities have focused to date on urgent, high priority areas. In order to validate the entire spectrum of biological countermeasures products and technologies, requirements for each of the technologies must be defined and consensus between the agencies on those requirements must be obtained. Additionally, standards need to be fully developed that are tested and evaluated for the various biological technologies, methods and processes. Also needed is the development of integrated policies and procedures based on conformance to the standards, and institute standardized training. All of these tasks are necessary and important and shall be incorporated in a long-term plan, but their accomplishment requires the necessary resources and cooperation of all of the key stakeholders. In addition, the Standards Program must assess and balance the need for standards in all homeland security areas based on the available resources. In the near future, (fiscal year 2005 and fiscal year 2006) the standards portfolio will address the need for standards for biological sampling activities and additional biological screening devices.

Question. Have any revisions or refinements been made to those standards?

Answer. The standards development process consists of a number of well-defined steps including periodic review and revision of standards when necessary. Revisions

or refinements have not currently been made to the published acceptance criteria for the performance of hand held immunoassays for the detection of anthrax. DHS intends to initiate a second round of testing of new and improved devices and will hold a meeting of the interagency task force to determine whether revisions are needed and incorporate lessons learned before the new round of testing is initiated. As always, voluntary consensus standards development is an open process, and interested stakeholders will have a means of providing comments and feedback on any necessary revisions or refinements.

Question. What process is used to update the biothreat standards?

Answer. Because DHS is not a regulatory agency, the process of updating standards will follow the voluntary standards development organization's guidelines. In the case of the hand held immunoassays, the Association of Analytical Chemists International (AOACI) was the standards development organization. Hence, the AOAC process to update the standards will be followed.

Question. Have end-users and industry found the biothreat standards useful in the development and use of new equipment? Can you give us an example?

Answer. End-users are now able to obtain reliable information on the performance of various manufacturers' hand held immunoassays before procurement. That information enables end-users to make knowledgeable decisions on whether to use these devices and if so which ones are most reliable. In addition, many of the manufacturers have indicated that they have already made adjustments to their technologies and are eager to submit the new and improved technologies for a second round of testing.

SAFETY ACT

Question. How much of the SAFETY Act has been implemented by the Department? Is it being implemented by industry, issue, or on an ad hoc basis?

Answer. The Department has placed significant emphasis on the full implementation of the Support Anti-terrorism by Fostering Effective Technologies Act (SAFETY Act) and has accomplished much in an extremely short time period. In less than 15 months, the Department has established an Office of SAFETY Act Implementation (OSAI), which is responsible for administration of the program. The Department has developed, published, and implemented a proposed rule (July 11, 2003) and an interim rule (October 16, 2003) governing the implementation of the SAFETY Act. In addition, the Department is in the process of developing revisions to the current implementing regulations to address public comments and operational experience.

More than 450 experienced technical and economic reviewers have been vetted and are available to evaluate SAFETY Act applications in accordance with the statutory criteria. OSAI has designed a reviewer training program specific to SAFETY Act requirements that each reviewer is required to attend.

The Department initially developed a SAFETY Act application kit for use by interested parties and has since revised the kit. The revised application kit reflects substantial feedback from applicants and industry as well as our operational experience, and we expect it to provide applicants with better guidance and tools for a successful application. On December 13, 2004, a Paperwork Reduction Act notice for the revised version of the new kit was published in the Federal Register. Further, a web-based, interactive application process has been instituted that allows sellers to submit applications electronically, obtain automatic feedback on the status of an application, submit questions to a help desk to obtain assistance with navigating the application process, and provide access to resource documents and frequently asked questions.

Significant elements of the Department's SAFETY Act implementation include:

- Website.*—The SAFETY Act website (www.safetyact.gov) contains the electronic application kit, reference materials, Frequently Asked Questions (FAQs), and specific instructions for applications submitted in connection with a procurement.
- Help Desk.*—OSAI established a help desk that can be accessed by way of online forms, an e-mail address (helpdesk@safetyact.gov), or a toll free phone (1-866-788-9318). The Department has received much praise for the help desk. Applicants not only receive timely responses, but they can actually speak with a staff member.
- Outreach.*—Throughout the past year, OSAI has made presentations at numerous SAFETY Act-relevant conferences, held meetings with applicants, and established internal procedures to ensure that each applicant has the opportunity to discuss an application with relevant staff early in the review process.
- Pre-Applications.*—OSAI implemented a pre-application process designed to provide applicants with a quick assessment of the likelihood of its technology being

approved for Designation or Certification if a full application is filed. These pre-applications are processed within the 21 days advertised and, in addition to a written assessment, each applicant is given the opportunity for a personal debriefing on its pre-application. Early processing delays have been eliminated—essentially all of the approximately 120 pre-applications filed since March 1, 2004, have been completed on time.

—*Application Kit.*—The initial application kit was designed with the expectation that changes would be required as operational experience was obtained. During the past year, OSAI has sought input from applicants, industry, and government on areas appropriate for revision. Utilizing this input and its own operational experience, OSAI prepared a revised Application kit in concert with the proposed revision to the interim rule. The Paperwork Reduction Act notice for the final version of the new kit was published in the Federal Register on December 13, 2004, and the Department anticipates early adoption of the new kit.

The SAFETY Act requires the Department to evaluate technologies on an application by application basis; however, the Department has undertaken a significant effort to coordinate the SAFETY Act application process with major anti-terrorism procurements where multiple Sellers will be providing the same technology to ease the burden on applicants and speed the evaluation process.

To date, the Department has received more than 200 pre-applications and 94 full applications. As of June 18, 2004, twenty Designations and Certifications have been granted and five applicants have received Designation only.

Question. How is the SAFETY Act being applied to Project BioShield products?

Answer. The Department is not aware of any application submitted in connection with the BioShield program. Any provider of an anti-terrorism technology may apply for the protections afforded by the SAFETY Act and it is reasonable to anticipate that participants in the BioShield program will apply for SAFETY Act protections as their technologies mature.

Question. Is the Department going to apply the SAFETY Act to the pharmaceutical industry when it comes to the development of biological countermeasures?

Answer. A very wide range of technologies may potentially qualify for protection under the SAFETY Act. The Act explicitly applies to any qualifying product, equipment, service (including support services), device, or technology (including information technology) that is designed, developed, modified, or procured for the specific purpose of detecting, identifying, preventing, or deterring acts of terrorism, or limiting the harm that such acts might otherwise cause. This broad definition of “technology” encompasses tangible products, software, services, various forms of intellectual property, and anything else that can be sold that has a specific anti-terrorism application. This definition of technology would encompass pharmaceutical products and their related delivery technologies when used for anti-terrorism purposes.

Question. How is S&T working with the drug and vaccine industry to determine which products should be considered for SAFETY Act protection?

Answer. The Office of Safety Act Implementation (OSAI) has a robust outreach program. Members of OSAI staff frequently provide informative presentations on the SAFETY Act at a variety of trade shows and industry meetings and often have a presence in the vendor areas where additional informative material on the application process and the benefits of protection under the SAFETY Act are available. OSAI staff members also provide informal guidance on an individual basis at these same events. In addition, OSAI will host another round of nationwide SAFETY Act seminars to introduce prospective applicants to the program including the benefits of SAFETY Act protections, the new application kit, and the revised interim rule.

The Department does not pre-determine if a particular technology is an anti-terrorism technology within the context of the SAFETY Act. Each applicant describes its specific anti-terrorism technology in its application and explains why it believes the technology or its proposed use of the technology meets the statutory criteria. OSAI does provide personalized guidance to applicants on a variety of issues at a number of points throughout the application process. Most often, the anti-terrorism application of the technology is reviewed, analyzed, and discussed with the applicant during the pre-application process, telephone discussions following receipt of the formal response to the pre-application, and through telephone conversations at the end of the completeness review before formal evaluation is commenced.

While we are not able to assess directly the extent to which this information has penetrated the pharmaceutical community, the fact that we have received some applications relating to vaccines indicates that some measure of penetration has been achieved.

Question. Is the SAFETY Act perhaps too limited with respect to certain areas? Is the Department reviewing the Act’s authorities and issuing regulations or other administrative means to best utilize the Act?

Answer. The Department is committed to the primary goal of the SAFETY Act—to ensure that the threat of liability does not deter potential manufacturers or sellers of critical anti-terrorism technologies from developing and commercializing technologies that could save lives. The SAFETY Act review process is not intended to guarantee that anyone will be able to purchase “the very best” product or services. It is designed, as required by the statute, to help individual effective technologies overcome market barriers on an application-by-application basis. Throughout its implementation of this program, the Department has engaged applicants, industry, and the public to solicit feedback to enhance the process. Many concerns raised by interested parties have already been addressed and the Department will continue to encourage input to improve the program. The Department is committed to fulfilling the intent of Congress as set forth in the language of the SAFETY Act and will continue to improve upon efforts working towards successful implementation of this important legislation.

Among the efforts being undertaken by the Department to improve its implementation of the SAFETY Act are revisions to the application kit and the interim rule. The initial application kit was designed with the expectation that changes would be required as operational experience was obtained. During the past year, Office of Safety Act Implementation (OSAI) has sought input from applicants, industry, and government on areas appropriate for revision. Using this input and its own operational experience, OSAI prepared a revised application kit in concert with the proposed revision to the interim rule. The Paperwork Reduction Act notice for the final version of the new kit was published in the Federal Register on December 13, 2004. In addition, the Department is in the process of developing revisions to the current regulation. The revised regulations will address public comments and address other areas with a view to facilitating greater participation in the SAFETY Act program.

RAPID PROTOTYPING

Question. How does the rapid prototyping function within S&T assist in the Department’s effort to combat bioterrorism?

Answer. The S&T Directorate’s Rapid Prototyping Portfolio assists in the effort to combat bioterrorism by reducing the time needed to develop and commercialize relevant technologies that can meet needs on an interim basis while technologies that meet long-range needs are in development. The S&T Directorate’s first rapid prototyping effort (conducted with the Technical Support Working Group (TSWG) in fiscal year 2003) produced thirteen separate efforts related to combating bioterrorism. When developed and completed, these efforts will provide such capabilities as: better methods to characterize biological backgrounds in facilities; methods for large-scale restoration of biologically contaminated urban areas; a low-cost, personal bio-decontamination system; a biological aerosol threat warning detector; direct detection assays for botulinum toxin; and improvements in biological detection systems.

The S&T Directorate’s Rapid Technology Application Program (RTAP) has worked intensively with the DHS internal customers and field agents to identify their most urgent needs for countering bio threats. These needs will be published to the private sector in early summer 2005 with the goal of delivering the prototypes to those customers within 18 months of contract award.

Question. Do bioterrorism-related technologies lend themselves well to rapid prototyping?

Answer. All technologies, including technologies for bioterrorism countermeasures lend themselves well to rapid prototyping. Technologies needed to combat bioterrorism range from near-term prototypes to extremely difficult long-term projects. Based on the expressed expectations of DHS customers, tactical concerns in the field dominate. They need technical capabilities to determine if a suspicious substance is a bio-agent or powdered sugar, other capabilities to tell them if an entire area is contaminated or not, and a fast, reliable method of definitive bio-agent identification. Technically effective isolation or containment of suspected bio-contaminants and improved protection of field personnel from bio hazards are cited often as developments needed in the short term.

In other areas, such as bioinformatics, forensics, bioassays for novel or engineered bio-agents, rapid prototyping must give way to careful, painstaking, long-term development.

Question. How do you determine which items are chosen for the rapid prototyping program?

Answer. The Rapid Technology Application Program annually conducts a series of meetings with DHS internal customers and field agents, and State and local responders to identify their highest priority needs for rapid prototyping developments.

These customers identify and prioritize their needs in any technical area. Within the constraints of technical feasibility, development time (no longer than 18 months), and available resources, their top priority rapid prototyping needs will be developed.

Question. Has the rapid prototyping effort incentivized both the scientific community and entrepreneurs to develop products?

Answer. Industry has been avidly interested in the S&T Directorate's solicitations. For example, the S&T Directorate's first rapid prototyping effort (with TSWG in fiscal year 2003) was valued at \$60 million over 2 years and resulted in 94 contract awards for research and development work now underway. When developed and completed, these efforts will provide such capabilities as: better methods to characterize biological backgrounds in facilities, methods for large-scale restoration of biologically contaminated urban areas, a low-cost, personal bio-decontamination system, a biological aerosol threat warning detector, direct detection assays for botulinum toxin, and improvements in biological detection systems. There were more than 3,000 initial submissions for that solicitation. The DHS Rapid Technology Application Program, currently valued at \$35 million is scheduled to release its first public, competitive, rapid prototyping solicitation in early Summer 2005 and a proportional strong response is expected.

Question. What is the most difficult hurdle when it comes to rapid prototyping?

Answer. The most difficult part of the rapid prototyping process is deriving meaningful customer requirements that are feasible, affordable, and have a high potential for actual deployment upon completion of development.

Question. Do antidote and vaccine development fall under the rapid prototyping effort or is that entirely under HHS' jurisdiction?

Answer. Section 302(4) of the Homeland Security Act of 2002 assigns to the Under Secretary for Science and Technology the responsibility for, . . . conducting basic and applied research, development, demonstration and testing, and evaluation activities that are relevant to any or all elements of the Department, through both intramural and extramural programs, except that such responsibility does not extend to human-health related research and development activities:" [emphasis added]. Section 304 (a) assigns this responsibility to the Secretary of Health and Human Services.

Question. Are different tools combined and cross-pollinated to accelerate research and development when rapid prototyping to address bioterrorism?

Answer. Yes. The S&T Directorate's Rapid Prototyping development period is nominally between 6 and 18 months from contract award. In all but a very few cases this implies that most rapid prototypes will not involve basic research, but will heavily involve development. These developments take forms such as modifications of existing equipment for new purposes, increases in effectiveness derived from new algorithms or software, changes in configuration to be smaller, lighter weight, or redesign for decreased power consumption for example. Many of these rapid prototyping developments use "tools" developed for other purposes. Personal Data Assistants can be modified for identification of, and use by emergency responders. Personnel protective equipment can be redesigned to be less bulky, more effective against an array of hazards and more user-friendly. Wireless communications technology, for example, has many uses in bio countermeasures and it can be licensed off-the-shelf for many applications.

Question. How are the legal ramifications to rapid prototyping being addressed when S&T is dealing with items which do not have patents filed? Under this scenario, who owns the intellectual property when the product is changed as it moves through the rapid prototyping process?

Answer. In all but a very few cases most rapid prototypes will be heavily focused on late stage development. These developments take forms such as modifications of existing equipment for new purposes, increases in effectiveness derived from new algorithms or software, changes in configuration to be smaller, lighter weight, or have decreased power consumption, for example. The S&T Directorate will use procurement contracts (or Other Transactions for Prototypes) for rapid prototyping developments. Both kinds of vehicles are legally binding and require negotiation of many aspects of the development. Generally the developer retains title in any invention or data developed with the Government receiving a license. When appropriate, the Government will require licenses for Federal, State, tribal, and local government use. Specific intellectual property treatment, ownership, licensing, usage and royalties are always addressed in these detailed negotiations and contractually secured on terms agreeable to the developer and the Government, subject to all applicable laws and regulations.

QUESTIONS SUBMITTED BY SENATOR PETE V. DOMENICI

CHEMICAL AND BIOLOGICAL DETECTION PROGRAM

Question. In 2003, the Department of Energy transferred to the Department of Homeland Security a highly successful Chemical and Biological Detection program, including \$78 million in annual funding. This was a capability supported in conjunction with the nuclear detection capabilities at our national laboratories.

How much progress has DHS made in implementing this capability and how much is budgeted for these activities?

Answer. The Department of Energy's Chemical and Biological National Security Program (CBNP) was a highly successful R&D program that served as the foundation of the S&T Directorate's Biological and Chemical Countermeasures Portfolio, which was eventually split into biological and chemical components. The program was continued, augmented, and expanded to cover a range of biological and chemical countermeasures R&D targeted at homeland security applications. Efforts initiated in the CBNP that have come to fruition include the Biological Aerosol Sentry and Information System (BASIS), a deployable capability for biological threat agent detection that is now part of the S&T Directorate's special event monitoring and National Security Special Events (NSSEs), and served as the foundation for the BioWatch program that was deployed to over 30 U.S. cities. The Program for Response Options and Technology Enhancement for Chemical Terrorism (PROTECT) currently is operational and owned and operated by the Washington Metropolitan Area Transit Administration and the associated program in the San Francisco International Airport has provided guidance on airport protection. A restoration demonstration effort is underway there and will be completed this year. PROTECT served as a basis for the operational NSSE chemical protection efforts in New York City and Boston in fiscal year 2004.

Another key CBNP chemical defense program is the MicroChem lab, an effort to develop a next-generation hand-held chemical detector with capability to detect a broader set of chemical hazards than currently available sensors and with fewer false positive responses. Under DHS funding in fiscal year 2003 and fiscal year 2004, the effort has now completed development through prototype phase and will be evaluated against other developing sensors under the S&T Directorate's Chemical Detection program test/evaluation phase. There is no current active funding for this project as it has already accomplished the target prototype needed for evaluation. After fair test and evaluation among all candidates, successful technologies will be selected for further support toward final engineering. The Local Integration of NARAC (National Atmospheric Release Advisory Center) with Cities (LINC) program will continue to operate in its current configuration in five U.S. cities through this fiscal year and will be subsumed into the Biological Warning and Incident Characterization System once it is mature. R&D efforts that transitioned with the program in March 2003 have been continued through this year and new ones, such as the foreign animal disease R&D efforts and NBACC-related activities have been initiated. In fiscal year 2004, Biological Countermeasures was funded at \$286.5 million and in fiscal year 2005, \$362.6 million.

Question. Under the DHS Chem-Bio Detection program many research and development contracts have been made through industry instead of the national labs. The laboratory program supported a long term capability, but has also been successful in commercializing handheld detection units.

How is DHS allocating funding between industry, universities and national laboratories?

Answer. The S&T Directorate collaborates with academia through the Centers of Excellence program and its associated Integrated Network of Centers, which is establishing a national network of affiliated universities. Additionally, the S&T Directorate has a sizeable number of interactions and programs with individual universities on specific research topics and needs.

The S&T Directorate solicits proposals from industry and uses a full range of contracting vehicles and its authority under the Homeland Security Act to engage businesses (large and small), federally funded research and development centers, universities, and other entities in development of advanced technologies for homeland security. The contracted research and development work now underway is the S&T Directorate's main form of collaboration with industry and academia. The S&T Directorate maximizes and leverages the existing capability base of the national laboratory complex. The Directorate engages all the national laboratories on a case-by-case basis, to tap into unique technical expertise that is critical to accomplishing portfolio objectives and goals. The Directorate also relies on national laboratory technical experts as needed throughout the RDT&E processes based on their years

of experience applying technologies and processes to field applications. This technical and practical expertise is used to accelerate spiral development of technologies for transitioning capabilities to operational end-users.

The S&T Directorate's CounterMeasures Test Beds (CMTB) program operates in close partnership with a number of Federal and national laboratories to execute its mission of testing and evaluating all threat countermeasures and systems. The following national laboratories participate in all CMTB Operational Testing and Evaluation (OT&E) efforts and enable deployments in response to heightened alert conditions as necessary. Multi-laboratory teams are encouraged to ensure objectivity and a healthy interchange of ideas.

The Office of Interoperability and Compatibility (OIC) is currently leveraging the resources of Eastern Kentucky University in developing effective test methodologies for equipment and to provide technical assistance to states and localities under the SAFECOM Program. At the same time, OIC has enlisted a consortium of well over one hundred universities and colleges to support the annual conference on Technologies for Public Safety in Critical Incident Response, jointly sponsored by DHS and the Department of Justice (DOJ).

Industry associations participate in SAFECOM Program activities, especially in standards development efforts. OIC has established a monthly vendor process which allows for constant communication and collaboration with our industry partners. Additionally, OIC/SAFECOM will be conducting an industry summit in late fall to allow for ever greater collaboration.

Question. Is this allocation sufficient to support long term research and development necessary to develop the next generation technology?

Answer. The S&T Directorate's strategic planning process uses a risk-based approach (including threats, vulnerabilities, and consequences) that identifies critical areas of need for RDT&E. The potential impact of RDT&E investments is evaluated and those efforts, both short- and long-term, that will have the greatest impact on reducing risk are pursued.

In the 2 years that this Department has been in existence, the S&T Directorate has focused its efforts on near-term development and deployment of technologies to improve our Nation's ability to detect and respond to potential terrorist acts. However, we recognize that a sustained effort to continually add to our knowledge base and our resource base is necessary for future developments. Thus, we have invested a portion of our resources, including our university programs, toward these objectives.

The S&T Directorate believes the distribution of funding between industry, universities, and national laboratories supports both long-term capabilities development as well as meeting near-term requirements for end-users. The current funding distribution may change based on national requirements and needs. We recognize the value of longer-term capability development to ensure that the Nation has the necessary knowledge for application development.

Question. Can you please provide me list of the grants the Department has made in allocating the Chem-Bio diction funding for this the past year?

Answer. The fiscal year 2004 grants that DHS has made in the area of chemical and biological detection and related areas are listed below:

Performer	Topic
U of Pitt	Surveillance—RODS Decision Enhancements for The BioWatch System
Johns Hopkins	Surveillance—ESSENCE Implementation of ESSENCE Bio-surveillance Systems
Arizona University	High Resolution DNA Signatures for biothreat
Multiple ¹	ECBC—Technical Advisory Group to HSARPA on Bioaerosol sensor testing and evaluation.
Multiple	Bioinformatics and Assay Development Program
Potomac Institute for Policy Studies	Bio-Alert
MIT/Lincoln Lab	Architecture Studies
Johns Hopkins University/APL	Real-Time Neutralization of Biological Weapons in Stadiums or Arenas
SAIC and Battelle	Demonstration & Verification of Chlorine Dioxide Decontamination Tech. in Large-Scale Test
National Center for Atmospheric Research	Urban Studies-Atmospheric Transport & Dispersion Calculations
MIT/Lincoln Laboratory	Water System Vulnerability Studies for Homeland Defense
Edgewood Chemical and Biological Command	Detection Systems for Biological and Chemical Countermeasures

Performer	Topic
MIT/Lincoln Laboratory	High-Collection-Efficiency Bio-aerosol Sampling
General Dynamics/CBRTA	DFU Filter Replacement Study
NYC DOHMH	Integration of Clinical Testing to Complement BioWatch and Disease Surveillance in NYC
Army Research Laboratory	Detection Systems for Biological and Chemical Countermeasures
Naval Research Laboratory	Detection Systems for Biological and Chemical Countermeasures
Battelle Laboratory	Detection Systems for Biological and Chemical Countermeasures
Ionian Corp	Detection Systems for Biological and Chemical Countermeasures
Johns Hopkins University/APL	Detection Systems for Biological and Chemical Countermeasures
Research Triangle Institute	Detection Systems for Biological and Chemical Countermeasures
Multiple	Detection Systems for Biological and Chemical Countermeasures
Agilent Corp	Detection Systems for Biological and Chemical Countermeasures
Smiths Detection/Pasadena	Detection Systems for Biological and Chemical Countermeasures
JHU/APL	Detection Systems for Biological and Chemical Countermeasures
Smiths Detection/Watford	Detection Systems for Biological and Chemical Countermeasures
Goodrich Corp	Detection Systems for Biological and Chemical Countermeasures
Sarnoff Corp	Detection Systems for Biological and Chemical Countermeasures
DOE National Laboratories	Enhanced Bioaerosol Detection System
Lawrence Livermore & Sandia Natl Laboratories	Bio-briefcase
Pacific Northwest Natl Lab	Botulinum detection system
Institute for Defense Analysis	IDA Chemical Hazard Analysis
Edgewood Chemical and Biological Command	Evaluation of Fielded Decontaminants Against Non-Traditional Agents
Institute for Defense Analysis	Infrastructure Sensitivity to Chemical Hazards
MITRE Corp	A JASON Study of Selected Topics for the Department of Homeland Security
Naval Research Laboratory	Detection Systems for Biological and Chemical Countermeasures use of CASPAR
Naval Research Laboratory	Autonomous Rapid Facility Chemical Agent Monitor
National Institute for Standards Technology	Solid State MEMs Microsensor Arrays to Detect Dangerous Chemicals
Goodrich Corp	TeraSpec
Sarnoff Corp	TeraSpec
Multiple	Detection Systems for Biological and Chemical Countermeasures
Monterey Institute	Survey/Evaluation of CBW Detectors
Multiple	Low Vapor Pressure Chemical Detectors
Los Alamos National Lab	Study of Receptor Development for Certain Chemical Threat Agents
Multiple	Novel Personnel Protection Equipment, BAA 04-13
Multiple	Bioinformatics and Assay Development Program
Lawrence Livermore Lab	Bioassays for Detection and Forensics
Los Alamos Nat'l Lab	Bioassays for Detection and Forensics
Sandia National Labs	Bioforensics
National Academy of Sciences	Assessing Vulnerabilities Related to the Nations Chemical Infrastructure
Scientific Applications International Corp	IBIS TIGER Biosensors
Space and Naval Warfare Command	Border Net (Chem/Bio Agent Support)
Naval Sea Systems Command	Chem/Bio Agent Support
Lawrence Livermore & other DOE Labs	High Throughput Diagnostics for Agricultural Applications
Palo Alto Sensor Technology Innovation	New System/Technologies to Detect Low Vapor Pressure Chemicals (e.g., TICs)

Performer	Topic
Seacoast Science, Inc	New System/Technologies to Detect Low Vapor Pressure Chemicals (e.g., TICs)
Intelligent Optical Systems, Inc	New System/Technologies to Detect Low Vapor Pressure Chemicals (e.g., TICs)
Synkera Technologies Inc	New System/Technologies to Detect Low Vapor Pressure Chemicals (e.g., TICs)
Cape Cod Research, Inc	New System/Technologies to Detect Low Vapor Pressure Chemicals (e.g., TICs)
CogniScent, Inc	New System/Technologies to Detect Low Vapor Pressure Chemicals (e.g., TICs)
Technispan LLC	New System/Technologies to Detect Low Vapor Pressure Chemicals (e.g., TICs)
Nanomat, Inc	New System/Technologies to Detect Low Vapor Pressure Chemicals (e.g., TICs)
Weld Star Technology, Inc	Chem-Bio Sensors Employing Novel Receptor Scaffolds
SomaLogic, Inc	Chem-Bio Sensors Employing Novel Receptor Scaffolds
Orthosystems, Inc	Chem-Bio Sensors Employing Novel Receptor Scaffolds
Nomadics, Inc	Chem-Bio Sensors Employing Novel Receptor Scaffolds
Peterson Ridge LLC (dba Fluence)	Chem-Bio Sensors Employing Novel Receptor Scaffolds
BioElectroSpec	Chem-Bio Sensors Employing Novel Receptor Scaffolds
Echo Technical	Chem-Bio Sensors Employing Novel Receptor Scaffolds
Operational Technologies Corporation	Chem-Bio Sensors Employing Novel Receptor Scaffolds
Accacia International LLC	Chem-Bio Sensors Employing Novel Receptor Scaffolds
BioTraces, Inc	Chem-Bio Sensors Employing Novel Receptor Scaffolds
CFD Research Corporation	Advanced Low Cost Aerosol Collectors for Surveillance Sensors and Personal Monitoring
Digital Flow Technologies, Inc	Advanced Low Cost Aerosol Collectors for Surveillance Sensors and Personal Monitoring
MesoSystems Technology Inc	Advanced Low Cost Aerosol Collectors for Surveillance Sensors and Personal Monitoring
Research International, Inc	Advanced Low Cost Aerosol Collectors for Surveillance Sensors and Personal Monitoring
InnovaTek, Inc	Advanced Low Cost Aerosol Collectors for Surveillance Sensors and Personal Monitoring
Enertech, Inc	Advanced Low Cost Aerosol Collectors for Surveillance Sensors and Personal Monitoring
Isotron Corporation	Wide-Area TIC Neutralization
Gumbs Associates, Inc	Wide-Area TIC Neutralization
Synergistic Advanced Technologies LLC	Wide-Area TIC Neutralization

¹ Multiple indicates contract awards to more than one recipient in a category from the funding provided for this solicitation. In most cases, there remain companies in negotiation for award.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

CHEMICAL DETECTORS

Question. In your oral testimony, you indicated that there are funds in the budget to deploy chemical sensors, yet the S&T budget document refers to “critical design review” of technologies, but nothing about deployment of sensors across the country. Based on your hearing comments, please provide specifics on the Department’s capabilities and deployment schedule for chemical monitoring.

Answer. The interface to which this question refers was a short discussion on the issue of PROTECT, a networked chemical detection system for enhanced response against chemical attacks on facilities, particularly transit systems. This system has been demonstrated in and transitioned to three subway systems (DC, Boston, and NYC). With successful demonstration, the program has transitioned away from DHS S&T Directorate and is available for installation in other transit systems via the fiscal year 2005 Transit Security Grants Program administered by the DHS Office of State and Local Government Coordination and Preparedness (SLGCP) Office for Domestic Preparedness. The reference to “funds in the budget” to support deployment was a reference to funds in the Department’s budget versus the S&T Directorate budget. The fiscal year 2005 Transit Security Grant Program includes \$108 million for rail transit security, targeted to specific urban areas for the prevention and detection of explosive devices and chemical, biological, radiological and nuclear agents. Expenditures to acquire the PROTECT system are permissible under this

program. The Science and Technology Directorate is assisting SLGCP with technical data package development and is prepared to offer technical assistance in the deployment of the system through this program.

BIOWATCH DETECTION

Question. Your budget proposes over \$100 million for bio-aerosol detection systems, better known as the “BioWatch” program. These sensors are located in over 30 major cities across the country.

Samples are taken manually 1 or 2 times daily and then tested at a lab to determine if a biological attack has occurred. If an attack really occurs, hundreds or thousands of people could be harmed before the lab results come in. What investments are you making to close the gap between the release of a biological agent and the time it takes to detect it?

Answer. We have a major program to develop the next generation of biodetection systems which we call Biological Autonomous Networked Detection (BAND). These systems will collect and analyze the sample on site, reporting out as often as every four hours, and will wirelessly transmit the data from any positives to the nearest Laboratory Response Network for confirmation and to initiate sample retrieval. The BAND system will simultaneously perform analyses for twenty or more agents, significantly more than the current BioWatch system, with sensitivities and false alarm rates equal to or better than the current BioWatch system. Because the sample collection and analyses is fully automated and done on site, the operational costs per “detection site” will be about one-fifth that of the current system or less. This greatly lower operational cost and the fully autonomous nature of the system will enable expansion of biological protection within existing BioWatch cities as well as to those cities and venues where it was previously not practical. We are currently on schedule for demonstrating a laboratory prototype of the BAND system in fiscal year 2006, developing engineering prototypes in fiscal year 2007, piloting them in a BioWatch city or cities in fiscal year 2008 and deploying them throughout the existing BioWatch cities in fiscal year 2009/fiscal year 2010.

Question. My understanding is that certain prototypes are being tested, but they won’t be deployable until 2009. Is this a matter of resources? What is needed to accelerate deployment of this system?

Answer. Your understanding is correct, as per the discussion previously, we are not scheduled to begin deployment of the BAND System to BioWatch cities until fiscal year 2009. This is in part technology limited and in part resource limited. If the available R&D funding for this system was increased from its projected fiscal year 2006-fiscal year 2007 levels of about \$25 million per year to \$60 million per year, we would be able to significantly reduce the technical risk in developing the system and speed its deployment by 6 to 12 months. This would be accomplished by pursuing more technology options more aggressively. The competition engendered by being able to carry two or three systems all the way through development would further assist in meeting the challenging technical performance and cost goals. In addition, manufacturing of these detection systems to enable wide scale deployment would benefit from creating a guaranteed market for 1,000–2,000 of these advanced detection systems, at a total estimated cost of \$50–100 million. A significant portion of this additional required funding would need to be available in fiscal year 2007 so as to enable deployment to start in fiscal year 2008.

BIOWATCH RESPONSE

Question. The budget notes as an accomplishment that the “BioWatch” detection systems, which are deployed in over 30 major U.S. cities, conducted over a million assays with no false alarms.

While that is certainly an indication that the system works, an official with the National Association of County and City Health Officials recently complained that not enough focus has been placed on what happens if the “alarm bell” rings.

If an incident of national significance is detected, are State and local governments prepared to respond?

Answer. The S&T Directorate, in collaboration with CDC, EPA, and DoJ, has prepared BioWatch Preparedness and Response Guidance (interim draft guidance) and distributed it to the BioWatch cities. This draft guidance is intended to assist the cities in their development of an incident characterization plan following a positive BioWatch signal. While some cities have developed a comprehensive plan, other cities’ plans are under development. The S&T Directorate continues to offer assistance to each city and currently has an effort underway to address the concerns of the local public health epidemiology community.

Question. What management practices are in place at the Federal level to ensure that State and local governments are prepared to respond to an incident of national significance? I would like to hear both Assistant Secretary Albright and Assistant Secretary Simonson respond to the question.

Answer. Contingency planning with State and local governments is an important and ongoing process. A key component of the National Incident Management System (NIMS) compliance for State and local jurisdictions is the requirement for updating and revising emergency operations plans. With the release of the National Response Plan (NRP), State and local jurisdictions are encouraged to align their plans with the NRP. State, local, and tribal organizations must adopt NIMS by fiscal year 2007 as a condition of receiving Federal preparedness assistance. State and local governments can use DHS grant funds to implement the NIMS.

The NRP and the NIMS provide the template, policies, and protocols for integrating all jurisdictions and the private sector as key components of the Nation's response to domestic incidents. The NRP and the NIMS are built on the principle that most incidents start, end, and are managed at the local level. The NIMS stresses the concepts of mutual aid, communications, resource typing, and preparedness, in addition to the command and control elements, including the Incident Command System and Multi-agency Coordination. The NRP details how those varying levels of responsibility work together during Incidents of National Significance (a new concept developed in the NRP to cover every significant incident), which require the Department of Homeland Security to take on the overall coordination role for Federal involvement in domestic incident management. The NRP provides the multi-agency coordination structures to support incident commanders and local entities at the scene. It also provides coordination structures for integrating with the private sector. One of the key concepts of the NRP is that preventing, preparing for, responding to, and recovering from Incidents of National Significance require the collective capabilities of all involved jurisdictions.

DOMESTIC NUCLEAR DETECTION OFFICE (DNDO)

Question. The DHS budget proposes \$227 million for a new office called the Domestic Nuclear Detection Office (DNDO). I share the Department's concerns that this threat warrants a coordinated effort at the Federal level to address it. However, the criticism following 9/11 that led to the creation of the Department of Homeland Security was that there were too many stovepiped agencies across the Federal Government dealing with homeland security that didn't know what the other was doing.

In your opinion, is enough being done by the Secretary's office to ensure that the DNDO will not become a stovepiped organization?

Answer. One of the principal motivators in the formation of the DNDO was to remove this type of stovepiping within the Department, and across the Federal Government, with regards to the prevention of nuclear terrorist attack. DNDO is charged with integrating and coordinating all planning and implementation efforts across the other Federal departments and agencies, and within DHS, to ensure that individual efforts are effectively and efficiently contributing to a global strategy to defend against the terrorist use of a nuclear weapon on our Nation.

The DNDO serves as a unique entity within the Department to consolidate all nuclear-detection related activities, allowing for the development of an integrated office that will be responsible not only for research and development, but also for developing a global nuclear detection architecture and developing and implementing a domestic detection system, to include acquisition programs for detection assets and operational support functions. This integration, as well as coordination with nuclear detection programs in other departments, will allow for the development of a single global nuclear detection architecture to protect the Nation from attempts to import or transport a nuclear device or fissile or radiological material intended for illicit use.

Question. For instance, the proposal for DNDO calls for its own office of assessments and evaluations. It has its own policy planning office. It has an R&D office as well as a systems development and acquisitions office. These are also functions currently performed by the Science and Technology Directorate and the Information Analysis and Infrastructure Protection (IAIP) Office.

Is the Secretary proposing to set up a separate intelligence unit and a separate R&D arm just for this office? How does this affect ongoing efforts within the Science & Technology Directorate?

Answer. With regards to intelligence collection and analysis, IAIP will continue to be the conduit for DNDO coordination with the larger intelligence community. Additionally, DNDO will leverage the current capabilities within IAIP for intelligence analysis. The DNDO's Joint Center for Global Connectivity (JCGC) will be

closely integrated with the Homeland Security Operations Center (HSOC) to ensure that effective information flows in both directions. DNDO expects to receive all relevant intelligence information from IAIP in a timely manner and will provide additional technical analysis capabilities on a 24/7 basis as part of the JCGC. The JCGC, by receiving information and finished intelligence from sources across the Federal, State and local levels, will be able to additionally provide continuous analysis of real-time data streams and the capability to provide continual national situational awareness.

With regards to research and development, the DNDO will continue to closely interface with the S&T Directorate on joint projects, as appropriate, for the development of technologies that may provide countermeasures against multiple threat types. The separation of the DNDO nuclear detection research, development, test, and evaluation (RDT&E) from the RDT&E conducted within the S&T Directorate will be conducted so as to not have any detrimental affect on potential collaborative efforts that would be gained through the S&T consolidation effort. The goal is to make sure that this Nation maintains a preeminent research and development program to address the technical challenges in radiation detection science and technology, while at the same time capitalizing on the benefits of integrating this program with larger acquisition and operational support efforts.

Again, the intent of the DNDO is to provide an integration of efforts across the Department, as well as the rest of the Federal Government, rather than another disconnected layer of bureaucracy. For exactly this reason, the DNDO will be a jointly-staffed office with detailed employees from other DHS components, as well as other departments, to provide strong linkages and a mutual continual awareness between the DNDO and the parent organizations. The DNDO will not operate in a vacuum separate from the rest of the Department, but will instead operate in a fully-informed environment, cognizant of all relevant Department efforts, including the intelligence and R&D efforts mentioned.

RADIOLOGICAL/NUCLEAR COUNTERMEASURES TEST AND EVALUATION COMPLEX

Question. The budget request includes \$9 million for a Radiological/Nuclear Countermeasures Test and Evaluation Complex. The budget indicates that \$13 million was appropriated prior to fiscal year 2004 and \$11 million was appropriated in fiscal year 2004. When was the \$13 million appropriated? Under which public law or laws was the funding included?

Answer. At the stand up of DHS and S&T, funds were transferred from other departments to provide an initial funding base. In particular, funds for the Radiological/Nuclear Countermeasures Portfolio were originally transferred from the Defense Threat Reduction Agency (DTRA) and the Department of Energy (DOE). The first \$13 million that was put on contract for the Radiological/Nuclear Countermeasures Test and Evaluation Complex was part of the fiscal year 2003 funding. Funding was included under a reprogramming of funds request, and Radiological/Nuclear Countermeasures received \$65 million which was approved by the House and Senate Appropriation Committees. The reprogramming did not specifically state that the S&T Directorate was using funds for the Radiological/Nuclear Countermeasures Test and Evaluation Complex; however, the S&T Directorate used \$13 million for this effort.

Question. The project schedule indicates that the construction phase is scheduled to begin on May 1, 2005. Is the project on schedule? If not, what impact does that have on the June 2006 completion goal?

Answer. The Radiological/Nuclear Countermeasures Test and Evaluation Complex (CTEC) construction project is currently on schedule to meet the expected June 2006 completion goal.

UNIVERSITY CENTERS OF EXCELLENCE

Question. Under Secretary McQueary testified last year that in addition to the risk analysis and agro-terrorism centers, two more solicitations would occur in fiscal year 2004 and if the budget request for fiscal year 2005 was maintained at fiscal year 2004 levels, an additional five Centers could be selected for a total of nine centers. In fiscal year 2005, the fourth center was named, but the fiscal year 2006 budget request indicated that a fifth is being evaluated and two additional Centers are anticipated in fiscal year 2005 and fiscal year 2006 for a total of seven.

Why has the number of Centers planned by the Department changed?

Answer. The Science and Technology Directorate plans on supporting seven Centers of Excellence and two Cooperative Centers in fiscal year 2005 and fiscal year 2006, for a total of 9 Centers supported. The Broad Agency Announcement (BAA) for the fifth Center had proposals due at the end of April 2005. The BAAs for the

sixth and seventh Centers are in development. The DHS–EPA Cooperative Center on Microbial Risk Assessment has been funded for fiscal year 2005, with the recipient to be announced shortly, and the second Cooperative Center is in development.

Question. What areas of mission relevant research are not being considered because of the reduction from nine to seven Centers?

Answer. We are planning on supporting a total of seven merit-based Centers of Excellence through fiscal year 2006; topics for the sixth and seventh Centers are being vetted within the Department for approval prior to announcement. We anticipate releasing Broad Agency Announcements requesting proposals for merit-based consideration in fiscal year 2005. In addition to the seven Centers of Excellence, the S&T Directorate will support two Cooperative Centers in fiscal year 2005 and fiscal year 2006. We believe that these seven centers will address all current mission relevant research.

NATIONAL BIO AND AGRODEFENSE FACILITY

Question. The budget proposes \$23 million for the National Bio and Agrodefense Facility, which according to the project schedule, will cost over \$450 million to complete. According to the project schedule, work to be performed in fiscal year 2006 will cost only \$3 million. Why is \$23 million needed in fiscal year 2006?

Answer. The \$3 million referenced will be spent in fiscal year 2005 to initiate a conceptual design study to define the scope and size of the new facility. The \$23 million fiscal year 2006 request will complete the conceptual design, the NEPA process including site selection, and initiate the detailed engineering design of the chosen concept.

Question. Has a site been selected for this facility?

Answer. No site has been chosen at this point in the NBAF development process. An interagency conceptual study has been undertaken by DHS, USDA and DHHS to explore three major options for NBAF each with increasing capability. The study will determine the programmatic requirements, scope and size of the facility taking into account cost, schedule, technical requirements and public support. This process will provide the basis for more detailed engineering design, NEPA evaluation and the site selection.

Question. Is an authorization required for this facility?

Answer. It is our understanding that under current legislation, an authorization for this facility is not required. However, should Congress decide to require one, we would of course comply.

CHEMICAL COUNTERMEASURES

Question. The budget request includes an additional \$49 million for the chemical countermeasures portfolio. The request indicates that \$24 million supports construction of a new facility for countermeasures testing. The object class for this funding is listed under “Purchase of goods/services from Gov’t accounts.” Will this facility be leased or owned by DHS? Where will it be located? Why isn’t this facility listed under the Capital Investment and Construction Initiative Listing?

Answer. The budget request identifies a \$24 million increase from fiscal year 2005 to fiscal year 2006 in “Purchases from Government Accounts.” This funding includes support of two activities: construction of a singular facility to conduct tests of countermeasures against non-traditional agents and the enhancement of threat characterization, analysis, and assessment, including initiation of toxicology and environmental fate studies of non-traditional agents. For clarity, of this \$24 million, only \$11 million are apportioned to support the construction of the countermeasure test facility. The test facility will be constructed at Edgewood Area, Aberdeen Proving Ground, MD, and will be a Department of Defense (DOD) facility. The DHS funds will be utilized to conduct a series of critical studies to provide much of the foundation data to support design and safe use of the facility, which is required for countermeasures assessment both by DOD and DHS. A Memorandum of Agreement (MOA) between DHS and DOD is in development to outline agreement on the requirements, shared expenses, and use terms of the facility. Since the DHS funding is provided to another government agency (Army) to support a facility of that agency, the object class is identified as “Purchase of goods/services from Gov’t accounts” versus Capital Investment.

QUESTIONS SUBMITTED TO STEWART SIMONSON

QUESTIONS SUBMITTED BY SENATOR JUDD GREGG

HEALTH AND HUMAN SERVICES AND BIOSHIELD

Question. Please provide a list of administrative, regulatory or legislative proposals needed to invigorate scientific research relevant to the development of needed countermeasures and products for natural pandemics and epidemics.

Answer. There is a very active scientific effort underway to develop needed medical countermeasures and products for natural pandemics and epidemics. Much of this effort is supported by the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH). For example, NIAID is using Project BioShield authorities to expedite the development of assays to be used for the high-throughput screening of candidate therapeutics for influenza. Influenza is currently considered a Category C biological threat agent by the Centers for Disease Control and Prevention (CDC). The influenza antiviral therapeutics currently available are limited and the rapid emergence of antiviral resistance with widespread use of these therapeutic agents is a potential concern.

Finding new options for treating influenza are a high priority for the Nation, as the Department of Health and Human Services (HHS) draft Pandemic Influenza Response and Preparedness Plan articulates.¹ Grants will support research projects focused on the development of needed diagnostic assays and screening techniques to permit speedier identification of compounds with the potential to be effective against a broad spectrum of influenza strains, including newly emergent influenza strains.

In an effort to address the pressing need for additional reliable influenza medical countermeasures, the RFP, NOT-AI-05-045, was released on June 17, 2005, and the receipt date for applications is September 1, 2005. Grants are expected to be awarded in fiscal year 2006. The Department of Health and Human Services will implement appropriate administrative and regulatory actions to facilitate this research activity.

Question. Many innovators complain that they cannot get access to your office for an evaluation of their new product ideas. Please describe your process for screening new products and new ideas.

Answer. HHS/OPHEP/ORDC has hosted numerous meetings with external stakeholders. These meetings provide a forum for innovators to give presentations on their products and to describe their capabilities to ORDC. We have had over thirty contacts from industry since January 2005. ORDC hosts a Project BioShield website <http://www.hhs.gov/ophep/bioshield/> that provides frequently updated information on ongoing and planned acquisitions under Project BioShield. The website also has an email link that allows users to send a message directly to ORDC.

New products or ideas are screened depending upon factors including the credibility and potential impact of the threat it proposes to treat and stage of development in the research and development pipeline.

If the product is in the early stages of development, companies and researchers need to seek NIH funding through grants, contracts, partnerships or the Small Business Innovation Research (SBIR) program. The SBIR is a set-aside program (2.5 percent of an agency's extramural budget) for domestic small business concerns to engage in Research/Research and Development (R/R&D) that has the potential for commercialization. The SBIR program was established under the Small Business Innovation Development Act of 1982 (Public Law 97-219), reauthorized until September 30, 2000 by the Small Business Research and Development Enhancement Act (Public Law 102-564), and reauthorized again until September 30, 2008 by the Small Business Reauthorization Act of 2000 (Public Law 106-554).

If an innovator's product is sufficiently advanced in development, then the Office of Research and Development Coordination (ORDC) in the Office of Public Health Emergency Preparedness (OPHEP) at HHS meets with developers to provide guidance concerning the Project BioShield acquisition process. This process includes a Material Threat Determination (MTD) and a Material Threat Assessment (MTA) by the Department of Homeland Security. A MTD is issued by the Secretary of Homeland Security if it is determined that the specific CBRN threat presents a material threat against the United States population sufficient to affect national security. The MTAs provide information about the extent of the threat and the vulnerabilities and are used to inform U.S. Government (USG) medical countermeasure requirements. The USG requirements and recommendations for acquisitions are estab-

¹A copy of the Pandemic Influenza Response and Preparedness Plan can be found at <http://www.hhs.gov/nvpo/pandemicplan/>.

lished by the interagency Weapons of Mass Destruction Medical Countermeasures Subcommittee of the National Science and Technology Council. The Project BioShield acquisition process also includes a joint recommendation for acquisition by the Secretaries of HHS and the Department of Homeland Security (DHS), and an approval for the acquisition by the White House.

Question. Several recommendations have been made to formalize access for screening new ideas for products, including convening a working group of outside experts, contracting with the private sector, and web-based submissions. Please provide a list of proposals on how you would recommend formalizing access for screening new ideas for products.

Answer. The NIH peer review process works very well in providing an initial evaluation of new ideas. Both NIH and ORDC staff frequently meet with developers using a "Technology Watch" process aimed at ensuring that USG medical countermeasure research and development experts are informed about promising, innovative products. As part of the Technology Watch process, ORDC issues periodic Requests for Information (RFI) to determine the level of maturity of the medical product targeting countermeasures of interest in the developmental pipeline. Finally, ORDC has a regularly updated website and an email address that allows for web-based submission of questions.

Question. You made mention in your testimony of a number of Project BioShield related procurement-related activities that include Pre-solicitation notices, Requests for Information, and Requests for Proposals. Can you provide additional information about these activities?

Answer. A copy of the current OPHEP/ORDC BioShield procurement activities is attached for your convenience. Furthermore, information on these procurement-related activities is available on our website at <http://www.hhs.gov/ophep/bioshield/PBPrctPrjct.htm>. This information is also available at <http://www.fedbizopps.gov>.

Question. As described in the Project BioShield Act of 2004, there are a number of determinations that must be made to support the acquisition of a security countermeasure using the special reserve fund appropriated in the fiscal year 2004 DHS Appropriations bill. Can you please describe the role of HHS and the process used to make these determinations, specifically that the determinations that countermeasures are necessary and are appropriate for inclusion in the Strategic National Stockpile and the joint recommendation for procurement?

Answer. The Secretary of Homeland Security is charged with making material threat determinations (MTDs). Upon receipt of the DHS MTD the Secretary of Health and Human Services determines if medical countermeasures are necessary to protect the public health. If countermeasures are needed, the Secretary of Health and Human Services must determine the number of doses required, if production and delivery of a approved or licensed product is feasible with 8 years of contract award, and an evaluation of whether there is a commercial market for the product(s) other than as a security countermeasure. Finally, the Secretaries of Homeland Security and Health and Human Services jointly recommend to the President that the Special Reserve Fund be made available for the recommended countermeasure procurement. The approval for the procurement is made by the President (now delegated to the Office of Management and Budget.)

Question. In your testimony, you've provided us with a summary of the many accomplishments of your office since the enactment of the Project BioShield Act of 2004, also known as BioShield I. As you know, I am sponsoring the so-called "BioShield II" bill to further expand on the efforts of BioShield I including indemnification for product manufacturers and liability protection for health workers and patent protections. Do you feel that the new bill appropriately addresses remaining obstacles to medical countermeasure development against weapons of mass destruction?

Answer. The Department of Health and Human Services is committed to the development and acquisition of priority security countermeasures and will work with Congress and stakeholders to address obstacles to the effective implementation of Project BioShield.

Question. It is often stated that it takes 10 years to develop medical products. What makes HHS believe that it can accomplish this in less time?

Answer. It generally takes 10 years to develop a medical product from inception to full FDA licensure or approval by proceeding along a conservative, serial regulatory path. Project BioShield allows for the procurement and delivery of medical countermeasures to the Strategic National Stockpile (SNS) prior to full FDA approval or licensure and their use under the Emergency Use Authorization provision of the Project BioShield Act of 2004.

In order to acquire these critical medical countermeasures as quickly as possible, Project BioShield encourages a parallel development process in which the developer

concurrently is finalizing a formulation while conducting animal or human clinical trials and scaling up and validating a current Good Manufacturing Practices (cGMP) production process. This approach has some increased risk of failure; however, the process is very closely monitored by relevant HHS staff.

Question. There are many different biological threats. Can you explain why so much of the BioShield activities are focused on anthrax?

Answer. 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—namely, smallpox and anthrax. An attack involving the aerosol dissemination of anthrax spores, particularly in an urban setting, was considered by public health experts to have the potential for catastrophic effects. The potential for large-scale population exposure following aerosol release of anthrax spores, the threat demonstrated by the anthrax letters, the persistence of anthrax spores in the environment 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 posed a material threat against the United States population sufficient to affect national security. And, because untreated inhalation anthrax is usually fatal, the Secretary of HHS determined that additional countermeasures were necessary to protect the public health.

Question. I understand that the NIAID rPA anthrax vaccine advanced development contracts with VaxGen and Avecia are still ongoing. Why did you make the decision to commit to the acquisition of 75 million doses of this product before those NIAID contracts were completed?

Answer. The material threat assessment provided by the DHS supported the requirement to acquire sufficient vaccine to protect 25 million persons (75 million doses). The development work performed under the NIAID contracts had proceeded to a level such that HHS had confidence that a final rPA vaccine product was achievable and licensable within 8 years of a contract award.

Question. In your statement you testified that the stockpile already contains sufficient smallpox vaccine to protect every American. Can you please explain why it is necessary to purchase any additional vaccine?

Answer. The smallpox vaccines currently in the Strategic National Stockpile are live virus vaccines derived from a virus called vaccinia. These replicating vaccines are contraindicated in some segments of the population, particularly those with weakened immune systems. Therefore, there is a need to develop a vaccine which will be more appropriate for use in these persons. An attenuated smallpox vaccine with limited replication in humans, such as the Modified Vaccinia Ankara (MVA) vaccine would be appropriate for use in such individuals.

Question. Former Secretary Tommy Thompson stated that food-borne bioterrorism was one of his greatest concerns. Certainly, deliberate contamination of food with botulism could result in a large number of casualties. Would you please further describe your planned procurement for botulism countermeasures?

Answer. Botulism toxin was determined to be a material threat by the Department of Homeland Security on June 9, 2004. Presidential approval for the acquisition of botulinum antitoxin using special reserve funds under Project BioShield was granted on August 17, 2004. HHS released a presolicitation notice on September 4, 2004 indicating its intention to acquire 200,000 doses of heptavalent equine botulinum antitoxin through a sole-source contract. The Request for Proposal was issued to the prospective offeror on July 14, 2005. Horses are currently being immunized to generate the plasma necessary to produce the botulinum antitoxin. A contract award is anticipated in the 3rd quarter of 2005.

Question. There is concern that we may not be responding adequately to the threat of nuclear or radiological terrorism. What is HHS doing to protect the public from illness after exposure to radiation? Particularly, would you provide more information regarding procurement of medical countermeasures against this threat?

Answer. The Strategic National Stockpile (SNS) currently contains medical countermeasures to treat the spectrum of potentially life-threatening effects of radiation exposures. These include drugs to block entry or to remove radioactive particles from the body as well as to treat a major effect of penetrating radiation known as acute radiation syndrome (ARS). Specifically, the SNS currently contains the following:

- Potassium Iodide and a pediatric liquid formulation of potassium iodide. Potassium Iodide is used to block the uptake of radioactive iodine that could be released following a nuclear detonation or a nuclear power plant accident;
- Calcium and zinc diethylenetriaminepentaacetate (Ca/Zn DTPA). The DTPAs are used to remove radioactive transuranic particles such as plutonium and americium from the body following the use of a dirty bomb or similar device;

- Prussian Blue. This drug is used to remove radioactive cesium from the body after a nuclear detonation or use of a dirty bomb or similar device; and
- Filgrastim. This drug is used to treat life-threatening suppression of infection-fighting white blood cells after whole-body exposure to high doses of penetrating radiation—a form of acute radiation syndrome.

Additionally, a Request for Information (RFI) for countermeasures for an acute radiation syndrome was published in October 2004. Responses to that RFI have been evaluated and a Request for Proposals (RFP) is being developed. We are in the process of determining what the specific requirements and acquisition options are so that we can proceed with the acquisition process. HHS is eager to enlarge the holdings of the Strategic National Stockpile (SNS) with respect to radiological/nuclear countermeasures. Accordingly, the quality of the proposals and the stage of product development will determine how HHS acts on the results of the RFI and RFP.

Question. Nuclear or radiological terrorism has been cited as one of the greatest threats this country faces with regard to homeland security. Several promising bone marrow protection drugs could be available in the near term to protect against this threat. When do you expect to procure such drugs for the National Strategic Stockpile?

Answer. The Strategic National Stockpile (SNS) currently contains medical countermeasures to treat the spectrum of potentially life-threatening effects of radiation exposures. These include drugs to block entry or to remove radioactive particles from the body as well as to treat a major effect of penetrating radiation known as acute radiation syndrome (ARS). Specifically, the SNS currently contains the following:

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Question. It is estimated that one quarter of the U.S. population cannot take the current smallpox vaccine that we have in our stockpile. NIH has been hard at work on the development of a safe MVA-based smallpox vaccine for that portion of the population that is contraindicated. Please describe where we are in the development of the vaccine and when you plan to issue your RFP for the purchase of the MVA vaccine?

Answer. HHS released a presolicitation notice in anticipation of releasing an RFP by the end of the summer to manufacture and deliver to the SNS up to 20 million doses of the attenuated smallpox vaccine, modified vaccinia Ankara (MVA).

Question. If the recent anthrax incident at the DC postal and DOD facilities had turned out to be a real anthrax attack requiring the use of both antibiotics and the vaccine for those exposed and vaccinations for first responders, how many doses of the FDA licensed anthrax vaccine that are currently in Strategic National Stockpile managed by HHS would be used?

Answer. The SNS currently contains sufficient antibiotics to treat about 180,000 symptomatic anthrax patients and to provide for a 60 day prophylaxis of more than 25 million persons. This stockpile of antibiotics is growing monthly. The USG is currently negotiating for the acquisition of specific anthrax antitoxins to treat symptomatic anthrax patients. In addition to the use of antibiotics, HHS would deploy as much anthrax vaccine from the SNS as was required to respond to the event and to protect the population. The vaccine and the prophylactic antibiotics would likely be used concurrently. There currently is no FDA-licensed vaccine for post-exposure use following anthrax exposure. In May 2005, HHS awarded a contract to BioPort Corporation for the manufacture and delivery of 5 million doses of licensed anthrax vaccine adsorbed (AVA) to the stockpile. There are at present over 1 million doses

of AVA available for the pre-exposure immunization of at-risk groups such as certain laboratory workers and first responders who would be involved with the response to an attack.

Question. For the past 1½ years, HHS has been in the process of acquiring 5 million doses of the FDA licensed vaccine for the CDC stockpile while the agency has committed nearly \$1 billion under government contracts to acquire 75 million doses of an early-stage anthrax vaccine from a single manufacturer. Why has it taken so long after the 2001 anthrax attacks for HHS to acquire any additional doses of the current FDA-licensed vaccine for the stockpile?

Answer. HHS acquired a small amount of the AVA vaccine for civilian use (21,400 doses) following the anthrax events of the fall of 2001. Thereafter HHS initiated a process to acquire licensed AVA anthrax vaccine from DOD. Various administrative and legal issues caused delays in this acquisition. Once Project BioShield was enacted, HHS determined that initiating a BioShield acquisition contract directly with the AVA vaccine manufacturer, BioPort Corporation, would be the best mechanism to acquire this vaccine. HHS awarded the contract on May 5, 2005 for 5 million doses and the company completed the initial delivery of over 1 million doses soon after contract award. We would be happy to provide timelines if helpful.

Question. Please explain the decision to eliminate from the President's fiscal year 2006 budget the funding for the CDC dose reduction studies to allow FDA approval for fewer doses of the FDA-licensed anthrax vaccine given that FDA approval of the new anthrax vaccine is still years away? If the number of doses for pre-exposure vaccinations against anthrax could be reduced in half, wouldn't that also result in significant net cost savings for the Federal Government and double the number of 1st responders and other who could be vaccinated and protected before an anthrax occurs?

Answer. At the inception of this program in 1999, HHS anticipated it would take 5 years to complete the necessary studies. It is important to note that this type of study is normally undertaken by the manufacturer in the interest of improving product utilization. To date the program has generated sufficient data to allow BioPort to submit a request to the FDA to change the route of administration from subcutaneous to intramuscular and to decrease the six dose priming series from six to five doses.

CDC has now completed the anthrax vaccine clinical trial interim safety analysis, has presented the results to key stakeholders and has submitted the final report detailing all findings from the safety analysis to the Food and Drug Administration (FDA). Accordingly, the HHS bioterrorism preparedness budget placed the highest priority on expanding mass-casualty treatment capacity and procuring additional pharmaceuticals for the Strategic National Stockpile.

Question. Would HHS provide assurance that the human clinical, animal and CDC laboratory dose reduction studies for the currently licensed anthrax vaccine will be continued and completed given the potential rapid deployment and cost saving benefits for first responders, lab workers and others from fewer doses?

Answer. Yes. As indicated above, HHS anticipated it would take 5 years to complete the necessary studies. CDC has now completed the anthrax vaccine clinical trial interim safety analysis. The program has generated sufficient data to allow BioPort to submit a request to the FDA to change the route of administration from subcutaneous to intramuscular and to decrease the six dose priming series from six to five doses.

Question. One of the chief purposes of the Project BioShield Act of 2004 (the "Act") was to provide contracting flexibility to enable the government to more rapidly acquire countermeasures against biological, chemical, radiological or nuclear agents that might be used in terrorist attacks. To what extent has HHS used simplified acquisition procedures in the following Bioshield procurements:

- Solicitation No. DHHS-ORDC-05-01 for Pediatric Formulation of Potassium Iodide;
- Solicitation No. RFP-DHHS-ORDC-04-01 for Licensed Anthrax Recombinant Protective Antigen (rPA) Vaccine for the Strategic National Stockpile;
- Solicitation No. 2004-N-01385 for Therapeutic Products for Treatment of Inhalational Anthrax Disease for the Strategic National Stockpile (the "Anthrax Therapeutics Solicitation"); and
- Solicitation No. 2005-B-01696 for Anthrax Vaccine Adsorbed (BioThrax™).

Answer. Simplified acquisition procedures were not used for these procurements. Some of these products could be obtained only through a sole source, therefore a Justification for Other than Full and Open Competition (JOFOC) was used. Since there was more than one potential source, other products were acquired under full and open competitive procedures as governed by the FAR.

Question. To what extent does HHS plan to use simplified acquisition procedures in the following upcoming procurements:

- Solicitation No. 2004–N–01183 for 200,000 Doses of Heptavalent Botulinum Immune Globulin Reference-Number;
- Request for Information (RFI) ORDC–05–01 for Therapeutics to Treat Neutropenia and Thrombocytopenia Associated with the Acute Radiation Syndrome (ARS); and
- RFI No. ORDC–05–03 for Development and Manufacture of Plasma Derived Human Butyryl-Cholinesterase as a Prophylactice/Therapeutic for Exposure to Nerve Agents?

Answer. For each proposed BioShield procurement, HHS reviews the contract options available and applies the most appropriate authorities to facilitate a fair, technically sound, and rapid acquisition. For example, HHS has selected to use a sole-source acquisition strategy for the procurement of the 200,000 doses of equine heptavalent botulinum immune globulin cited above.

Question. Certain discretionary procurement laws and regulations, such as the requirement for submission of certified cost and pricing data under the Truth in Negotiations Act, place tremendous burdens on commercial entities that do not regularly do business with the Federal Government. Given that the express goal and clear intent of the Act is to encourage greater participation by commercial entities in supplying the Nation with needed countermeasures, to what extent has HHS, in its discretion, required compliance with such laws and regulations (and specifically, the submission of certified cost and pricing data) notwithstanding the existing regulatory exemptions for commercial entities to avoid such unnecessary burdens and the clear intent of the Act to reduce the regulatory burden on procurements conducted under the Act as much as possible?

Answer. In order to obtain the best value to the government and to negotiate a fair price it is essential for the USG to have certified cost and price data unless the contract can be awarded based on adequate price competition. Cost or pricing data is especially needed in regard to those entities that may not as yet have a commercially marketed product or may be using a unique, innovative production process.

Question. Please provide an explanation for any failure in Project Bioshield procurements, both completed or on-going, to use the simplified acquisition authorities granted to HHS under Sections 319F–1(b)(1) and 319F–2(c)(7)(C)(iii) of the Public Health Service Act (“PHSA”) as intended by the Act.

Answer. Simplified acquisition procedures have not been used for Project Bioshield procurements to date. Some products could only be obtained through a sole source, therefore a Justification for Other than Full and Open Competition (JOFOC) was used. Since there was more than one potential source, other products were acquired under full and open competitive procedures as governed by the FAR.

Question. Another chief purpose of the Act was to create incentives for manufacturers to develop countermeasures. The main incentive included in the Act was a grant of authority to the Secretary of HHS to issue a call for development of countermeasures and to include in that call a commitment that, upon the first development of a countermeasure that meets the criteria of the Act, the Secretaries of HHS and the Department of Homeland Security (“DHS”) will recommend procurement of the countermeasure to the President. This provision was intended to promote the development of a biodefense industry by informing the markets that there is some certainty that there will be a government market for the product. The Act also requires that calls for countermeasures include: an estimated quantity of purchase, necessary measures of minimum safety and effectiveness; estimated price for dose and other information necessary to encourage and facilitate research, development and manufacture of the countermeasure. Sec. 319F–2(c)(4) of the PHSA.

—What calls for countermeasures have been issued by HHS? Please provide copies of these announcements.

—BioShield requires HHS to provide a single estimate of the quantity of countermeasures needed by the government. Has this process been included in every Bioshield procurement to date and if not, why not?

Answer. The publication of a Request for Information (RFI) signals the USG interest in a particular countermeasure. The publication of the Request For Proposal (RFP) is essentially a “call for countermeasures” and indicates, by setting specific requirements and expectations, the government’s commitment to an acquisition, including that funds are available to proceed with the procurement. The publication of the RFP and the statement of the specific requirements in the RFP establish that there is a certainty for a government market for the product.

It is expected that most RFPs for BioShield acquisitions will provide a single baseline required quantity for procurement. Some RFPs also may provide options to acquire additional product beyond an initial requirement, based on ongoing threat as-

assessments and ongoing requirements reviews. The RFP for “Therapeutic Products for the Treatment of Inhalation Anthrax Disease” (RFP-2004-N-01385) indicated a range of treatments required (10,000 to 200,000 treatments). This was structured to allow for the flexibility to acquire several products of differing therapeutic classes to meet the stockpile goal.

Question. The Act envisions the use of animal models to permit expedited consideration by the FDA of request for approval for countermeasures. What steps have been taken to assure that the FDA has developed and implemented new procedures under the animal rule and related emergency-like powers under BioShield to signal its commitment to not slow down industries work to develop more countermeasures as quickly as possible?

Answer. The FDA has been actively engaged in the review of animal models and the applicability of the “Animal Efficacy Rule” (Federal Register 67: 37988–37998, 2002) to facilitate the acquisition of critically needed medical countermeasures. Meetings with developers and the review of submissions related to bioterrorism countermeasures are given a priority status. The FDA staff work closely with NIH and DOD staff in the early phases of protocol designs and test methodology development. The FDA has a major role in the Product Development Tools (PDT) Working Group of the Weapons of Mass Destruction Medical Countermeasures Subcommittee which includes representatives of DOD, DHS and USDA as well as HHS. This PDT working group evaluates the need for animals, appropriateness of animal models in use and the need for additional models, facilities and reagents to support medical countermeasures R&D.

Question. As you are aware, the issue of liability protections has been widely discussed as a necessary component to encourage greater participation in Project BioShield. While additional legislation may be needed, what steps has HHS made to maximize use of its existing authorities under Public Law 85–804 and the SAFETY Act to mitigate the risks associated with the development of countermeasures? Specifically, has HHS made clear that indemnification will be included as a contract term during the Request for Proposal process, thus allowing potential bidders the assurance that liability will not be an issue should they be successful in winning the award in advance of incurring proposal costs? If not, why not? Has HHS sought and/or received an exception from the requirement under the implementing Executive Order for Public Law 85–804 that application under the SAFETY Act is a condition for application for indemnification? If not, has HHS been willing to indemnify contractors for risks not otherwise excluded by the SAFETY Act? Has HHS worked with the Department of Homeland Security to integrate the SAFETY Act application process into the procurement process for countermeasures in order to expedite review and consideration of a SAFETY Act application by bidder? If not, why not?

Answer. In a number of instances, HHS has required contractors to apply for SAFETY Act protection as a condition of indemnification. Moreover, we have complied with Executive Order No. 13286, which requires that before granting indemnification, the indemnifying agency obtain (1) the Department of Homeland Security’s (DHS) judgment as to whether the agency’s requirement may constitute a qualified anti-terrorism technology (QATT) eligible for SAFETY Act protection, and (2) Office of Management and Budget approval in light of the DHS determination.

HHS has not generally indicated in its solicitations that indemnification will be included as a contract term. Subpart 50.4 of the Federal Acquisition Regulation, concerning indemnification under Public Law 85–804, contemplates that contractors will request indemnification, rather than that the procuring agency will offer indemnification on its own initiative. Not all BioShield contractors have sought indemnification. Moreover, the Secretary must personally consider each request for indemnification on its own merits based on contractor submissions regarding, e.g., the availability of insurance. Thus, the contracting officer cannot preempt the Secretary by guaranteeing indemnification in the solicitation.

Executive Order No. 13286 does not require that contractors apply for SAFETY Act protection as a condition of indemnification; rather, as described above, the indemnifying agency must obtain DHS’ determination whether the agency’s requirement may constitute a QATT eligible for SAFETY Act protection. HHS has not sought an exception to this requirement. HHS has indemnified contractors for risks not excluded by the SAFETY Act.

Question. The Project BioShield Act grants HHS authority to enter into personal service contracts and streamlined personnel authorities to aid in the performance, administration or support of countermeasure research and development. Sec. 319F–1(d) and (e) of the PHS Act. To what extent has HHS used this authority? Please explain any failures to use this authority.

Answer. To date, NIAID has used Project BioShield authorities to hire two individuals, with a third appointment pending. The positions filled are:

- One individual in the dual positions of NIAID Associate Director for Biodefense Product Development and Director of the Division of Microbiology and Infectious Diseases' Office of Biodefense Research Activities; salary >\$100,000.
- One individual for the position of Associate Director for Product Development in the Division of Allergy, Immunology, and Transplantation; salary >\$100,000.
- One individual for the position of Associate Director for Radiation Countermeasures Research and Emergency Preparedness, in the Division of Allergy, Immunology, and Transplantation; salary >\$100,000.

Question. Section 5(c) of the Act requires the Secretaries of DHS and HHS to issue a report to Congress within 120 days after the enactment of the Act concerning whether there is a lack of adequate large scale biocontainment facilities necessary for the testing of countermeasures in accordance with Food and Drug Administration requirements. Why has this report not been issued? What work has been done on this report? When will it be issued?

Answer. An interim report was submitted to Congress on April 28 2005, and the final report will be submitted soon. Additional time was needed to sufficiently conduct an assessment of U.S. Biocontainment facilities.

Question. The Act requires the Secretaries of HHS and DHS to enter into an interagency agreement for procurement of countermeasures in accordance with the requirements of the Act. Sec. 319F-2(c)(7)(B). Please provide a copy of this agreement.

Answer. A copy of this agreement as it applies to the acquisition of rPA anthrax vaccine is attached.

Question. The Act requires HHS to institute appropriate controls concerning the use of procurement authorities under the Act. Secs. 319F-1(b)(1)(C) and 319F-2(c)(7)(C)(iii)(III) of the PHSA. Please provide a copy of the written guidance explaining these controls. Does HHS intend to publish the controls as regulations? Does HHS intend to promulgate implementing regulations for the entire Act? If so, when? If not, why not?

Answer. The BioShield Act is sufficiently detailed and prescriptive to obviate the need for regulations. The procurement control process is conducted consistent with the Federal Acquisition Regulations (FAR) and the Health and Human Services Acquisition Regulations (HHSAR). HHS will be happy to provide the Committee with a copy of these documents should you so desire.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

Question. What role do you envision CDC would play in any new BioShield legislation? Should not CDC be heavily involved in the implementation of any future BioShield program?

Answer. CDC plays a significant role in current BioShield programs. The Strategic National Stockpile (SNS) is located within CDC, is very actively engaged in the BioShield acquisition process, and provides the primary storage sites and distribution mechanisms for BioShield products. Subject matter experts (SMEs) at CDC are participants of the Weapons of Mass Destruction Medical Countermeasure Subcommittee (WMD MC), which reviews and establishes the requirements for BioShield acquisitions.

Section 10 of President Bush's Homeland Security Presidential Directive/HSPD-8 issued in December of 2003 States that "the Secretary of HHS . . . and heads of other Federal departments and agencies that provide assistance for first responders preparedness will base those allocations on assessments of population concentrations, critical infrastructures, and other significant risk factors, particularly terrorism threats, to the extent permitted by law."

Question. Has HHS abided by this Presidential directive in the allocation of State and Local bioterrorism preparedness funding?

Answer. The Department of Health and Human Services (HHS) funding priorities for State and local bioterrorism preparedness are consistent with Homeland Security Presidential Directive 8 (HSPD-8). A large percentage of public health emergency preparedness funds are allocated using a ratio of jurisdictional to U.S. population. In addition, this year CDC allocated funds for mass prophylaxis preparedness in 21 major metropolitan areas through the Cities Readiness Initiative (CRI). Mass preparedness is one of our Nation's priorities as described in the Interim National Preparedness Goal. Urban areas are selected for CRI based on population, risk, threats, and infrastructure. All of the CRI awardees are also Urban Area Security Initiative (UASI) grantees. This year HHS awarded funds to 15 additional metropolitan statistical areas to support preliminary planning for becoming full CRI awardees in fiscal year 2006, as proposed in the President's budget request. CDC

has developed Preparedness Goals designed to measure urgent public health system response performance parameters that are directly linked to health protection of the public. The Preparedness Goals are intended to measure urgent public health system response performance for terrorism and non-terrorism events including infectious disease, environmental and occupational related emergencies. Preparedness measures are a subset of the overarching targeted capabilities list and are consistent with national preparedness goals

Question. What is the process for determining the prioritization of items to be purchased for the Strategic National Stockpile? At what level of the process are the scientists and infectious disease experts of the National Institutes of Health and the Centers for Disease Control and Prevention included?

Answer. The classifications of Category A, B, and C agents (agents that are likely to be used in a bioterror attack) have been generated from infectious disease and medical analyses to which NIH and CDC scientists contributed significantly. We have initially focused our countermeasure procurement efforts on Category A agents that pose the greatest threats. To address the threat of any one particular agent, consideration is given to currently available countermeasures, such as antibiotics and vaccines. Further consideration includes the need for or role of new countermeasures, such as antitoxins, next generation vaccines, or antibiotics. Perceived need and absence of a new countermeasure informs research initiatives. Scientists from OPHEP, NIH, CDC, Food and Drug Administration (FDA), Department of Defense (DOD), and Department of Homeland Security (DHS) are asked to determine which new countermeasures are scientifically advanced enough to invest in advanced development and testing, would have the greatest public health impact, and have the greatest likelihood of success.

The process to determine which countermeasures are placed in the SNS is informed by the interagency WMD MC subcommittee. This is an interdepartmental subcommittee initially chartered by the Office of Science and Technology Policy (OSTP) and co-chaired by senior government officials from DHS, HHS, and DOD. The material threat assessments (MTA) developed by DHS based on a plausible attack scenario informs the sizing of the procurement requirement. HHS, through the coordination efforts of OPHEP, then evaluates the availability of currently developed countermeasures and assesses the scientific opportunities to develop new countermeasures. The WMD MC then deliberates on the nature of the medical consequence and the availability of appropriate countermeasures to develop a recommendation for the acquisition of a specific countermeasure. HHS can issue a Request for Information (RFI) to determine the market availability and to alert industry to the U.S. Government interests. Once a U.S. Government requirement for a particular new medical countermeasure has been established by the WMD MC and approved by OMB is granted, a Request for Proposals (RFP) announcing the specific requirements follows. HHS implements the acquisition process.

QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

LACK OF BIOSHIELD FUNDING FOR RAD/NUC RESPONSE

Question. On April 13th, the Department of Homeland Security wrote Congress notifying us of the creation of the Domestic Nuclear Detection Office. In the letter, the Department justified the creation of the Office based on the assertion that, "The risk that terrorists will acquire and use a nuclear/radiological device is one of the gravest threats that confronts the Nation."

Yet despite this assertion, our Nation is still without a practical way to medically treat the thousands or even hundreds of thousands of Americans who may be exposed or who may believe they have been exposed to radiation in the event we are attacked in this way. While I understand that radiological and nuclear threats have been certified as a "material threat," I was surprised to learn that the Bioshield program has not actually been used to procure several very promising drugs that are now in late-stage development and could be available in the near term to respond to this most insidious of threats.

Beyond your limited plan to purchase pediatric potassium iodide, what is your schedule for procuring drugs for the national stockpile to respond to what is called Acute Radiation Syndrome (ARS)?

Answer. HHS is eager to enlarge the holdings of the SNS with respect to radiological/nuclear countermeasures. A Request for Information (RFI) for countermeasures for an ARS was published in October 2004. Responses have been evaluated; and a Request for Proposals (RFP) is being developed. We anticipate releasing a draft RFP for industry comment on the general topic of ARS as soon as July 2005.

Accordingly, the quality of the proposals and the availability of resources will determine how HHS acts on the results of the RFI and RFP. The SNS currently contains Potassium Iodide, Pediatric Potassium Iodide, Calcium/Zinc Diethylenetriaminepentaacetate (Ca/Zn DTPA) and Prussian Blue (Ferric hexacyanoferrate (II)) as countermeasures for a radiation event. In addition, Granulocyte-Colony Stimulating Factor (G-CSF) is available to the SNS under Investigational New Drug (IND).

PRIVATE SECTOR INTEREST IN BIOSHIELD

Question. When the President signed the BioShield Act into law last July, the Washington Post reported that “Few companies have shown much enthusiasm for diverting staff and money from programs to develop drugs, such as cancer and cholesterol treatments, with bigger and more established markets. Of about 1,000 U.S. biotechnology companies, about 100 are working on biodefense projects, according to the Biotechnology Industry Organization, an industry trade group.”

Has the interest in BioShield increased or are companies still reluctant to participate in the program? What recommendations would you make to increase private sector interest in BioShield?

Answer. We have seen significant interest in BioShield, however we recognize the need for continuing improvement and expanded outreach. Many of the innovative approaches to developing a medical countermeasure occur in small biotech companies that are inexperienced in manufacturing, clinical trials, and the regulatory process. They are generally funded by venture capital investors and are operating at a loss. They usually need funds to validate a current Good Manufacturing Practices (cGMP) manufacturing process and to conduct the necessary animal studies or human safety studies to qualify for an Investigational New Drug (IND) application.

The large pharmaceutical companies have numerous opportunities to consider when establishing their business model and the priority targets of their research and development portfolios. They must weigh the opportunity costs for the biodefense market with its intrinsic uncertainty regarding the size and sustainability against more predictable and quantifiable markets for medical products for diseases with relatively well-established target populations, many of which will be sustained over many years. As large pharmaceutical companies consider the profits for traditional medical products versus the profits available for vaccines or other medical countermeasures, the reason for their reluctance appears to be driven by the markets. For example, as mentioned by Dr. Fauci in his February 8, 2005 testimony, a year’s supply of Lipitor to lower cholesterol is \$1,608; a year’s supply of 50-milligram Viagra is \$3,500; but a flu vaccine generally sells for \$7 to \$10.

Today, the U.S. Government is involved throughout the pipeline of countermeasure development, through basic research support at NIH and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) all the way to the procurement activities undertaken through Project BioShield. Both NIH and the USAMRIID have excellent records in this regard. The U.S. Government can further target and facilitate research and development efforts by setting clear requirements and specifications for: medical countermeasures; facilitating partnerships as needed between government and industry or between industry and industry; and providing critical resources such as facilities (e.g. laboratories with high-level biocontainment), animals (for testing), reagents and assays.

Grant Coordination—for Assistant Secretary Simonson

Question. The recent TOPOFF 3 training event recently portrayed a scenario that exercised first responders, hospital capacity and the ability to treat a sudden rush of people affected by chemical and biological agents. We look forward to a report on the exercise around mid-summer. Since fiscal year 2002, Congress has appropriated \$11 billion to first responders through the Department of Homeland Security and \$5.5 billion through the Department of Health and Human Services to provide local monitoring for outbreaks and surge capacity for treatment. BioShield has \$5.6 billion over 10 years to feed our Strategic National Stockpile. We have committed a significant amount of money into these programs, over \$22 billion. However, when tragedy strikes the citizens of this country demand a seamless operation that provides emergency care, timely correct information, and treatment if needed.

Do local health agencies have the capacity and infrastructure to deal with a surge in activity?

Answer. CDC funding, distributed through cooperative agreements, has enabled local health departments to increase both capacity and infrastructure to deal with surges by providing for increased epidemiologic capacity, terrorism preparedness and response trainings for public health practitioners, improved communications systems (in terms of not only equipment but also improved relationships between

the public health, medical and homeland security communities), and enhanced technology and staff in public health laboratories. HHS recognizes that not each of the approximately 4,000 local health departments can or should have the same response capability, especially considering the wide variation in size, risks and populations served as well as a finite amount of funding. Therefore, HHS encourages and supports local health departments to work together to develop regional capacity and infrastructure through shared equipment, personnel, information and other assets. For example, during a mass prophylaxis event, neighboring local health departments might assist the affected jurisdiction in some aspect of the response, such as staffing, so that the local health department can focus on mass prophylaxis.

Local health departments have been developing volunteer pools and strengthening partnerships with other agencies and businesses to provide support activities such as mass prophylaxis. Another example is laboratory capacity—a key asset for public health emergency preparedness and response that is expensive for a local jurisdiction's budget. Not every local health department can have advanced laboratory capability. Therefore, some local health departments have basic laboratory capability and refer some samples to a Laboratory Response Network (LRN) laboratory. Other local health departments have collaborative relationships with neighboring laboratories that have existing capability. The State public health laboratory can provide additional capability to all local health departments within their jurisdiction. While local health departments continue to improve, maintaining this capacity and infrastructure will also be necessary.

For healthcare surge capacity, HHS has proposed in its fiscal year 2006 budget funding for the procurement and maintenance of portable hospital units (Federal Medical Contingency Stations) as a part of its Mass Casualty Initiative. These units can be rapidly deployed to anywhere in the country and would supplement local hospital surge capacity by 5,500 beds in the event of an emergency.

Question. What lessons have we learned through coordinating first responder efforts with medical response efforts?

Answer. Force Protection.—Important steps have been taken to establish the necessary medical counter and preventive measures to protect first responders. Vaccination and prophylaxis for the most common agents have been studied and best practices developed. Personal Protective Equipment (PPE) standards have been established by the first responder industry in conjunction with public health. Manufacturers are now certifying equipment such as Self Contained Breathing Apparatus (SCBA) as Weapons of Mass Destruction (WMD) compliant.

Surge.—Issues of surge capacity have been addressed in multiple ways. Solutions are being sought both in and out of the hospital. Within the hospitals, mechanisms are being implemented to open beds in case of a catastrophic incident. These mechanisms include the use of adding beds to the existing infrastructure as well as discharging or transferring patients who could receive care elsewhere. First responders are being asked to support efforts to sustain develop and various levels of treatment outside the hospitals that are free standing or potentially an annex to an existing hospital.

Incident Command Structure.—With the advent of the National Incident Management System (NIMS) and the National Response Plan (NRP), we now have a common methodology for managing an event that incorporates first responders and medical communities. As planning efforts continue to move forward in these communities, the essential link between them may be articulated.

Forensic Epidemiology.—CDC has created a course on Forensic Epidemiology in collaboration with the Federal Bureau of Investigation (FBI) from which more than 13,000 public health and law enforcement officials have graduated. Criminal and epidemiological investigative methods are used to demonstrate an understanding of the similarities and differences in public health and law enforcement investigative goals and methods. Common operating procedures about how findings are communicated between the two groups are of primary importance.

Equipment Standardization.—HHS has supported the efforts and participated in the Interagency Board (IAB) for Equipment Standardization and Inter Operability Working Group since its inception. The IAB is designed to “establish and coordinate local, State, and Federal standardization, interoperability, and responder safety to prepare for, respond to, mitigate, and recover from any incident by identifying requirements for Chemical, Biological, and radiological, Nuclear or Explosives incident response equipment.”

Early Event Detection (Syndromic Surveillance).—Information recorded by the first responders such as 9–1–1 call information, Emergency Medical Services patient care records, and other public health data are reviewed for statistical anomalies in the syndromes that present. These anomalies are reviewed against signs and symptoms of bio and chemical terrorism, as well as unforeseen natural disease outbreaks.

By collaborating with the first responder community, public health authorities can obtain advanced insight into the changing health conditions of a given population or frequency with which they occur.

Decontamination.—The capability of first responders to properly decontaminate hundreds of people has become well established in the majority of metropolitan statistical areas, which can be attributed in large part to leadership from Health Resources and Services Administration (HRSA) grants. Hospitals understand the importance of not allowing facilities to become contaminated, and have taken important steps to protect themselves. While acute mass decontamination continues to be a challenge, significant efforts are under way to develop methods to quickly decontaminate thousands of people.

Rapid Registry.—The Rapid Response Registry (RRR) is an HHS response tool intended to assist local officials in rapidly identifying, enumerating, and obtaining contact information for individuals who have been, or who believe they may have been, exposed. The emergency contact information collected is necessary for both short-term and long-term follow-up for exposed, injured, and ill individuals and would be available to public health officials to guide public health response services directed at the affected population during the emergency response. In addition to the data collection tool, the Agency for Toxic Substances and Disease Registry (ATSDR) staff can provide either remote or on-scene technical assistance to support public health needs assessment activities, medical assistance, health interventions, or health education in the affected population during or immediately following the recognition of a Chemical, Biological, Radiological, and Nuclear Warfare, and Explosives (CBRNE) emergency. This process allows State and local public health responders to target enrolled individuals with updated information, triage their specific risk for potential exposures, determine appropriate self-decontamination procedures, and recommend any immediate medical evaluation or interventions (countermeasures). Real time data collection also enables future health studies by State and local public health as part of long-term mitigation activities, should these be determined appropriate.

HHS Secretary's Emergency Response Team (SERT).—The SERT acts as the Secretary's agent on emergency sites working along with the first responder community under the direction of the Assistant Secretary for Public Health Emergency Preparedness (ASPHEP). The ASPHEP, on behalf of the Secretary, directs and coordinates the Department's efforts to prevent, prepare for, respond to, and recover from, the public health and medical consequences of disaster or emergency. The SERT directs and coordinates the activities of all HHS personnel deployed to the emergency site to assist State, local, Tribal, and other Federal and government agencies as applicable.

Health Alert Network (HAN).—The HAN ensures that each community has rapid and timely access to emergent health information; a cadre of highly-trained professionals; and evidence-based practices and procedures for effective public health preparedness, response, and service on a 24/7 basis. The HAN is dedicated to strengthening the core public health infrastructure for information access, communications, and distance learning at the State and community levels. Through continuous, high-speed internet connectivity and broadcast capacity to support emergency communication, HAN provides the national public health system with a network of public health officials and other first-responders who are continuously connected to information vital to emergency and non-emergency public health practice.

Medical Reserve Corp (MRC).—MRC units are community-based and function as a way to locally organize and utilize volunteers who want to donate their time and expertise to prepare for and respond to emergencies, and promote healthy living throughout the year. MRC volunteers supplement existing first responders and public health resources. MRC volunteers include medical and public health professionals such as physicians, nurses, pharmacists, dentists, veterinarians, and epidemiologists. Many community members—interpreters, chaplains, office workers, legal advisors, and others—also fill key support positions in the first responder community.

SNS.—The SNS has large quantities of medicine and medical supplies to protect the American public if there is a public health emergency severe enough to drain local supplies. Should Federal and local authorities agree that the SNS is needed, medicines will be delivered to any State in the United States or territory within 12 hours. Each of our 62 grantees has plans to receive and distribute SNS medicine and medical supplies to local communities as quickly as possible. Many of these medical countermeasures will initially be used by the first responder community so that they can continue to fulfill their vital role in support of an event.

The National Incident Communications Coordination Line (NICCL).—NICCL is a special toll free line with limited access via PIN number, is maintained by DHS and

is used to bring together the key Public Affairs representatives from Federal, State and local agencies during major incidents. DHS convenes calls to ensure all agencies are fully aware of the facts concerning the incident, achieve agreement as to which agencies have the public communications lead concerning the various aspects of the incident and coordinate all public announcements concerning the incident. The NICCL has been used effectively during a number of incidents over the past year and as part of the Top Officials 3 (TOPOFF3) exercise. In each case not only Federal agencies participated in the calls but also State and local Public Affairs Officers from the affected areas were included.

Question. Are grant programs coordinated by DHS and HHS so that Americans, in their time of need, are protected and treated to the highest standard possible without confusion or lack of direction?

Answer. HHS cooperative agreement programs and DHS grant programs are being coordinated at the Federal, State, and local levels. Since 2003 HHS has required that the State-wide joint advisory committees required by CDC and HRSA cooperative agreements include members from State homeland security or emergency management, fire, and police agencies. In 2005, DHS added similar language to its program guidance documents, which now requires State homeland security agencies to reach out to the public health and medical communities. Many intra-state coordinating bodies, which have been established by local jurisdictions, require participation by homeland security, emergency management, public health, and medical communities in regional planning and response efforts as well. HHS also requires its awardees to comply with the NIMS, which facilitates coordination, communication and cooperation between first responders (e.g., fire, police, public health) and first receivers (e.g., hospitals) during an event.

At the Federal level, both HHS and DHS review and comment on the program announcements and guidance documents of their sister agencies, to which States and local jurisdictions respond in order to receive funds. Both Departments also have ten regional emergency coordinators, who work closely with one another and with States to plan, train and exercise across jurisdictional lines. More recently, HHS and DHS have formed a steering committee to identify additional mechanisms to increase coordination and collaboration between the awardees and grantees, as well as between the Departments at the Federal level. Future activities may include joint site visits and regional meetings.

BioShield Benchmarks—for Assistant Secretary Simonson

Question. In 1999, Congress charged the Department of Health and Human Services and the Centers for Disease Control and Prevention with the establishment of the National Pharmaceutical Stockpile. The Homeland Security Act of 2002 re-named the effort the Strategic National Stockpile and tasked the Department of Homeland Security with defining the goals and performance requirements but the Stockpile was to be jointly managed by DHS and HHS. The Project BioShield Act of 2003 returned oversight and guidance of the stockpile to HHS.

With all of the changes in command, what information and tools are we using to ensure that Project BioShield is properly feeding the Strategic National Stockpile so that it is truly ready to provide rapid access to large quantities of the right types of pharmaceuticals and medical supplies? What specific benchmark are we using to gauge ourselves in the ability to respond to an unknown attack or natural disaster?

Answer. The SNS staff has remained intact during the recent departmental changes. In addition, the deliberative process to set requirements and implement acquisitions for the SNS under Project BioShield has also remained constant. The SNS engages in deployment exercises with various State and local entities on a regular schedule to assess the readiness of State and local partners and to improve the deployment process. In addition, CDC and the SNS participate in National and international exercises, such as TOPOFF3, to fully assess their response capabilities for communication, logistics, resource allocations, and stockpile utilization. These exercises serve as a benchmark for the Nation's level of preparedness for an unknown or natural disaster. SNS performance measures to deliver assets within 12 hours of decision to deploy. While project Bioshield is focused on development of new countermeasures which will be incorporated into SNS once available, SNS acquires and maintains significant countermeasures currently available.

CONCLUSION OF HEARINGS

Senator GREGG. Well, if you have got thoughts, we would be interested in language you think would improve that because I do be-

lieve unless we address this issue of liability, we will never get this straightened out and we will never get the participation we need.

Well, all of your input has been excellent. I am trying to think of what title we should have on this novel award. We will have to come up with something. We will call it the Franz award.

In any event, thank you very much. We appreciate your input. This is not an end. This is just an ongoing discussion as to how we make this whole system work better and just one part of the discussion. We intend to continue to pursue this as a committee. You obviously intend to pursue it as professionals. So thank you.

Dr. READ. Thanks for your leadership.

Senator GREGG. The subcommittee is recessed.

[Whereupon, at 12:15 p.m., Thursday, April 28, the hearings were concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]