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2002

SCIENCE OF BIOTERRORISM:
IS THE FEDERAL GOVERNMENT PREPARED?

HEARING

BEFORE THE

COMMITTEE ON SCIENCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

FIRST SESSION

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SCIENCE OF BIOTERRORISM: IS THE FEDERAL GOVERNMENT PREPARED?

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WEDNESDAY, DECEMBER 5, 2001

House of Representatives,

Committee on Science,

Washington, DC.

The Committee met, pursuant to call, at 10:07 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Sherwood L. Boehlert [Chairman of the Committee] presiding.

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HEARING CHARTER

COMMITTEE ON SCIENCE

U.S. HOUSE OF REPRESENTATIVES
Science of Bioterrorism:

Is the Federal Government Prepared?

WEDNESDAY, DECEMBER 5, 2001

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10:00 A.M.–12:00 P.M.

2318 RAYBURN HOUSE OFFICE BUILDING

Purpose

On Wednesday, December 5, 2001 the House Committee on Science will hold a hearing to receive testimony regarding the role of federal agencies in responding to bioterrorism. Specifically, this hearing will explore the research and development underway at various federal agencies to improve our nation's ability to detect, prevent, respond to, and remediate bioterrorist attacks. In addition the hearing will explore the relationship and information sharing among federal agencies and what efforts the Administration has underway to better coordinate the response to bioterrorism, particularly in the area of research and development.

Witnesses

The Committee will hear testimony from:

1. *The Honorable John H. Marburger, III, Ph.D.,* Director, Office of Science and Technology Policy, Executive Office of the President.

2. *The Honorable Linda Fisher,* Deputy Administrator, Environmental Protection Agency.

3. *Anna Johnson-Winegar, Ph.D.,* Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense, Department of Defense.

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4. *Donald A. Henderson, M.D.,* Director, Office of Public Health Preparedness, Department of Health and Human Services.

Background

Recently public and congressional concerns over biological weapons, in particular those deployed in acts of bioterrorism, have increased dramatically. During the past 20 years only a limited number of incidents involving biological agents had occurred in the United States.(see footnote 1) But since Bob Stevens of American Media, Inc. was first diagnosed with inhalation anthrax this past October, 23 confirmed cases of anthrax infections have occurred and 5 deaths have resulted. Bioterrorism has become a household word.

The responsibility of responding to a bioterrorist attack initially falls on personnel in the state and local emergency response agencies. These are the so-called "first-responders" and include health care workers, law enforcement officers, firefighters, and public works personnel. Federal agencies usually engage after the initial response according to the Federal Response Plan, required by the Disaster Relief and Emergency Assistance Act (P.L. 93–288) for any kind of emergency, including chemical, biological or even natural emergencies.

When compared to other types of emergencies, a response to a bioterrorist attack is unique, since it

requires, among other things, disease surveillance, an epidemiological investigation, the laboratory identification of infectious agents, and the production and distribution of antibiotics and/or vaccines. The challenge facing federal scientific and defense agencies, in conjunction with the private sector, is to develop effective and safe methods to prevent, detect, respond to and remediate future bioterrorist attacks. And a key component to this response is the ongoing and future research and development activities within federal agencies.

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Bioterrorism Research and Development Activities of the Federal Government

The Federal Government conducts a wide range of research and development activities in response to bioterrorism. For example, devices to detect the presence of a biological or chemical agent, diagnostic tools, vaccines, antibiotics, technologies for decontamination, and models to predict the spread of disease-causing germs are all the subject of research and development within federal agencies.

According to the General Accounting Office (GAO), there are more than 20 federal departments and agencies that have a role in responding to bioterrorism, including by conducting research and development. (see footnote 2) These include the Departments of Agriculture (USDA), Defense (DOD), Energy (DOE), Health and Human Services (HHS), Justice (DOJ), Transportation (DOT), Treasury, the Federal Emergency Management Agency (FEMA), the Environmental Protection Agency (EPA), and to a limited extent, the National Science Foundation (NSF).

With so many agencies involved in bioterrorism, coordination becomes critical. The agencies have been working together in both formal and informal settings, such as a variety of interagency working groups and less formal "one-on-one" interactions among researchers sharing a common interest. However, in some cases interagency coordination appears inadequate. For example, the Science Committee's hearing on decontamination on November 7, 2001 found that there was a lack of consensus about what constitutes a safe environment following decontamination. As a result of this hearing, Chairman Boehlert and Ranking Member Hall sent the attached letter to the President requesting that he convene a panel of experts to establish safety standards. To the best of our knowledge, this issue has not been resolved and is gaining increasing importance as the various government and private buildings infected with anthrax spores undergo remediation.

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Another concern illustrating the importance of interagency coordination is that different agencies have developed separate lists of dangerous biological agents and this has important implications when prioritizing a research agenda. In addition, there are also examples in which key federal agencies have not been included in bioterrorism-related policy and planning. And there appears to be systematic way of coordinating research and development priorities with "lessons learned" or needs determined from actual experiences with bioterrorism, like the recent anthrax attacks.

There have been a number of efforts to improve interagency coordination, however. For example, Presidential Decision Directive (PDD) 62, which was issued in 1998, organizes and clarifies the roles and activities of the federal agencies responsible for combating terrorism. Also, in an effort to better coordinate the federal response to terrorism, the National Security Council (NSC) and Office of Management and Budget (OMB) created a process as part of the annual budget cycle to reduce overlap and improve interagency coordination in 1999. In addition, in May 2001 the President asked Vice President Cheney to oversee the development of a coordinated interagency effort to deal with weapons of mass destruction.

And in response to the September 11 attacks, the importance of good interagency coordination was further recognized when President Bush issued the first Homeland Security Presidential Directive that established the Office of Homeland Security headed by Governor Tom Ridge. The mission of the Office is to develop and coordinate the implementation of a comprehensive national strategy to secure the United States from terrorist threats or attacks. The Office coordinates the executive branch's efforts to detect, prepare for, prevent, protect against, respond to, and recover from terrorist attacks within the United States. Within the Office, there are 11 functional areas, one of which is research and development. The research and development function is the only area for which a head has not yet been named. The President's science advisor, Dr. John Marburger, has temporarily filled that position.

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The following is a brief description of the efforts of several key federal agencies related to bioterrorism research and development:

1. Department of Energy—DOE is responsible for nonproliferation monitoring and verification. Within DOE, the National Nuclear Security Administration develops devices for the detection of nuclear, chemical and biological weapons. The vast majority of its work is limited to research and development and focused on domestic threats.

2. Department of Defense—All of DOD's chemical and biological programs are coordinated through the Office of Chemical and Biological Defense, headed by Dr. Anna Johnson-Winegar. DOD's research and development efforts are focused on international threats and the military's response. A large component of the funding is directed at detection devices, although the department does invest in most other aspects of bioweapon research. These include medical concerns such as vaccinations and therapeutics, modeling and simulation, and remediation.

3. Department of Health and Human Services—HHS has various agencies concerned with responding to bioterrorism, including the newly created Office of Public Health Preparedness. For example, the Centers for Disease Control and Prevention (CDC) is conducting studies that will enhance surveillance and laboratory capacity within the health care system and is conducting studies that have direct relevance to bioterrorism (e.g., anthrax vaccine research). The Food and Drug Administration (FDA) is concerned with approving new vaccines, therapies and developing safety standards for various medical devices. The National Institutes of Health (NIH) invests heavily in research and development for improved vaccines and treatments, better disease-detection methods, and new antibiotics.

4. Environmental Protection Agency—Currently EPA's research in fields related to bioterrorism is limited, focusing primarily on the security of water supplies. However, the agency has experience with risk-analysis and this could be utilized in the future with regards to bioterrorist threats.

Ultimately, the Office of Homeland Security is responsible for coordinating the Federal Government's response to terrorism (chemical, biological, and otherwise) and reports to the Homeland Security Council. And the Office of Science and Technology Policy (OSTP), headed by Dr. Marburger, serves as a conduit for research and development activities to the Office of Homeland Security. One activity currently underway at OSTP is an inventory assessment of federal research related to terrorism.

Federal Funding for Terrorism, including Bioterrorism, and Preparedness

Federal Government spending for all preparedness activities against any kind of domestic terrorist attack (chemical, biological, radiological or nuclear attacks) has increased 310 percent since fiscal year 1998, and currently stands $1.7 billion a year.

However, it is difficult to get an accurate estimate of federal funding for bioterrorism. This is in part due to the nature of this type of research—some kinds of bioterrorism-related research are classified as secret, while others serve multiple purposes. For example, research on botulinum toxin could be considered medical since the toxin is used for treating certain neuromuscular diseases, or it could be specifically directed at defending against the toxin's use as a potent agent of bioterrorism.

The most detailed funding study conducted by the non-profit RAND Corporation, estimates that the total federal research and development spending related *specifically to bioterrorism* totaled between $35 to $40 million last year (FY 2000). The GAO estimates that the Federal Government spends approximately $160 million for *all terrorism*, including bioterrorism, research in FY 2001 (table attached). However the GAO estimate does not include DOD and DOT funding levels.

These figures may increase in fiscal year 2002 as portions of the $40 billion emergency supplemental appropriation (P.L. 107–38) are allocated to federal agencies. The House-passed FY02 Defense Appropriations bill, which contains the FY01 Emergency Supplemental, contains $2.2 billion for bioterrorism. The President's request was $1.6 billion. It's unclear what portion of this funding is directed toward research and development activities.

Conclusion

Over 20 federal agencies have ongoing research and development projects involving bioterrorism preparedness. While these departments and agencies have made efforts to better coordinate their activities on both a formal and informal basis, it is unclear how much progress has been made since September 11. If our nation is to respond well to future bioterrorist attacks, interagency coordination should improve.

Witnesses have been asked to address the following questions:

1. What research and development work does the Federal Government have underway to improve the Nation's ability to detect, prevent, respond to and remediate bioterrorist attacks? How much is the Federal Government spending in these areas?

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2. How is the Federal Government coordinating with other federal agencies in determining and carrying out activities related to bioterrorism?

3. What efforts does the Administration have underway to develop a comprehensive, coordinated plan to deal with bioterrorism, particularly in the area of research and development?

In addition, we have asked Dr. Marburger to address these questions:

1. What initiatives does OSTP have underway or planned to identify and coordinate federal and other research and development efforts designed to improve the Nation's ability to detect, prevent, respond to and remediate bioterrorist attacks?

2. How is OSTP coordinating efforts with Homeland Defense, OMB and other White House agencies?

3. What changes in federal policy and spending are needed to ensure that the U.S. has a long-term capability to respond to bioterrorism?

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Science of Bioterrorism: Is the Federal Government Prepared?

Chairman **BOEHLERT.** The hearing will come to order. I want to welcome everyone this morning to our fifth hearing on terrorism and our second hearing on bioterrorism. We have held two hearings on cyber terrorism, which led to H.R. 3394, the bill I introduced yesterday with Mr. Hall, which we will mark up tomorrow. We also have held a hearing on water security, which produced H.R. 3178, which is pending House action.

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We held a hearing before Thanksgiving with leading experts on decontamination to understand the science behind bioterrorism. And today we will hear from most of the top bioterrorism officials in our government to learn more about how the federal bioterrorism effort is being organized. I suspect that this effort, like our previous forays into terrorism issues, will be followed by legislation. This Committee is moving ahead swiftly and deliberately to respond to the terrorism threat.

I want to emphasize, as I have in past hearings, our Committee's particular take on terrorism issues. We see it as our job to ensure that the Nation is investing in the R&D needed to combat terrorism over the long haul. Yes, there are immediate steps to take, but in the long run, like the Cold War, the war against terrorism will be won in the laboratory as much as on the battlefield.

And, as on the battlefield, organization is a key to victory. We won't be able to take full advantage of the enormous resources of the Federal Government and the enormous expertise that resides throughout the Nation unless we have a clearly led, well-organized, well-planned R&D effort. And we don't have that yet.

I am not being critical when I say that. Despite some missteps, I think the Federal Government has done a remarkable job of responding to such unprecedented events as the anthrax attacks. I think, for example, that Dr. Marburger's efforts, at Governor Ridge's request, to put together scientific teams to work with the post office on mail irradiation, were a model of quick response and cooperation.

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But—and this is critical—so far most efforts, of necessity, have been ad hoc and put together on the fly. If that is still true six months from now, we will have failed to respond adequately to the terrorist threat. Even the smartest people can't make the most of muddling through forever.

I know that there are numerous and quite promising efforts underway to coordinate R&D related to bioterrorism. We need to put these in place swiftly and ensure that they work. The staff of this Committee, on a bipartisan basis, had a week of briefings from federal agencies in advance of this hearing. The agencies were extraordinarily cooperative and the briefings were extremely informative. But time and time again, the staff came across cases of gaps in coordination, of questions that could not yet be answered.

The purpose of today's hearing is to ensure that coordination efforts are put together methodically and swiftly. I suspect that the four very distinguished witnesses before us today have not been in the same room at the same time before this moment. Bringing you together may alone be worth the price of admission.

Let me emphasize that this coordination issue is important because it has real consequences. We are not just pushing this because we like to see pretty flowcharts.

Here is an example: We are all learning things from the anthrax experience, including that there is a lot we still don't know. An obvious example of that is that we don't have a standard for what level of anthrax in a building is safe. Do we have a coordinated effort to collect the research questions that are arising out of the anthrax attacks, assign a priority to them, assign federal agencies to study them, and provide a budget for all that activity? My sense is that, for now, the answer is no, although efforts are in the works.

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So let me compliment all the witnesses on the fine work their agencies have been doing on bioterrorism. I am eager to hear from you now and how, through coordination, we can capitalize on those efforts even further. The Chair recognizes the distinguished gentleman from Texas, Mr. Hall.

[The prepared statement of Mr. Boehlert follows:]

PREPARED STATEMENT OF CHAIRMAN SHERWOOD BOEHLERT

I want to welcome everyone this morning to our fifth hearing on terrorism, and our second hearing on bioterrorism. We have held two hearings on cyberterrorism—which led to H.R. 3394, the bill I introduced with Mr. Hall yesterday, which we will markup tomorrow. We also have held a hearing on water security, which produced H.R. 3178, which is pending House action.

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So, let me compliment all the witnesses on the fine work their agencies have been doing on bioterrorism. I'm eager to hear from you how, through coordination, we can capitalize on those efforts even further.

Mr. **HALL.** Mr. Chairman, thank you. And of course, no one could have predicted the nature of the attacks that you have spoken about. And we are told that the Federal Government had already started to organize to respond to a terrorist attack some time well before September the 11th. I guess today we will hear just exactly how much that was and while I don't really think we should expect that it would have been to a considerable amount, I am sure there was an effort in that direction. But nobody could envision that. No one that is a fair-minded person could put blame on anyone for lack of preparation against that type offense because we have never had it.

I am told that this preparation the Federal Government had started included interagency panels that were involved in all the organizations that are here today. And I think what the Chairman said and what I certainly agree with is we are interested in how well that coordination prepared our government to respond to the crises that have unfolded around us and what mechanisms for coordination may have sprung up to meet these needs and what lessons should be learned from the response. That is the most we can expect and that is what we hope has happened.

This is a different war. Everybody knows that. Today, you know, unlike wars of the past where people received jobs and it spawned the economy, this depressed the economy and people lost their jobs. Companies closed down, even after we had voted, what, $40 billion—half of it to go to New York and much of the rest of it to go to the airlines. That seemed like, to me, the very next day the airlines started laying off and trying to shut down.

War—I guess what I am saying is wars bring changes. You know, back there in World War II, even women started wearing slacks of all things. Some of them were welders. I don't like to break things like this to you, and a guy like our Chairman, but women started smoking in public. And seriously, we moved a generation of Japanese off the west coast back inland in answer to a fear that we all had from the catastrophe called Pearl Harbor.

So I think of particular interest to us today is future research efforts and what level of effort is appropriate. And in the research area, diversity is our greatest strength of this nation. We have always had people step up. Howard Hughes helped us devise a fighter. I am told he had set up the Zero for us and we didn't think it was a good enough plane because it didn't protect the pilots. The Japanese took it and used it.

Henry Kaiser taught us about assembly lines. And, you know, Americans and men and women like the four here in front of us step up to the lick log and lead us and give us advice and make suggestions that this Committee can put into fruition and use. We are going to need to minimize agency rivalries and promote some communications. And, for example, most bioterrorism R&D is and has been conducted by the Department of Defense. And yet, the military's needs for results are quite different from those of—for defense from the civilian population.

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And we—our health agencies, on the other hand, have to be concerned with the protection of our citizens, like the elderly lady that was lost. And we need to develop a new research agenda to protect the entire population that draws on the great experience and results that the Department of Defense has established. And we have, once again, very mixed emotions. Maybe you all can solve some of them.

But I have always thought that our military, for example, could stop a lot of infiltration from Mexico by putting them on the border. But there was opposition to that. Nobody ever agreed to it. And I don't think we ever really debated it out. But, you know, they could have locked arms up and down that 2,000-mile border of the Rio Grande there and stopped a lot of it if it took that.

And the same—by the same comparison, I think the Department of Defense should have had more input into the space program. Because if we fight a war and we have a war, much of it is either going to be fought or controlled by space. Why shouldn't the Department of Defense be heavily involved in that? It makes sense to me.

But, Mr. Chairman, we need to be clear about agency responsibilities—not aggressive about them, but clear about them. And I look forward to pursuing these. And I thank you and thank the Panel and this Committee for that that we will do with the information they bring us. Thank you.

[The prepared statement of Mr. Hall follows:]

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PREPARED STATEMENT OF THE HONORABLE RALPH M. HALL

Thank your Mr. Chairman.

The whole world changed on September 11, but in a sense we had been expecting it to change. While no one would have predicted the horrific nature of the attacks on the World Trade Center or the subsequent anthrax attack with its lingering disruptive effects, the Federal Government had begun to organize to respond to a terrorist attack well before September 11.

That preparation includes interagency panels involving all of the organizations that are here today. We are interested in how well that coordination prepared our government to respond to the crises that have unfolded around us, what new mechanisms for coordination may have sprung up to meet *ad hoc* needs, and what lessons should be learned from our responses. Of particular concern is how lessons can be used to guide future research efforts and what level of effort is appropriate.

In the research arena, diversity is our nation's greatest strength. Our research system, with its strong and varied mix of civilian agencies, military R&D, universities, and the private sector, is the envy of the world. But in times of crisis like today, we will need to minimize agency rivalries, promote communication, and reduce redundancy.

For example, most bioterrorism R&D is and has been conducted by the Department of Defense. Yet the military's needs for research results are quite different from those of the civil population. As one obvious example, DOD is concerned about protecting healthy 18 to 35-year olds who may be able to abandon a contaminated battlefield. Our health agencies, on the other hand, must be concerned with protecting all of our citizens, including those like the 94-year-old Ottilie Lundgren who recently succumbed to what was probably only a few spores of anthrax. We need to develop a new research agenda to protect the entire population that draws on the great experience and results that the Defense Department has established.

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We also need to be very clear about agency responsibilities. In the wake of contamination of various postal and Congressional facilities in Washington, D.C., we have seen a fair amount of confusion about the infective power of anthrax spores and about which agency is in charge of certifying when a building is clean. Some of this confusion surfaced during our last hearing on this topic. We will provide the agencies in front of us today—EPA and HHS—with a fresh opportunity to set the record straight on these matters.

Mr. Chairman, I look forward to pursuing these and other issues with the fine panel you have assembled and commend you for calling this hearing.

[The prepared statement of Ms. Morella follows:]

PREPARED STATEMENT OF REPRESENTATIVE CONSTANCE MORELLA

Mr. Chairman, thank you again for calling attention to this important topic. This is the second hearing in a month where this committee has focused on our nation's response to bioterrorism, and I commend the Chairman's leadership in addressing this issue.

Bioterrorism questions are gripping our nation and the daily news reports seem to be giving us conflicting answers. Our response is disjointed, and we do not seem to have a clear command and control structure in place. A recent GAO report called coordination of federal terrorism research, preparedness, and response programs "fragmented" and noted the presence of several different responsible agencies "limits accountability and hinders unity of effort." This needs to be corrected. Moreover, state and local authorities have not been provided clear direction on how to obtain needed assistance from Federal sources. For

example, FEMA, DOJ, CDC, and HHS's Office of Emergency Preparedness all offer separate assistance. This seems needlessly duplicative and we should examine whether there should be a single point of contact for these front line responders when they encounter what appears to be a biological attack.

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In addition, our research priorities are not clear. At least 11 agencies and departments have efforts dedicated to various aspects of bioterrorism research, from detection of biological agents, to countermeasures like vaccines and prophylaxis, to emergency response protocols and decontamination procedures and standards. These agencies differ in their focus and even on which biological agents they choose to study. These efforts need to be coordinated to assure we are getting the maximum use out of our investment dollars.

Lastly, it is unclear how the President's new Office of Homeland Security is fitting in with previously existing structures. This office was created to formally umbrella all of the efforts in homeland defense and we need to keep track of its progress in dealing with the established bureaucracies.

Despite these concerns, I want to be clear that I have no intention of micromanaging the executive branch. The agencies have different missions and different focuses. Therefore, we should expect they deal with the issue of bioterrorism differently. However, given the threat to our nation that bioterrorism represents and the tremendous amount of research that needs to be done, it is Congress's responsibility to ask these questions and make sure we are proceeding along the right track. I hope the panelists will provide some insight into these questions, and I look forward to their testimony.

[The prepared statement of Mr. Smith follows:]

PREPARED STATEMENT OF CONGRESSMAN NICK SMITH

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I want to thank the Committee Chairman, Mr. Boehlert, for holding this hearing to explore current federal investments in research and development to fight bioterrorism. With so many agencies contributing to this effort, this committee's focus on the coordination and cooperation is particularly important.

As we struggle with the implications of the horrific events of September 11, and the most devastating bioterror attack in U.S. history, we must begin to make our nation more secure by developing effective and safe methods to prevent, detect, respond to, and remediate future attacks. Our investments in research and development have produced tools and techniques that are truly amazing. Bioterrorism's most effective weapon is fear. Deadly, invisible, potentially contagious disease agents were, until recently, undetectable in the environment. But this is no longer true. Thanks to federal research efforts we have technologies to detect biological and chemical agents, we have new drugs, vaccines and therapies to treat the infected, and we have techniques and novel materials to decontaminate the environment. Some of the most promising technologies are still in the laboratory and most of these advances have never faced the challenge of real world application. So we still have a lot of work to do.

Some twenty federal agencies are engaged in this effort. Our role is to ensure that they are effectively working together to advance progress in this critical national priority. We are at war. We are at risk. We must not loose sight of the real and urgent need of our nation for the very best that science and technology have to offer. We trust our government, in cooperation with academia and industry, to meet this need. It is our job to ensure that this is done swiftly, safely, and effectively.

This panel has a wealth of experience and expertise about out current research efforts and the role and effect of coordination. I thank the panel for taking the time to speak to us today and I look forward to testimony.

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[The prepared statement of Mr. Forbes follows:]

PREPARED STATEMENT OF REPRESENTATIVE J. RANDY FORBES

Thank you, Mr. Chairman and Ranking Member, Mr. Hall, for holding this very important hearing today. I appreciate our distinguished panel taking time from their very busy schedules today to help us sort through this difficult and complex issue.

Not long after the terrorist attacks of September 11th and the subsequent discovery of anthrax-tainted mail, I held a series of town hall meetings in my district. The threat of biological or chemical weapons was a common concern at all of these meetings. As this Committee has been told before in briefings, there are so many agents that could be used as weapons in the wrong hands and there are so many methods of delivery available to evil and cunning minds that it is nearly impossible to get out ahead of this threat entirely.

The best way to minimize this threat is to meet it at its source, and that means making sure our first responders—our police, firefighters, paramedics, and local doctors—know how to spot it and know what to do when they encounter it.

I recently received a copy of a video seminar from the Eastern Virginia Medical School on bioterrorism. The school made its faculty and several experts in biological threats available to local physicians, first in a live seminar and then in a video replay, to answer their questions on such things as anthrax, smallpox, and tularemia. This is an invaluable resource for local doctors who are far more familiar with broken bones, tonsillitis, and the common cold. I encourage my colleagues to see if their local medical schools are performing a similar service for the local medical community.

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Having the right knowledge is critical to spotting these diseases when they are in their earliest stages. As we have learned so tragically with anthrax, early diagnosis and treatment is the key to saving lives. But, it is equally important that first responders have the right tools to neutralize these threats.

I have also introduced legislation that will help our local first responders perform this important service. The First Responders Homeland Defense Act expands a successful federal program that currently helps state and local law enforcement purchase the equipment they need for use in counterdrug activities. Communities across the Nation have used this program to get items as diverse as surveillance monitors, first aid kits, and spare helicopter parts with as much as a 700 percent discount. This could really help our first responders—who are our frontline of defense against terrorism—to stretch already tight budgets to perform these new duties. And, a paramedic with the right knowledge and tools in her hands can mean the difference between life and death for the patient, between a single incidence and an epidemic for the community.

I look forward to the panelists' remarks, and to working with my colleagues on this critical matter. Thank you.

[The prepared statement of Mr. Costello follows:]

PREPARED STATEMENT OF THE HONORABLE JERRY F. COSTELLO

Good morning, I want to thank the witnesses for appearing before our Committee to discuss the role of federal agencies in responding to bioterrorism. As you are aware, coordination among federal agencies is critical for homeland security and hopefully this hearing will allow us to gauge our preparedness. Over the last two months, my colleagues and I have found ourselves deeply affected by bioterrorism, so much so that stringent precautions are now being taken to deal with our mail coming to the Capitol Hill complex. However, we must remember the issue of bioterrorism and bioterrorism preparedness is not just something affecting metropolitan areas. Instead, bioterrorism is a threat to all Americans and the Federal Government must provide an efficient response.

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As a member of the Homeland Security Taskforce and through information garnered from recent committee hearings, I have been working with my colleagues to keep America safe from bioterrorism. However, the main challenge facing the Federal Government in dealing with bioterrorism is not that more assets need to be built, but that federal involvement needs to be coordinated and streamlined. Many federal agencies have been fiercely competing for the missions and money associated with a bioterrorism response, an unfortunate circumstance that has resulted in redundant capabilities, wasteful spending, and, at the local level, confusion as to which agency would lead the federal component of a response. Because of this, I am particularly interested in learning more about how we can improve accountability without hindering a unified effort, particularly in the area of research and development, and the cost of providing resources to address deficiencies in bioterror preparedness. In addition, I would like to learn more about the role Governor Ridge and the Office of Homeland Security will play in coordinating a response to bioterrorism and updating the Federal Response Plan to meet the new challenges facing our nation.

I thank all of the witnesses for being with us today and providing testimony to our committee.

[The prepared statement of Ms. Lee follows:]

PREPARED STATEMENT OF REPRESENTATIVE SHEILA JACKSON LEE

Chairman Boehlert and Ranking Member Hall, thank you for holding this important hearing on the Science of Bioterrorism. We are fortunate to have a distinguished panel of witnesses who have given their time to speak about this very important issue.

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In the wake of the horrible terrorist attacks on our country that took place on September 11, it is more important than ever that we focus our attention on research and development with the more than 20 federal agencies involved in bioterrorism activities.

The Federal Government is conducting a variety of activities related to research and preparedness for the public and medical consequences of a bioterrorist attack against the civilian population. Research activities focus on detection, treatment, vaccination, and emergency response equipment. Preparedness efforts include increasing state and local response capabilities, improving federal response capacity, developing response teams, increasing availability of medical treatments, participating in sponsoring exercises, aiding victims, and providing support at large public events. Activities in many departments and agencies have a dual use, and are not only relevant for bioterrorism but also for other types of terrorism and emergencies.

For example, the Federal Emergency Management Agency (FEMA) has a broad emergency and terrorist response system, which includes a bioterrorist response system. Department of Health and Human Services (DHHS) has programs on emerging infectious diseases that benefit its activities of bioterrorism as well as other research. I am pleased to know that some federal agencies such USDA, DOD, DOE, HHS, DOJ, Department of Treasury, and EPA are all working together and have all sponsored or conducted projects to improve the detection and characterization of biological agents.

However, according to a GAO Report, overall coordination of federal programs to combat terrorism, including bioterrorism, is fragmented within the Federal Government. For example, officials from a number of the agencies that combat terrorism indicated that the coordination roles of these various agencies are not always clear and sometimes overlap, leading to a fragmented approach. Fragmentation is also evident in the different threat lists of biological agents developed by federal departments and agencies.

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With this in mind, I look forward to hearing the testimony of these distinguished witnesses and hearing their ideas how to better coordinate bioterrorism efforts and research and development activities between federal agencies, given the events of the September 11 terrorist attacks. Thank you.

[The prepared statement of Mr. Larson follows:]

PREPARED STATEMENT OF THE HONORABLE JOHN B. LARSON

Before I begin, I would like to thank Chairman Boehlert and Ranking Member Hall for holding a hearing on this timely topic. It is my hope that this hearing will host an enlightening discussion on preparedness our

federal agencies in combating this newest threat to National Security. Let me also welcome our witnesses, Dr. Marburger, Ms. Fisher, Dr. Johnson-Winegar, and Dr. Henderson, and thank them for lending their expertise and informing us on the status of their respective agencies today.

As we have learned in the past two months, the threat of a bioterrorist attack is all too real. Five people have died of Anthrax exposure—one in my home state of Connecticut. In the past, this country has been fortunate in that we have had very few experiences of bioterrorist attacks; however, as the events of September 11th made clear, times have changed. While we have enjoyed our good fortune in the past, the recent bioterrorist attacks raise questions about our ability to deal with future threats. I have spoken with countless local law enforcement agencies, firefighters, emergency medical technicians, doctors, and constituents. They expressed to me their concerns about the coordination of future responses to bioterrorist attacks. Will the national pharmaceutical stockpile reach the cities in Connecticut in time? Will they be able to identify which type of chemical or biological weaponry they are facing? Will the manpower exist to handle an immediate surge in patient loads in medical facilities?

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We have more than 20 federal departments and agencies involved in various aspects of bioterrorism including the Department of Health and Human Services (HHS), Defense (DOD), the Federal Emergency Management Agency (FEMA), and the Environmental Protection Agency (EPA). Within HHS alone, three separate agencies, the Centers for Disease Control, the Food and Drug Administration, and the National Institutes of Health, work on various aspects of bioterrorism. Each of the agencies is working, with good intention, on preparing themselves for a bioterrorist attack. The Department of Energy works on nonproliferation and verification, the Department of Defense focuses detection devices and vaccinations, while the EPA develops water security. However, it would seem that each of these agencies—working out of separate facilities and faced with unrelenting bureaucracy—works with virtual blinders. These agencies must remove the blinders and pool their knowledge and resources to ensure our national security. With the number of agencies involved coupled with the increasing threats, it is evident that coordination and preparation are key to successful bioterrorist responses.

My discussions with local authorities and my own interest in our national security prompted my membership in the Democratic Homeland Security Task Force, and also makes this hearing of particular importance to me. Building upon the feedback I received, I incorporated the principles of coordination and preparation into two legislative proposals. I am honored to have one of my bills, the Municipal Preparation and Strategic Response Act, included in the Bioterrorism Protection Act (BioPAct), H.R. 3255. It addresses the topic of preparedness by providing $1 billion for the funding of local communities for strategic emergency response planning, counter-terrorism training, and equipment for local law enforcement agencies and firefighters.

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Whereas, the Municipal Preparation and Strategic Response Act focuses on the first responders of law enforcement, my second proposal focuses on the first responders of the field of medicine. The Regional Medical Response Act would provide $250 billion in funding to hospitals, community health centers, or

medically associated regional coordinating entity to develop regional medical disaster response plans to bioterrorism attacks. Specifically, these response plans would:

Assign responsibilities of local health units and establish a system to procure and distribute emergency supplies until federal assistance can arrive;

Specify which facilities would convert to care of infectious disease cases and which facilities would attend to the other medical emergencies that would persist through an epidemic;

Develop a system to handle the overflow of patients and provide prophylaxis to victims; designate auxiliary facilities near major hospitals and establish protocols for the conversion of sporting arenas to impromptu hospitals or the use of fire stations or other neighborhood facilities to conduct patient screening and prophylaxis;

Address how to draw upon local reserves of medical personnel such as nursing students or retired physicians;

Organize the timely distribution of the national pharmaceutical stockpile.

The two proposals when linked together should provide a basis for preparation and coordination for two spheres of a bioterrorist response. We must ensure that we are prepared on every level, federal, state, and local, to deal with such a bioterrorist attack. Any lapses in preparation and coordination will translate into the loss of life. We have already lost too many people in the attacks of September 11th. Although we may be unable to anticipate exactly when a bioterrorist attack will occur, we owe it to the American people to have the necessary procedures and responses in place to prevent any further casualties.

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Chairman Boehlert and Ranking Member Hall, I want to thank you for calling this hearing, and for allowing me to share some of my thoughts on this topic. I look forward to hearing from today's witnesses and engaging in a dynamic discussion about the role of our federal agencies in responding to bioterrorism.

[The prepared statement of Mr. Israel follows:]

PREPARED STATEMENT OF THE HONORABLE STEVE ISRAEL

Mr. Chairman, I appreciate this hearing, and I hope that it is instructive in developing a concerted and sensible response to the threat of bioterrorism. I am particularly pleased to see Dr. John Marburger here. I worked with him 20 years ago when he was president of the State University at Stony Brook.

I want to share with my colleagues an incident in my district, which reflects the inadequacies of our emergency preparedness policies—despite the heroic efforts of our first responders.

Last month, the Central Islip Post Office received a suspicious letter with a powdery substance. Postal officials properly cleared the building and contacted the Suffolk County Police Department. A police HAZMAT team responded swiftly and removed the suspicious envelope, and requested that it be tested.

Mr. Chairman, that envelope sat for nearly a week, despite efforts of local postal and police officials to home testing performed. Finally, my office intervened, the envelope was tested, and the tests proved negative.

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But it should not have taken the intervention of a Congressman to ensure testing.

Mr. Chairman, we are learning that postal workers are on the front lines in facing a bioterrorist threat. Any policy and coordination that excludes them is no better than the inappropriate decision last month to close Congress down and send us home while postal workers were left behind to continue sorting suspicious mail. So I have a few questions based on this incident. . ..

What information has been provided by EPA to "first responders" regarding how to handle suspicious items? What information is available regarding how to clean-up sites that *may* have been contaminated by anthrax?

Why did it take so long to get a definitive test from EPA's labs? What steps have been taken to improve the performance of testing and enhance communication with local officials and those who may have been exposed?

Chairman **BOEHLERT.** Thank you very much, Mr. Hall. For the purpose of an acknowledgment, the Chair recognizes the distinguished Vice Chairman, Mr. Gutknecht.

Mr. **GUTKNECHT.** Thank you, Mr. Chairman. I have distributed to members, and I hope you will take a look at the—a little gray brochure that includes some information. I want to thank the Chairman for having this hearing. And I would hope that we would have future oversight hearings because I have two principal concerns. One is that there will not be the kind of coordination that there should be among the Federal agencies. And, secondly, the temptation of those agencies to reinvent the wheel.

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And what I have distributed—and there are two gentlemen here representing a company called TSI from —and not in my district, but from the State of Minnesota, that are currently building technology that will detect biological agents in the air, and will do it continuously. As a matter of fact, I believe there is one of these devices actually being used somewhere here in the Capitol Complex even as we speak.

And the point really is that rather than reinventing the wheel, there are companies that are doing work, technology companies, today with very little in terms of Federal support that are developing these kinds of technologies that are off the shelf. And I would hope that if members have any greater interest, we do have representatives. We have Mr. Martin Abbott and Mr. Gerald Gerard from the company who can give you more information. But it really is an exciting prospect.

And I hate to say it quite this way, but if this technology had been deployed at some of our—the postal centers, it is likely that there would be postal workers who would be alive today. And, you know, we can't close—we can't go back and change that now, but I think we can make changes in the future, not only in our post offices, in our customs offices, and other Federal buildings. This technology does exist and I hope members will take an opportunity to at least read through it as the testimony is presented today. Thank you very much, Mr. Chairman.

Chairman **BOEHLERT.** Thank you very much, Mr. Gutknecht. And let me point out that the Committee intends to sponsor early in '02 a Tech Fair where we can bring together all the various innovative approaches to doing what we need to do. And we will expose the Members of the Congress to these ideas. And we are also very anxious to have a central source within the Federal Government where all these ideas can be funneled and very quickly and thoroughly evaluated.

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With that, let us go to our first and only Panel. It is a very distinguished Panel, and it is my pleasure to introduce them. The Honorable John H. Marburger, who is the Director of the Office of Science and Technology Policy, commonly referred to as the Science Advisor to the President. Dr. Marburger. The Honorable Linda Fisher, Deputy Administrator, the Environmental Protection Agency. Ms. Fisher. Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense. Dr. Winegar. And, Dr. D.A. Henderson, Director, Office of Public Health Preparedness, Department of Health and Human Services. And I would ask that you testify in the order designated.

And we would appreciate it if you could summarize your remarks in five or so minutes. I won't be arbitrary because this is a very important subject and you are very important witnesses and resources for this Committee. But if you are able to summarize, your entire statement will appear in the record. That allows more opportunity for the members of the Panel to have some questions, and we open it up to a good old-fashioned dialogue which we have always found in this Committee is the most productive. With that, let me go first with Dr. Marburger.

STATEMENT OF THE HONORABLE JOHN H. MARBURGER, III, Ph.D., DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY POLICY, EXECUTIVE OFFICE OF THE PRESIDENT

Dr. **MARBURGER.** Thank you, Mr. Chairman, and, members of the Committee. It is a pleasure to be here today at my first hearing before the House Science Committee, and I look forward to coming back in the future and responding to your requests and helping to clarify the role that the Administration has in coordinating the science and technology efforts in this war against terrorism.

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I had been very impressed with the avalanche of offers to assist, from Americans who want to help in any way they can. I have tried to find out just what the scope of these offers has been, to establish the capabilities of the various organizations outlined in my written testimony. I've been meeting with them non-

stop since I came to Washington shortly after the September 11 events. OSTP has broad mandates from both Congress and the Executive Branch to coordinate activities within the Federal agencies. And that is particularly relevant to the anti-terrorism activities that you are hearing about today.

The National Security Council under this Administration established the Policy Coordinating Committee on Preparedness Against Weapons of Mass Destruction, which is evolving in the aftermath of 9/11. The R&D subgroup of that committee will continue under a new National Science and Technology Council forum. That subgroup has initiated briefings from agencies on their bioterrorism-related R&D programs and on specific projects, ranging from intelligence assessments of threats to possible uses of the Department of Transportation's planned intelligent highway system for detecting and tracking threats. There are a number of these kinds of activities that are taking place, some of which are described in my written testimony.

When President Bush introduced the powerful concept of a war against terrorism, my first thought was how a map for such a war would differ from a conventional battle map. Conventional wars are fought for territory, easily measured on a chart with latitude and longitude and two dimensions. But the fronts in the war against terrorism cover multiple dimensions. How can we detect an unprotected flank in this complex territory? How do we measure progress? We need a taxonomy and a common language to assess threats, avoid duplication, and facilitate interagency cooperation and coordination.

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Developing such a taxonomy is a deep problem, for which I have sought the assistance from the National Academies and also from the RAND Corporation with which our office has a contract not only to perform such studies, but also to operate a database, a so-called radius database, which is turning out to be useful in this context. Some of these issues are described in greater detail in my written commentary.

I would like—as you referred to our actions on mail security, I would like to highlight them at this point. In October, I called a meeting of chief science officials from more than 15 agencies to discuss the possible role of science and technology in their agencies in combating terrorism. The need for such coordination actually arose the following week when Governor Ridge called me to ask that OSTP provide technical support for the treatment of U.S. mail potentially contaminated by Bacillus anthracis. The day after his phone call, I convened an interagency meeting with chief science officials and the U.S. Postal Service to ascertain the technical issues that they were encountering. This led to the formation, very rapidly, of an interagency technical team that within days began evaluating the irradiation facilities at the Lima, Ohio, and Bridgeport, New Jersey sites.

The point is that when the request came to OSTP, we were able to assemble an interagency team quickly and formulate a plan of attack that has worked. A similar initiative on baggage inspection is described in my written testimony, and I will be glad to answer questions about that.

Under the structure of the National Science and Technology Council, which I mentioned before, I am establishing an interagency Anti-terrorism Task Force with several working groups to address broad categories of issues.

I would like to draw special attention to what I call the fifth working group, a Technical Response Team, which is an action-oriented team that will establish small subgroups on an ad hoc basis to grapple with emergencies as they arise. This team can also serve as a clearinghouse for technical reviews of the many incoming proposals on technologies related to homeland security. It is important that we look at all of these proposals, such as the one that the Congressman from Minnesota has called our attention to, evaluate them for scientific merit, and refer them as necessary to the appropriate agency for further review.

I have been in office for a little over a month now and I have discovered that OSTP can play an important role in coordinating various S&T activities related to anti-terrorism. The overarching goal for all of the initiatives that I have described orally and in my written comments is coordination of the activities of all those who can contribute to the war against terrorism. We will draw upon the technical expertise housed in our science and technology agencies, making sure that relevant information and test results are disseminated to the appropriate parties, preventing unproductive duplication of effort and identifying opportunities for collaboration.

We also continue to work closely with the Office of Homeland Security, the Office of Management and Budget, and other offices in the Executive Offices of the President, both to make certain that they are aware of technology developments and needs and to help with their technical issues and questions.

Mr. Chairman, I have been tremendously impressed at the degree of cooperation that we have received from all the agencies that we have contacted and with the capabilities that exist in these agencies to rise to the occasion and provide rapid technical support where it is needed. Thank you.

[The prepared statement of Dr. Marburger follows:]

PREPARED STATEMENT OF THE HONORABLE JOHN H. MARBURGER, III

Introduction

Good morning Mr. Chairman and Members of the Committee. It is a pleasure to be here today at my first hearing before the House Science Committee. Your hearing focuses on an issue of critical importance—the science of bioterrorism. The Federal Government has been addressing bioterrorism issues for years, but the hideous terrorist attacks on September 11 have infused a sense of urgency in this work. Harnessing the Nation's collective S&T expertise is critical for long-term success in the war on terrorism.

The federal budget for bioterrorism R&D has been close to $400 million over the past couple of years. The agencies most heavily involved in this research are DOD, HHS, DOE, and the Department of Agriculture. In addition, there is basic research at NSF that contributes to the effort.

Those of us engaged in the federal response to the terrorist attacks have been impressed by the avalanche

of offers to assist from Americans who want to help in any way they can. During my brief tenure as Director of OSTP, I have endeavored to grasp the scope of this volunteered assistance, and to shape a federal interface to mobilize it effectively in support of the Nation's war against terrorism. To this end, I have been meeting with industry associations, non-profit groups, umbrella organizations for universities and scientific societies, and the National Academies. OSTP has established well-defined relationships with these entities to receive input from and provide guidance to their own antiterrorism projects and initiatives. At the same time, OSTP has exercised its congressional and executive mandates to coordinate activities within the federal agencies relevant to terrorism issues. OSTP is consequently in a position to call on organizations external and internal to the Federal Government as we provide technical support to the Office of Homeland Security, and other offices responsible for different aspects of the war against terrorism. I would like to describe specific examples of this activity.

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OSTP's Role in the Weapons of Mass Destruction R&D Subgroup

Under this Administration, the National Security Council established a Policy Coordinating Committee (PCC) on Preparedness against Weapons of Mass Destruction. This PCC has an R&D Subgroup that OSTP chairs. 16 agencies are represented on this R&D Subgroup including: DOD, DOC, DOE, HHS, DOJ, State, Agriculture, Treasury, DOT, EPA, NSF, the National Security Council, the Intelligence Community, and OMB.

Although the issue areas of the Weapons of Mass Destruction PCC include chemical, biological, radiological, and nuclear threats, the R&D subgroup focuses its work primarily on biological and chemical threats. Earlier this year, the R&D Subgroup reviewed a list of R&D objectives arrayed in broad categories. The categories relevant to bioterrorism included: personal protection; collective protection; detection and measurement of bio agents; recognition and characterization of covert biological weapon exposure; decontamination; vaccines and therapeutics; psychological effects; information systems, modeling simulation, and analysis; and device disablement. We identified over 100 different specific R&D objectives in these categories. This provided a framework for analyzing and assessing the program.

Some of this analysis went into the July 2001, Annual Report to Congress on Combating Terrorism, that was produced by OMB. That report followed the Subgroup's categories, gave examples of R&D in various areas, and provided a general discussion of priority areas. OSTP and the Subgroup also gave advice to OMB in the "crosscut process" on antiterrorism.

The R&D Subgroup also initiated briefings from agencies on their bioterrorism-related R&D programs and on specific projects, ranging from intelligence assessments of threats to possible uses of DOT's planned Intelligent Highway System for detecting and tracking threats. Such activities at the working level are an important method of making certain that agencies are aware of each other's work.

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Projects Tasked to RAND Corporation

In the summer of 2001, OSTP initiated discussions with the RAND corporation on the possibility of using their RaDiUS database to identify programs contributing to each of the R&D Subgroup's specific objectives. A test case was run on personal protection and the full search is now beginning and will be carried out with input from OMB.

When President Bush introduced the powerful concept of a War Against Terrorism, my first thought was how a map for such a war would differ from a conventional battle map. Conventional wars are fought for territory, easily measured on a chart with latitude and longitude, but the fronts in the war against terrorism cover multiple dimensions. How can we detect an unprotected flank in this complex territory? How do we measure progress? We need a taxonomy and a common language to assess threats, avoid duplication, and facilitate interagency cooperation and coordination. Developing a useful taxonomy is a deep problem, and I have sought assistance from the National Academies, which have established a committee to help with this and other terrorism issues.

I have also asked RAND to address this task. They began by polling the agencies on current antiterrorism R&D, starting with a simple spreadsheet on which the agencies identify their activities in broad categories. RAND will work with OSTP to make sure the level of detail is uniform and appropriate to each specific category. RAND is also coordinating its efforts with the National Academy committee. The ultimate goal of these projects is to identify gaps, duplication, and opportunities for collaboration.

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Examples of Interagency Coordination

In October I called a meeting of chief science officials from more than 15 agencies to discuss the role of science and technology in combating terrorism. Several representative agencies made presentations on their current antiterrorism-related activities, and all were asked for additional input to follow up the meeting. I convened a second meeting of this group in November to discuss the RAND project and the formation of a new antiterrorism task force under the National Science and Technology Council. These meetings gave science officials from various agencies an opportunity to interact and discuss areas of potential cooperation. It also provided a database of contacts that could be immediately contacted when necessary. Representation by other offices in the White House in these and other terrorism-related meetings varies but generally includes: OMB, Office of Homeland Security, Domestic Policy Council, Office of the Vice President, and Cabinet Affairs.

Mail Security—The need for such coordination actually arose the following week when Governor Ridge called me to ask that OSTP provide technical support for the treatment of U.S. mail potentially contaminated by *Bacillus anthracis.* The day after his phone call I convened an interagency meeting with chief science officials and the U.S. Postal Service to ascertain the technical issues that the Postal Service was encountering. This led to formation of an interagency technical team that within days began evaluating the irradiation facilities at Lima, Ohio, and Bridgeport, New Jersey. The key point is that when the request came to OSTP, we were able to assemble an interagency team quickly and formulate a plan of attack that has worked.

Baggage Inspection at Airports—The Office of Homeland Security has also asked OSTP to review the technology available for screening baggage at airports. We made use of the PWMD R&D subgroup to get suggestions of technologies not currently in use for airport baggage screening that might be deployed within a year. Last week OSTP was briefed on some of the candidates, including x-ray backscatter, neutron activation, acoustic frequency-swept interrogation, and radiometry. The purpose is not to replace the FAA's process for introducing new technologies, but rather to ensure that good candidates are considered rapidly. I would note that FAA is itself vigorously pursuing the issue and just last week held a conference devoted to potential new technologies.

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Future Structure of Interagency Coordination on Biological and Chemical R&D

Beyond these specific examples of responsiveness to Homeland Security technical needs, OSTP has been asked to fulfill the research and development component of OHS for the time being. We have been focusing most of our energies on short-term issues such as mail security, baggage screening, and civilian preparedness. But we are also taking steps to identify long-term S&T opportunities that will help the United States win the war against terrorism.

Under the structure of the National Science and Technology Council, I am establishing an interagency Antiterrorism Task Force with several working groups to address broad categories of issues. The four categorical working groups focus on Biological/Chemical Detection and Response; Radiological/Nuclear/ Conventional Detection and Response; Protection of Vulnerable Systems; and Social, Behavioral, and Education Sciences. We are establishing the Technical Response Team as a fifth working group. This action-oriented team will establish small subgroups on an ad hoc basis to grapple with emergencies as they arise. The team will also serve as a clearinghouse for technical reviews of the many incoming proposals on technologies related to homeland security. It is important that these proposals be assessed for scientific merit and referred, as necessary, to the appropriate agency for further review.

The Biological/Chemical Detection and Response working group will include most of the participants in the Weapons of Mass Destruction R&D Subgroup. The Subgroup has continued to meet informally in the interim and I expect a seamless transition to the new working group.

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Conclusion

Although I have been in office for little over a month, OSTP's role in coordinating various S&T activities related to antiterrorism has been significant. An overarching goal for all of the initiatives I have described is coordination of the activities of all those who can contribute to the war against terrorism. We will draw upon the technical expertise housed in our science and technology agencies, making sure that relevant information and test results are disseminated to the appropriate parties, preventing unproductive duplication of effort, and identifying opportunities for collaboration. We also will be working closely with the Office of

Homeland Security, OMB, and other offices in the Executive Office of the President, both to make certain they are aware of technology developments and needs and to help with their technical issues and questions.

BIOGRAPHY FOR JOHN H. MARBURGER, III

John H. Marburger, III, Science Adviser to the President and Director of the Office of Science and Technology Policy, was born on Staten Island, N.Y., grew up in Maryland near Washington D.C. and attended Princeton University (BA, Physics 1962) and Stanford University (Ph.D., Applied Physics 1967). Before his appointment in the Executive Office of the President, he served as Director of Brookhaven National Laboratory from 1998, and as the third President of the State University of New York at Stony Brook (1980–1994). He came to Long Island in 1980 from the University of Southern California where he had been a Professor of Physics and Electrical Engineering, serving as Physics Department Chairman and Dean of the College of Letters, Arts and Sciences in the 1970's. In Fall 1994 he returned to the faculty at Stony Brook, teaching and doing research in optical science as a University Professor. Three years later he became President of Brookhaven Science Associates, a partnership between the university and Battelle Memorial Institute that competed for and won the contract to operate BNL.

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While at USC, Marburger contributed to the rapidly growing field of nonlinear optics, a subject created by the invention of the laser in 1960. He developed theory for various laser phenomena and was a co-founder of USC's Center for Laser Studies. His teaching activities included "Frontiers of Electronics," a series of educational programs on CBS television.

Marburger's presidency at Stony Brook coincided with the opening and growth of University Hospital and the development of the biological sciences as a major strength of the university. During the 1980's federally sponsored scientific research at Stony Brook grew to exceed that of any other public university in the northeastern United States.

During his presidency, Marburger served on numerous boards and committees, including chairmanship of the governor's commission on the Shoreham Nuclear Power facility, and chairmanship of the 80 campus "Universities Research Association" which operates Fermi National Accelerator Laboratory near Chicago. He served as a trustee of Princeton University and many other organizations. He also chaired the highly successful 1991/92 Long Island United Way campaign.

While on leave from Stony Brook, Marburger carried out the mandates of the Department of Energy to improve management practice at Brookhaven National Laboratory. His company, Brookhaven Science Associates, continued to produce excellent science at the Lab while achieving ISO14001 certification of the Lab's environmental management system, and winning back the confidence and support of the community.

Chairman **BOEHLERT.** Thank you much—very much, Dr. Marburger. It was my high honor and distinct privilege to present you, as you well recall, to the Senate for the confirmation hearings. And I assured my colleagues in the Senate that as soon as you got in the job, all our problems would be solved. And you have been there a month already and we haven't gotten everything resolved. But I have great confidence as we look to the future.

Dr. **MARBURGER.** I apologize, Mr. Chairman, for not solving everything in a month, but I think another month might do the trick.

Chairman **BOEHLERT.** Right. And we are looking forward to great things from you and your office. Ms. Fisher.

STATEMENT OF THE HONORABLE LINDA FISHER, DEPUTY ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY

Ms. **FISHER.** Mr. Chairman, and, members of the Committee, thank you very much for the opportunity to appear before you today and describe the role that EPA has in combating bioterrorism and the Agency's research and development activities as a part of its overall mission to protect human health and the environment.

As you know, there are several Presidential decision directives that specify the role for EPA in counter-terrorism activities. Among the missions that are assigned to EPA are, first of all, assisting the FBI during crisis management in threats assessments, and determining the types of hazards associated with releases or potential releases of materials in a terrorist incident. Secondly, providing environmental monitoring, decontamination, and long-term cleanup at the site of an attack. And, third, to help ensure the safety and security of America's public water supply system.

EPA is working hard to meet each of these responsibilities. And today I would like to focus on two issues —how we are using science and, secondly, how we are working with our fellow agencies to improve the Federal Government's response to and the preparedness for future attacks.

Since coming to EPA, Administrator Whitman has made reliance on sound science one of her highest priorities. Despite the need for rapid response actions after September 11, the Agency has continued to adhere to that goal. Indeed, a team of science experts has been integral to our daily activities.

In moving to decontaminate anthrax at buildings on Capitol Hill and at other locations, our cleanup experts have been drawing on their years of experience, as well as the expertise of many others within the Federal Government and outside the Federal Government. Because the science of killing anthrax spores in an enclosed environment is still quite new, we have sought to apply the ingenuity of American business to this challenge as well. We have established a hotline for vendors who believe they have products that can effectively treat anthrax, and we are working quickly to verify those claims so that additional methods of cleanup that are developed and found to be effective can be used.

Within EPA we are also conducting a thorough review of specific cleanup technologies for anthrax. From our review, we have already determined a number of liquid and foam applications, including Sandia foam

and liquid chlorine dioxide, are effective in actually killing anthrax spores. In addition, we have found that the high efficiency particulate air filter vacuums are effective in removing particles of anthrax down to less than 1/2 micron in size.

Despite our considerable progress on all of these fronts, it is clear that the recent bioterrorism attacks have generated many scientific and technical issues that still remain unresolved. And EPA is actively involved in efforts to improve the Nation's ability to detect, prevent, and respond to, and remediate any damage resulting from future bioterrorist attacks.

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To support our current and future homeland security needs, EPA is expanding our biological testing capabilities. Recently we have taken the steps to make one of EPA's labs in Cincinnati, Ohio, capable of conducting anthrax and other biological agent tests, and we are looking at other steps that we might be able to take to further expand our capacities in this area.

We are working closely with CDC to make sure that we are fully prepared for potential future biological testing needs. In collaboration with CDC and other Federal agencies, EPA is developing a state-of-the-knowledge report that will address the chemical and biological threats to water, the capabilities for detecting these threats, and the ability of treatment to mitigate these threats to our water supply.

EPA is also in the process of planning, designing, and revising research needed to support the Agency's efforts to better prevent and manage terrorist response activities. For example, EPA is working on detection methods for biological agents. Finally, EPA is supporting efforts to address scenario-based future risks.

Since September 11, EPA has worked hard to coordinate with the other Federal agencies to develop both short and long-term solutions to the challenges posed by bioterrorism. For instance, over the past month we have participated in the meetings that were described by Dr. Marburger a minute ago. In addition, we have been asked by his office to participate in the government-wide survey on counter-terrorism science and technology. That exercise, as he described, is currently being conducted by the RAND Corporation.

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I am also pleased to report to you that EPA has developed very strong working relationships with numerous Federal partners in developing the appropriate health and safety standards for sampling and for our cleanup work. We are working very closely with CDC and the Agency for Toxic Substances and Disease Registry in the Department of HHS in the areas of sampling strategy, remediating processes, and the criteria for judging remediation process to be effective.

I should note the role of NIOSH and OSHA in providing EPA with experience in the area of worker protection both for response operations and in establishing our cleanup goals. The advice that has been provided to us by these agencies and others has been invaluable as we have tried to address the cleanup of anthrax in the Capitol Hill locations and other places around the country.

While we have been working alongside our Federal partners, we have also initiated an effort within EPA to develop a comprehensive, coordinated plan to meet the Agency's ongoing role in meeting the threat of bioterrorism, including looking at our research and development.

To help coordinate that effort, the Administrator asked me to chair a Homeland Security Work Group that includes representatives from each of our offices and regions. We are going to develop a strategic plan that will describe the Agency's efforts at preparedness and response needs, and we plan to share this product as a road map as we work with other Federal agencies that are part of the Office of Homeland Security.

Thank you for giving us the opportunity to appear before you today. In addition to our efforts to immediately respond to the threats posed by September 11, we have tried to take a step back and look at what our future needs are going to be, and we would be glad to share those with you as they become developed. Thank you, Mr. Chairman.

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[The prepared statement of Ms. Fisher follows:]

PREPARED STATEMENT OF LINDA J. FISHER

Mr. Chairman and Members of the Committee, thank you for the opportunity to describe the Environmental Protection Agency's (EPA) role in combating bioterrorism and the Agency's research and development activities as part of its overall mission to protect human health and the environment. I am pleased to say that EPA's efforts to meet its counter-terrorism obligations are consistent with the President's statement that combating terrorism and protecting the Nation's critical infrastructures are a high priority for his Administration.

INTRODUCTION

There are several Presidential Decision Directives (PDDs) that specify a role for EPA in counter-terrorism activities. PDD 39 assigned EPA the task of assisting the FBI during crisis management in threat assessments and determining the type of hazards associated with releases or potential releases of materials in a terrorist incident. EPA, as the lead agency for Hazardous Materials Response under Emergency Support Function (ESF) 10 of the Federal Response Plan, is also assigned to assist the Federal Emergency Management Agency, during consequence management with environmental monitoring, decontamination, and long-term site cleanup. PDD 62 reinforces our mission to enhance the Nation's capabilities to respond to terrorist events. PDD 63 which addresses the protection of America's critical infrastructure, named EPA the lead agency for water supply systems. EPA is working with the drinking water community to protect the Nation's drinking water supplies from terrorist attacks by assessing the security of drinking water systems and by sharing information in a secure way with water systems.

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Under the provisions of PDD 62, signed by President Clinton in 1998, the EPA is assigned lead

responsibility for cleaning up buildings and other sites contaminated by chemical or biological agents as a result of an act of terrorism. This responsibility draws on our decades of experience in cleaning up sites contaminated by toxins through prior practices or accidents.

In this testimony, I will describe EPA's cooperative role and interaction with other federal agencies and departments to deal effectively with threats to human health and safety from bioterrorism. I will also discuss our strategies and tools for sampling and remediation, touch on EPA's counter-terrorism incident response activities, and conclude with a discussion of EPA's research and development activities.

SHARING SCIENTIFIC INFORMATION AMONG FEDERAL AGENCIES

Working with our federal partners, private sector experts, and drawing upon our considerable in-house expertise, EPA has been developing new methods and protocols, and standard operating procedures to deal with bioterrorism threats to the health and safety of the American people. And we have been doing so on a real-time basis. The speed of our response, however, has not been at the expense of sound science. Indeed, a team of science experts has been integral to our daily activities.

EPA's interagency involvement in scientific issues related to counter-terrorism and critical infrastructure protection predate the events of September 11. Since 1998, EPA has been actively involved in Interagency Research and Development Working Groups on both Critical Infrastructure Protection and Weapons of Mass Destruction. These groups, formed and chaired by the White House's Office of Science Technology Policy (OSTP), were created in response to PDDs 62 and 63. For several years, these groups have allowed federal agencies to work together to share information and to prepare the federal research and development programs and budgets for these topics. Representatives from the Office of Management and Budget's (OMB) National Security Office have been active participants in the working groups. More recently, these groups have served as fora for sharing scientific and technical information on threats, including anthrax. Scientific and technical representatives from civil, military, and intelligence agencies and departments have all been involved in this effort.

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Over the past month, EPA has participated in government-wide meetings of chief agency and departmental counter-terrorism scientists. These meetings, convened and chaired by Dr. John Marburger, the Director of OSTP, were designed to help him fulfill his role as science consultant to Governor Ridge and the Office of Homeland Security. In late November, following the second of the senior science officials meetings, EPA was asked by OSTP to participate in a government-wide survey on counter-terrorism science and technology, which is intended to facilitate interagency cooperation in these areas. This exercise is currently being conducted by the RAND Corporation at the request of Dr. Marburger.

In order to develop a comprehensive, coordinated plan to deal with bioterrorism, including the area of research and development, the Administrator has assembled a Homeland Security Working group that includes representatives from each EPA program office and region. This work group is in the process of drafting an EPA strategy for homeland security that includes a plan for bioterrorism using the Agency's Scientific Advisory Board (SAB) and other advisory committees to the Agency to develop research related to bioterrorism.

EPA established and maintains a National Incident Coordination Team (NICT) to assure full agency coordination of all emergency preparedness and response activities including counter-terrorism. In the regions, the Agency's first responders are the On-Scene Coordinators (or OSCs). The OSCs have been actively involved with local, state, and federal authorities in preparing for and responding to threats of terrorism. EPA's OSCs, located throughout the U.S. have broad response authority and a proven record of success in responding rapidly to emergency situations.

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SHARING FEDERAL EXPERTISE TO DEVELOP REMEDIATION STRATEGIES

We have developed extraordinarily strong working relationships with numerous federal partners in developing the appropriate health and safety standards and in conducting our sampling work We have worked very closely with the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ASTDR) in the Department of Health and Human Services in the areas of sampling strategy, remediating processes and criteria for judging a remediation process to be effective. In particular, the National Institute for Occupational Safety and Health (NIOSH) within CDC has been extremely helpful as has been the Department for Labor's Occupational Safety and Health Administration (OSHA) in providing EPA expertise in the area of worker protection, both for response operations and in establishing cleanup goals. We also appreciate the input from the Department of Defense, particularly the Center for Health Promotion and Preventive Medicine and United States Army Medical Research Institute for Infectious Diseases. The Coast Guard and Marines have assisted with sampling and cleanup. Finally, the District of Columbia government has provided invaluable expertise and assistance in involving the community. The advice provided by these agencies has been invaluable in our efforts to develop specific remediation plans for buildings in the Capitol complex.

Within EPA, we are conducting a thorough review of specific clean-up technologies. Specifically, our Office of Solid Waste and Emergency Response, the Office of Pesticides, our Emergency Response Team out of Edison, NJ, the Emergency Operations Center here in Washington, and the legion of responders from across the country led by our folks from Region III, have all played important roles in this effort.

From our review, we have determined that a number of liquid and foam applications are effective at actually killing spores. Sandia Foam is a patented product, developed by the Sandia Labs, that we have been able to use on a number of surfaces. Similarly, chlorine dioxide in a liquid form, has been an extremely effective sporocide. We know these techniques work because we have used them in a number of areas. To address airborne particles, HEPA (high efficiency particulate air) filter vacuums are able to capture particles down to less than one-half micron in size. We have resampled these areas after using these techniques and they have come back clean.

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The Agency continues to work closely with other federal agencies, emergency response teams, and independent experts to develop effective remediation tools. On the basis of site specific information, EPA

recommends proper methods of decontamination including which antimicrobial or other substances will be used. EPA has also established a hotline for venders who believe they have products that could effectively treat anthrax and has begun daily briefings to establish routine communication between on-site personnel and key centers within the Agency who oversee and/or support them. EPA laboratories are assisting in testing samples from potentially contaminated sites and the evaluation of antimicrobial products for effectiveness against anthrax has been made a top priority. In addition, EPA is using its experience in this situation to develop approaches to handling future biological and chemical exposures should they occur.

EPA is responsible for registering pesticides, including antimicrobial products used to treat anthrax spores, prior to their marketing in the U.S. Before issuing a pesticide registration, the Agency reviews a significant body of data to determine whether use of that pesticide will result in unreasonable adverse effects to humans or the environment. These data can include information on short- and long-term toxic effects and examine the potential for exposure under expected application scenarios. For pesticides that have public health uses, such as those used on anthrax spores, EPA also critically evaluates their efficacy. Under emergency conditions, EPA may allow a new use of a previously registered pesticide or use of an unregistered pesticide where the Agency has sufficient data to make a safety finding. These decisions can often be made quickly, based on the data that EPA receives and reviews.

Responding to the anthrax contamination has presented some unique challenges for EPA. For example, currently there are no registered pesticides approved for use against anthrax. Since the beginning of the anthrax-contamination events, EPA has been working hard to identify and evaluate existing pesticide products that are sporicidal, that is, those that kill spore-forming bacteria, even though such products may not have been tested on anthrax per se. Since October, the Agency has approved three pesticide products for treating anthrax spores under emergency exemption provisions of existing pesticide laws—the aqueous solution of chlorine dioxide, the chlorine dioxide fumigant, and a foam used to treat anthrax-contaminated surfaces. We have identified several potential chemicals and new technologies which may be effective against anthrax.

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The tools in our toolbox are growing rapidly. Each method, though, will have to prove its effectiveness before we add it to our Standard Operating Procedures. And that proof will come from confirmation samples that are taken after remediation is complete and come back demonstrating no threat to human health.

EPA'S COUNTER-TERRORISM INCIDENT RESPONSE ACTIVITIES

As EPA continues to strengthen its counter-terrorism program by building on the existing national response system for hazardous materials (hazmat) prevention, preparedness, and response, the Agency is involved in a variety of activities with federal, state, and local officials that include: responding to terrorism threats; pre-deploying for special events; planning, coordination, and outreach; and training and exercises. Most recently, EPA was asked to chair the Security and Safety of U.S. Facilities Group of the National Security Council's Policy Coordinating Committee for Counter-terrorism and National Preparedness.

EPA'S RESEARCH AND DEVELOPMENT ACTIVITIES

The recent bioterrorism attacks have generated many scientific and technical issues that remain unresolved. EPA is actively involved in efforts to improve the Nation's ability to detect, prevent, respond to, and remediate the damage resulting from bioterrorist attacks or future threats. EPA is providing scientific expertise and advice for the monitoring and risk assessment efforts at the World Trade Center (WTC). In addition, EPA continues to provide scientific expertise and guidance on biological testing and risk assessment and risk management efforts, as needed.

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To support current and future homeland security needs, EPA is examining the possibility of expanding its biological testing capabilities. EPA's laboratory in Cincinnati is capable of conducting anthrax and other biological agent tests. EPA is working closely with CDC to make sure we are fully prepared for potential future biological testing needs.

In collaboration with CDC and other federal agencies, EPA is developing a "State of Knowledge" report that addresses: (1) the chemical and biological threats to water; (2) capabilities for detecting these threats; and (3) the ability of treatment to mitigate these threats. EPA is in the process of planning, designing and revising research needed to support Agency efforts to better prevent and manage terrorist response activities. For example, EPA is working on developing rapid detection methods for biological agents. Finally, EPA is supporting efforts to address scenario-based future risks.

CONCLUSION

September 11th has changed the world in which we live. EPA continues to rely on sound science and effective treatment techniques to address incidents of bioterrorism. We are proud to be a part of a massive public-private effort to meet the challenges of this new world.

Thank you for the opportunity to appear before you today. I would be happy to answer any questions that you may have.

BIOGRAPHY FOR LINDA J. FISHER

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Linda J. Fisher, Deputy Administrator of the U.S. Environmental Protection Agency, has spent more than 17 years in government service and in the private sector devoting herself to environmental issues and improving the protection of public health in America. During the decade she has been involved directly with EPA, she has held more high-ranking positions than any other person in the Agency's history. Those positions include serving as the Assistant Administrator for the Prevention, Pesticides and Toxic Substances program, as the Assistant Administrator for the Office of Policy and Planning, and as the Chief of Staff to EPA Administrator Lee M. Thomas.

During her tenure at EPA, she has been responsible, among many projects, for working with Congress to ensure the continuation of a reformed and improved Superfund program for cleaning up toxic wastes and

strengthening our nation's food safety laws. She also played an instrumental role in developing the Agency's first reports on climate change.

In addition to her EPA experience Ms. Fisher worked in the U.S. House of Representatives. In the private sector she served as an environmental attorney for the law firm of Latham & Watkins and was a Vice President of Monsanto for government and public affairs.

Ms. Fisher is dedicated to EPA's employees and workforce and has described them as "among the most skilled and dedicated public servants working in government today." She has stated that her goal in returning to EPA as its current Deputy Administrator is "to support President Bush and Administrator Whitman in working closely with local communities to ensure that all Americans have cleaner air and safe waters, and to do so in ways that make solid economic sense."

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Ms. Fisher is originally from Columbus, Ohio, and received her undergraduate degree from Miami University of Ohio; her Masters degree in Business from George Washington University; and her law degree from Ohio State University.

Chairman **BOEHLERT.** Thank you very much. Dr. Johnson-Winegar.

STATEMENT OF ANNA JOHNSON-WINEGAR, Ph.D., DEPUTY ASSISTANT TO THE SECRETARY OF DEFENSE FOR CHEMICAL AND BIOLOGICAL DEFENSE, DEPARTMENT OF DEFENSE

Dr. **JOHNSON-WINEGAR.** Mr. Chairman, and, distinguished Committee members, I thank you for the opportunity to speak with you today. As many of you are well aware, the Department of Defense has seriously considered the threat of biological weapons a possible means by which state or nonstate actors might, indeed, try to counter America's overwhelming conventional war-fighting strength. Much of our investment to address the biological weapons threat, I think, may be helpful to the civilian community.

As you have requested, I wish to focus my comments today on two topics. First, some of the research and development work that the Department of Defense has invested in over the years that may, indeed, today improve the Nation's ability to detect, prevent, respond to, and remediate bioterrorist attacks. And, second, a few comments on how we, at the Department of Defense, are working with some of our other Federal agency partners.

Within our program for biological defense, we generally categorize our efforts into three operational principles. First, contamination avoidance; second, protection; and, third, restoration. Our Contamination Avoidance Program provides automated capabilities to detect, locate, identify, quantify, sample, and plot the extent of suspected biological agent threat hazards and to provide for medical surveillance capabilities. Our protection programs include both medical and non-medical means taken to protect the war fighter from battle-space biological agent hazards. And, third, restoration capabilities include, again, both medical and non-medical measures required to restore our forces, our units, our facilities, and equipment, to near normal operating conditions.

I would like to ask that we could have the slides on, please. I took the liberty of bringing a few pictures with me today to point out some of the things that the Department of Defense has worked on and fielded. Shown here is our biological integrated detection system, which is mounted on a military vehicle. And the chart on the right shows a similar system, which is configured to be mounted on our ships. Both of these are capable of detecting a number of different biological warfare agents in a relatively short period of time, although not real time, as you can see. And we are working diligently to reduce the time required for these systems to work, as well as to increase the specificity and sensitivity.

On this chart is shown a picture of the inner workings of the Biological Integrated Detection Suite, and you can see that it is comprised of an aerosol particle counter, bioluminescence analyzer, and an antibody-based detector system. I have provided more detail of this to your staff, and would be happy to answer any specific questions on those.

Shown here is the—excuse me—biological and chemical mass spectrometer, which is, again, an item that we are using to provide a detection capability for chemical and biological agents. Shown here is the M99 portal shield. This particular device is currently fielded at a number of different locations. Again, as shown here, it can detect eight different biological warfare threat agents using an immuno-assay based system. Again, we are working to reduce the size and weight and to provide a better capability for that particular device.

The next chart shows our biological sampling kit, which is, again, based on an immuno-assay type of procedure, which can be used to assay material taken from swabs of surfaces in a number of different areas.

Moving to the area of decontamination, shown on this chart is our M291 skin decontamination kit, which is a resin-based material that can be used to remove chemical and biological agents from human skin. Shown here are pictures of individuals applying decontamination materials. And my final chart shows pictures of a sorbent decon material which we think is an improvement over existing types of decontamination materials. If we could have the slides off? That was the last of my charts.

In addition to the areas of detection and decontamination that I have mentioned, we are also continuing to improve our efforts in medical programs, addressing countermeasures that can be used before attack, as well as things that can be used post-exposure.

I think that the Department of Defense brings an awful lot of technology and expertise to the table. We are anxious to work with the other Federal agencies, with the civilian sector, with academia, and industry. We have been, and continue to be, participants in a number of the interagency groups that have been described by Dr. Marburger, and we look forward to continuing opportunities to work with them.

As well as OSTP and EPA, who have already mentioned it, the Department of Defense has received innumerable inquiries and offers of help from the public, from industry, and from academia. We are

rigorously pursuing those and looking at the best way that we can to interact with those folks. I think that for operational responses to biological terrorism, the Department of Defense is working closely with those agencies that are identified as the lead Federal agencies, as defined in the Federal Response Plan. We are working closely with them, both on our R&D efforts, as well as those things which are fielded and ready to be used today.

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I give you my commitment that we will continue to work closely with the other agencies, both in the context of ensuring that the war fighter is protected, which is the primary mission for the Defense Department, as well as working with the other agencies to provide those technologies so that all U.S. citizens are provided as great a deal of protection as we can possibly imagine.

I fully appreciate the great challenge that we have in front of us and look forward to the opportunity to answer your questions and to work with the other agencies.

[The prepared statement of Dr. Johnson-Winegar follows:]

PREPARED STATEMENT OF ANNA JOHNSON-WINEGAR

INTRODUCTION

Mr. Chairman and distinguished committee members, I am Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense. My office is the single focal point within the Office of the Secretary of Defense responsible for oversight, coordination, and integration of the joint Chemical and Biological Defense Program.

The tragic events of September 11th and the anthrax cases have heightened the public's awareness of the threat posed by biological terrorism. The Department of Defense has seriously considered the threat of biological weapons as a possible means by which states or non-state actors might counter America's overwhelming conventional warfighting strength. In response to the threat and consequences of bioterrorism. Today I wish to focus on the following topics:

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First, research and development work of the Department of Defense that may improve the Nation's ability to detect, prevent, respond to, and remediate bioterrorist attacks;

Second, planning, coordination, and execution of activities to counter bioterrorism—with a focus on science and technology development activities—between the Department of Defense and other federal agencies.

DOD RESEARCH AND DEVELOPMENT TO ADDRESS BIOTERRORISM

Overview and Program Drivers for DOD Biological Defense Science and Technology

Following Operation Desert Storm, the Department of Defense studies identified shortfalls in biological defense capabilities. One result was Congressional direction to the Department of Defense to consolidate chemical and biological defense efforts. In response to Congressional direction in the FY94 National Defense Authorization (P.L. 103–160), DOD established a joint Chemical and Biological Defense Program. The vision of the DOD Chemical and Biological Defense Program (CBDP) is to ensure U.S. military personnel are the best equipped and best prepared force in the world for operating in future battlespaces that may feature chemically and biologically contaminated environments. The capabilities developed and fielded by the CBDP focus on addressing the needs of the warfighter. As the events of the past few months have shown, the future battlespaces for our warfighters are evolving. Likewise, civilian organizations may increasingly turn to the Department of Defense to leverage technology development efforts to support the needs of homeland security.

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The objective of the CBDP is to ensure our forces can maintain freedom of action during deployment, maneuver and engagement, while providing multi-layered defenses for our forces and facilities at all levels. This is accomplished by protecting the force, and minimizing the impact of biological weapons on joint force operations. The CBDP does not provide one capability, but rather a system-of-systems to support joint force operations, intelligence and logistics capabilities. Specific programs and plans are developed to support national military strategy and objectives. The *Joint Warfighting Science and Technology Plan* is the key planning document, which outlines DOD needs and plans for biological defense to support the warfighter. Key science and technology programs are reviewed annually by an independent expert panel to ensure relevant technologies are being considered and technology risks are appropriately addressed. Specific programs for biological defense programs are defined within Operational Requirements Documents, which provide the basis for advanced development and acquisition. In order to ensure science and technology efforts support future warfighter needs, the Services develop a report documenting Joint Future Operational Capabilities to provide guidance to the science and technology community. Key science and technology projects are defined by Defense Technology Objectives, which highlight high priority science and technology efforts. Finally, the Department funds and leverages a broad array of basic research efforts in biological sciences and related fields.

Programs for biological defense are categorized broadly under three operational principles: *contamination avoidance, protection,* and *restoration. Contamination avoidance* provides automated capabilities to detect, locate, identify, quantify, sample, and plot the extent of all suspected threat agent hazards, and medical surveillance capabilities. *Protection* includes all medical and non-medical means taken to protect the warfighter from all battlespace biological agent hazards while maintaining normal operational mission tempo. The focus of protection is to prevent exposure or the effects of exposure, and includes medical capabilities, such as vaccines, and non-medical capabilities such as masks for respiratory protection. *Restoration* capabilities include medical and non-medical measures required to restore the joint force, units, facilities, and equipment to near-normal operating conditions after being challenged by a biological agent hazard. These measures include non-hazardous decontamination operations, effective supply and sustainment of all defense assets, and effective medical diagnostics and post-exposure countermeasures

required to allow rapid determination of agent exposures and subsequent treatment. *Battlespace management* supports all three principals. *Battle management* includes capabilities to securely access, assimilate, and disseminate medical and non-medical information throughout the joint battlespace, to analyze this information, to predict current and future operational impacts of agent hazards' and to model and simulate the totality of mission operations within the context of the contaminated environment.

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DOD Biological Defense Science and Technology Efforts

The fiscal year 2002 President's Budget Request for the DOD Chemical and Biological Defense Program, the Department of Defense included $508 million for research, development, test, and evaluation and $349 million for procurement for a total of $857 million. The specific funding allocations are detailed in the Annual Report to Congress on the Chemical and Biological Defense Program as well as in the detailed budget requests submitted to Congress. This funding provides support for a variety of state of the art research and development activities to address future warfighting needs. I will provide an overview of some of the technologies used in currently fielded systems, and provide some detail of the science and technology base efforts to provide advanced capabilities to meet current and future needs. Following the descriptions of the science and technology programs, I will provide an overview of the process by which we coordinate these research efforts with other federal agencies.

DOD Biological Defense Science and Technology Efforts—Contamination Avoidance

Three of the key biological detection systems fielded today are the Biological Integrated Detection System, Portal Shield, and the Biological Weapons Agent Sampling Kit.

Biological Integrated Detection System (BIDS) uses a multiple technology approach to detect biological agents with maximum accuracy. BIDS is a vehicle-mounted, fully integrated biological detection system. The system is modular to allow component replacement and exploitation of "leap ahead" technologies. The initial version is capable of detecting and presumptively identifying four biological agents simultaneously in less than 45 minutes. The planned upgrade will be capable of detecting and providing presumptive identification of 8 biological agents simultaneously in 30 minutes. The suite is semi-automated and contains next generation technologies such as the Ultraviolet Particle Sizer, Chemical Biological Mass Spectrometer, and the Biological Detector. The Ultraviolet Particle Sizer provides near real-time generic detection and indicates whether particles are biological and whether they are respirable (that is 1 to 10 microns in size). The Biological Detector is an antibody-based device capable of identifying specific biological agents. It consists of electronics processing equipment, fluid processing modules, reservoirs for antibody reagents, and a light addressable potentiometric sensor to provide biological agent identification. It provides identification of the biological agent detected and the relative concentration of biological particles in the atmosphere. The Chemical Biological Mass Spectrometer (CBMS) detects and characterizes chemical and biological threat agents. The CBMS does not provide specific identification of biological agents, but provides generic detection (biological or non-biological) and categorizes them based on the predominant phospho- or other polar lipid detected in the mass spectra (for example, indicates whether the particle are encapsulated viruses, or gram-positive or gram-negative bacteria).

Portal Shield is a network sensor system that provides automated biological point detection capability to protect high value fixed sites against BW attacks. The sensor is modular in design and can detect and presumptively identify up to eight biological agents simultaneously in less than 25 minutes. It uses an aerosol collector and ultraviolet particle sizer and detects agents by means of immunochromatographic assay tickets.

Biological Weapons Agent Sampling Kit uses low cost, disposable assay ticket which can provide rapid detection from environmental samples. This uses a similar detection technology as Portal Shield but is intended to support manual sampling.

One of the key developmental capabilities that could further enhance detection capabilities is the Joint Biological Point Detection System, which will provide automated point biodetection, with reduced size, weight, and power requirements compared to existing systems.

Within the science and technology base, the following Defense Technology Objectives detail key biological detection efforts.

Standoff Biological Aerosol Detection—The objective of this effort is to develop and demonstrate technology for an advanced, wide-area, standoff biological detection capability to both detect and discriminate biological aerosol clouds at operationally significant concentrations. Some technologies under consideration include imaging (ultraviolet (UV), near infrared (IR), long wave IR), millimeter wave, and polarization (UV, IR) spectroscopy.

CB Agent Water Monitor—The objective of this effort is to develop system concepts and technologies for the detection and identification of hazardous chemical and biological agents in potable water. The system will most likely consist of two or more integrated technologies that have been optimized to meet a specific challenge. Current biological detection technologies rely on analytical techniques, which range in processing times from hours to days. Hundreds of commercially available water test kits have been evaluated for potential to meet user needs. In addition, key technology development effort include Fourier Transform InfraRed Attenuated Total Reflection (FTIR–ATR) spectroscopy, molecular imprinted polymers, Biodetection immuno-tickets, Pyrolysis-Gas Chromatograph-Ion Mobility Spectroscopy (GC–IMS), Surface-Enhanced Raman Spectroscopy, and automated colorimetric test kit.

Activity-Based Detection and Diagnostics—The objective of this effort is to demonstrate engineering of cells and tissues that is directed toward the development of activity detection systems for biological and chemical threats. The program approach is based on robust extraction of cell and tissue signatures of agent response and could provide detection of hazardous materials based on physiological response rather than the specific construction of the biological pathogen or toxic compound.

CW/BW Agent Screening and Analysis—The objective of this effort is to provide enabling technologies to

support monitoring of non-proliferation efforts such as the Biological Weapons Convention, and which may be used for security screening for homeland security. A variety of technologies are being explored to support specific objectives, including (1) Agent and Byproduct Extraction Technologies-for effective and rapid isolation of target compounds from complex samples; (2) Agent and Byproduct Screening Technology-develop hand-held real-time, simple-to-operate screening methods devices for field operations; (3) Agent and Byproduct Determinative Analysis-to increase instrument analytical speed and sample throughput, improve instrument portability and ruggedness, and develop target compound-specific analytical libraries; and (4) Remote and Nondestructive Evaluation Techniques-develop highly portable, noninvasive interrogation equipment for agents and their precursors or byproducts within containers of all compositions shapes and configurations.

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Biological Warfare Defense Sensor Program—The objective of this effort is to develop a fully integrated, well-characterized sensor system for the effective real-time detection of biological agents to enable pre-exposure detection and discrimination. To accomplish this task, the fabrication of the first-generation automated time-of-flight mass spectrometer was developed and characterized.

In addition to these technologies, a variety of other technologies are being developed under the science and technology program to address specific technology limitations related to the detection and identification of biological agents. Key technologies to *detect aerosols at a distance* include differential scattering/ differential absorption of light (DISC/DIAL), Frequency Agile Laser (FAL), Light Detection and Ranging (LIDAR), and infrared sensors. Key technologies for *point detection and identification* of biological agents by species and strain include flash GC/MS, Bio MS, microfluidics, force diffusion assay, polymer technologies (e.g., electroactive, nonspecific doped), aerogel characterization/development, Up-converting phosphors, gene probe sensors for Polymerase Chain Reaction (PCR) diagnostic systems, biodiffractive grating sensors, multi-array and single-particle detection technologies, and molecular recognition technologies (e.g., DNA sequencing). Key technologies for *surface contamination detection* of biological agents include Time-of-Flight Mass Spectrometer, and biocontaminant detection and identification strategies, such as culture quantitation and quantitative PCR analysis. Key technologies for *medical surveillance* are being developed to support disease identification as rapidly as possible. Technologies for mobile laboratory specimen analysis include rapid and automated dissemination, recording and archiving of medical surveillance reports and analyses, rapid hand-held screening assays and immuno-assays, and specimen processing/gene amplification. Technologies for rapid biological sample preparation and screening include microfluidics, biomarker ionization, PCR, optical fiber simultaneous orthogonal detection, bacterial endospore detector, force amplified biosensor, and gene probe detection.

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In addition, basic research and supporting sciences are being leveraged. One example is *aerosol sciences* for advance aerosol collection systems with significantly reduced size and power requirements and improved collection efficiency. One of the most important research areas being exploited is genomics and related basic sciences. Advances in genomics have provided genome maps of many of the pathogens of

concern, including *Yersinia pestis* (plague) and *Bacillus anthracis* (anthrax) among others. Genome maps provide fundamental scientific understanding that will be used to develop understanding of disease pathogenesis, advanced vaccines, diagnostics, detection systems, and other methods to counter the effects of pathogens.

DOD Biological Defense Science and Technology Efforts—Protection

Protection capabilities include non-medical and medical technologies. *Non-medical protection* includes efforts to prevent exposure to or the effects of biological agents. The primary route of exposure for biological agents is by inhalation. A variety of protective masks have been developed and fielded to protect individual from exposure. To protect against exposure as a result of contact, various protective clothing items, including suits, boots, and gloves, have been fielded and advanced systems are under development. Within the science and technology base, the following Defense Technology Objectives detail key protection efforts.

Advanced Adsorbents for Protection Applications—The objective of this effort is to develop advanced adsorbent bed materials and compositions to enhance the chemical agent and toxic industrial materials air filtration protection capabilities of current single-pass filters and regenerative filtration systems under development; and reduce the size, weight, encumbrance, and cost of existing filtration systems. Technologies being developed include temperature and pressure swing adsorption (TSA/PSA) techniques to support regenerable filtration, and a variety of novel adsorbent technologies, such as carbon nanotubes; novel carbon, silica, alumina-based reactive sorbents; metal oxide nanoparticles, surface modified carbon, reactive impregnated carbon, novel structured carbons, and layered adsorbents.

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Self-Detoxifying Materials for CB Protective Clothing—The objective of this effort is to incorporate agent reactive catalysts and biocides directly into protective clothing and demonstrate their capability to self-detoxify. Technologies may include electrospun self-detoxifying membranes, N-halamine treated textiles, and materials containing reactive nanoparticles.

Medical protection includes efforts to prevent the effects of biological agents. Technologies include vaccines to protect against viral, bacterial, and toxin agents, and advanced delivery mechanisms. While advances in biotechnology and genetic engineering poses the threat resulting from the development of biological agents designed to defeat detection or protection capabilities, advances in these sciences provide powerful tools to protect against a broad spectrum of pathogens. Within the science and technology base, the following Defense Technology Objectives outline key medical protection efforts.

Medical Countermeasures for Encephalitis Viruses—The objective of this effort is to develop medical countermeasures against threat of the Venezuelan equine encephalitis (VEE) viruses (members of the alphaviruses family). Recombinant vaccine technology will be exploited to provide effective vaccine candidates.

Multiagent Vaccines for Biological Threat Agents—The objective of this effort is to produce a vaccine or vaccine delivery approach that could be used to concurrently immunize an individual against several

biological threats. Bioengineered and recombinant vaccine technologies (naked DNA vaccines or replicon vaccines) will be exploited to achieve multivalent vaccines that are directed against multiple agents, yet use the same basic construct for all of the agents.

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Medical Countermeasures for Brucellae—The objective of this effort is to develop a genetically characterized live, attenuated vaccine that elicits cellular and humoral immunity against the four pathogenic species of Brucella and that is capable of protecting 90 percent of vaccinated warfighters against disease after aerosol challenge.

Recombinant Protective Antigen Anthrax Vaccine Candidate—The objective of this effort is to characterize (biochemically and immunologically) a recombinant protective antigen (rPA) anthrax vaccine, including preliminary development of an appropriate *in vitro* correlate of PA-induced protective immunity against *Bacillus anthracis* aerosol exposure. This supports the development of the next generation anthrax vaccine that will provide equal or greater protection over the current vaccine, reduce the number of shots required to induce immunity, and have fewer adverse effects.

Recombinant Plague Vaccine Candidate—The objective of this effort is to complete the pre-clinical development of the recombinant F1–V fusion protein plague vaccine candidate. Successful completion of this recombinant vaccine will provide protection against aerosol exposure.

Needle-less Delivery Methods for Recombinant Protein Vaccines—The objective of this effort is to develop alternatives to the injection of recombinant protein-based vaccines that result in mucosal and systemic immunity to these agents. This effort will seek to determine whether the route of administration of a vaccine can induce improved mucosal, systemic, humoral, or cellular immunity, especially for protection against aerosolized pathogens, including staphylococcal enterotoxins (SE), *Bacillus anthracis* (anthrax), and *Yersinia pestis* (plague). Intranasal, transdermal, inhalation, or oral immunization strategies may be safer and more efficacious methods for stimulating mucosal and systemic immunity. These strategies will be useful for the administration of a significant number of vaccines currently planned to obtain total force protection.

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In addition to these technologies, a variety of other technologies are being developed under the science and technology program to address specific technology limitations related to the development of medical prophylaxes against bacterial, viral, and toxin agent hazards, including all identified validated threat agents. Key technologies include recombinant vaccine development efforts (e.g., gene insert, gene shuffling techniques), immunomodulators to provide enhanced immunity against any pathogen, active and passive immunoprophylaxes, novel genomic, molecular genetics, molecular phylogeny, active site-directed inhibitors, receptor antagonists, and small molecule antibiotics and protein inhibitors.

Vaccines provide a critical capability for protection against biological warfare agents. In order to

transition vaccine technologies from the laboratory to production, the Department of Defense established the Joint Vaccine Acquisition Program (JVAP) in 1997 to facilitate compliance with clinical trials and to procure sufficient quantities of biological defense vaccines to protect U.S. forces. However, production efforts under the JVAP are not sufficient to meet all requirements. Currently, the Department of Defense is working with numerous other organizations—including Health and Human Services, the Office of Homeland Security, and others—to evaluate the feasibility of a national vaccine production facility that would provide sufficient vaccines to protect not only U.S. forces, but the civilian population of the United States, and possibly other countries as well. The overall plan and requirements for this facility have been outlined in a report entitled, "Report on Biological Warfare Defense Vaccine Research & Development Programs," which was submitted to Congress in July 2001.

DOD Biological Defense Science and Technology Efforts—Restoration

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Restoration capabilities include technologies for *medical therapeutics, medical diagnostics*, and *decontamination.* The medical treatment of biological agents requires a response tailored to each specific threat. Advanced technology approaches are also focusing on generic approaches that will provide broad spectrum protection against a variety of biological agents. A critical capability for effective treatment includes training to recognize and treat biological agents through such courses as "Medical Management of Biological Casualties" and related courses, which are available on the internet at *www.biomedtraining.org.* Therapies that improve survival and lessen time for return to duty have been developed. These include commercially available antibiotics, including ciprofloxacin, doxycycline, and tetracycline. Antiviral therapeutics are being developed for orthopoxviruses. In the near term, DOD plans to deliver a technical data package supporting investigational new drug for labeled use of cidofovir for post-exposure treatment of smallpox. Rapid portable diagnostics enabling quick medical response for exposed warfighters are being pursued. Currently fielded diagnostics capabilities rely on immunological response assays. The Joint Biological Agent Identification and Diagnosis System is being developed and would be based on genetic primers using polymerase chain reaction (PCR) technology to provide more rapid and accurate diagnosis. The key Defense Technology Objectives that support therapeutics and diagnostics are:

Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases—The objective of this effort is to develop state-of-the-art technologies (platforms/devices) capable of diagnosing infectious disease and biological agents in clinical specimens. The devices will be used by preventive medicine personnel for disease surveillance and monitoring, and by medical laboratory personnel for the diagnosis of disease due to natural and BW threat agents. Efforts will focus on an immunologically based membrane device to rapidly detect host immune responses to etiologic agents or the antigens or products of the agents themselves, and on miniaturized polymerase chain reaction technology for detection and identification of nucleic acids of natural infectious disease and biological agents.

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Therapeutics Based on Common Mechanisms of Pathogenesis—The objective of this effort is to develop a suite of medical countermeasures against broad classes of biological pathogens (bacterial, viral,

bioengineered, etc.) that share common mechanisms of pathogenesis.

In addition to these technologies, a variety of other technologies are being developed under the science and technology program to address specific technology limitations related to the development of medical therapeutics and diagnostics. Some technologies for *therapeutics* include gene therapy, immunotherapy, antibacterial therapeutics (e.g., bacterial lytic enzymes, complex biosignatures, novel broad spectrum antibiotics, genetic metabolic path, broad spectrum antibodies, thioaptamers, nanoparticles, target pathogen DNA, antigenomic countermeasures, transcriptional/translation inhibitors), antiviral therapeutics (e.g., novel viral blocking, stock drug subunits, universal path protection, second-generation vaccines, genome based agents, pokeweed antiviral protein, combinatorial technology, antigenomic countermeasures, prodrug development, countermeasures for viral induced effects), and antitoxin therapeutics (e.g., toxin neutralization, target replacement, respiratory/mucosal countermeasures, neutralization of toxin-induced effects, superantigen toxin inhibitors).

Some technologies for *diagnostics* include mini-PCR, fluorescent probe chemistry, rapid portable nucleic acid analysis, rapid portable immunoassay techniques, GC/MS, colorimetric assays, microsonication technology, cellular or tissue activity detectors (e.g., detectors utilizing cellomics), specimen processing/ reagent preparation for field use.

Decontamination supports post-attack restoration of forces and operations to a near-normal capability. Decontamination is organized into three categories that reflect operational urgency: immediate, operational, and thorough decontamination. Decontamination also entails special considerations for patients, sensitive equipment, aircraft, fixed sites, and the retrograde of equipment. DOD doctrine addresses consequence management decontamination operations, which uses civilian standard operating procedures, including hypochlorite solutions, and soap and water solutions. Some of the existing systems include the M291 Skin Decontaminating Kit, the M295 Individual Equipment Decontaminating Kit, and the sorbent decontaminating system, which is replacing the existing decontaminant with a non-aqueous and less caustic decontaminant. There are three key development efforts. One is the *Joint Service Sensitive Equipment Decontamination* which is focused on the development a non-aqueous decontaminant to provide a first ever capability to decontaminate chemical and biological warfare agents and toxins from sensitive electronic, avionics, electro-optic equipment, and vehicle interiors. A second effort is the *Joint Service Fixed Site Decontamination System,* which will provide a family of decontaminants and applicators to provide the capability to decontaminate ports, airfield, and rear-area supply depots. A third effort is the Superior Decontaminant System, which seeks to develop effective decontaminants that react effective with all valid chemical and biological threats and are less corrosive and expensive than current decontaminants. Within the science and technology base, the following Defense Technology Objectives detail key restoration efforts.

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Enzymatic Decontamination—The objective of this effort is to develop and demonstrate a new generation of enzyme-based decontaminants that are nontoxic, noncorrosive, environmentally safe, and lightweight (freeze-dried concentrate).

Oxidative Decontamination Formulation—The objective of this effort is to develop a non-corrosive,

material compatible, non-toxic and environmentally oxidative CB decontaminant to replace Decontamination Solution 2 (DS2) and supertropical bleach/ high test hypochlorite (STB/HTH).

Environmental Fate of Agents—The objective of this effort is to develop a validated threat agent fate model that is capable of accurately predicting the persistence of a chemical agent dispersed on surface materials relevant to fixed site operational scenarios. These models will support decontamination efforts by allowing clean up efforts to focus on areas that pose greatest hazards and where decontamination might be achieve through non-material processes (e.g., hot air/hot water wash, weathering).

Decontamination efforts also draw on an extensive array of basic research and supporting technologies. Current decontaminants cause adverse effects to physical, optical, electronic, or mechanical properties of the items being decontaminated and are not environmentally friendly. Some of the technologies being explored to address these limitations include material survivability technology, supercritical fluidics, decontaminant coating technologies, thermal desorption methodologies, gas phase decontamination, chemical matrix strategies, and novel approaches using non-ozone depleting solvents, plasma, oxidation catalysts, peroxycarboxylic acid (peracids), novel surfactants and microemulsions, dioxiranes, and nanoparticles. To reduce dependence on water, non-aqueous technologies are being explored, including gas phase decontaminants, destructive adsorption, and organic chemical matrix strategies. A critical challenge is personnel and patient decontamination. Enzymatic decontamination, antimicrobial nanoemulsions, skin and wound decontaminants, and other methods for personal decontamination that does not harm the individual are being explored.

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DOD INTERAGENCY COORDINATION ON BIOTERRORISM RELATED RESEARCH AND DEVELOPMENT

The key organizations responsible for the management and transition of science and technology efforts for chemical and biological defense are (1) the Joint Science and Technology Panel for Chemical and Biological Defense, and (2) the Joint Medical Chemical and Biological Defense Research Program. These organizations help to ensure effective coordination of efforts among the Service Laboratories and Defense Agencies, including the Biological Warfare Defense program of the Defense Advanced Research Projects Agency (DARPA). In addition to management responsibilities, DOD provides many unique resources that can be used in the development of countermeasures to biological terrorism. Some of these unique resources include high containment (biosafety level 4) laboratories, aerosol exposure test chambers, live agent test facility, simulant test grids, and personnel with exceptional scientific expertise.

The Department of Defense has established a set of requirements for the successful completion of military operations in chemical and biological environments. We submit an Annual Report to Congress documenting our progress in meeting these requirements. My office regularly coordinates its efforts with the Department of Energy, Department of Health and Human Services, and the intelligence community through the Counterproliferation Review Committee, which reports annually to Congress on its progress (provided as a classified document to Congress).

In order to coordinate efforts between the Departments of Defense and Energy, we submitted a report to

Congress in March 2001 on the integrated chemical and biological defense research, development, and acquisition plan. This plan focused on biological detection technologies and seeks to leverage similar technologies to support different mission, that is Department of Defense is focused on support for the warfighter, while Department of Energy is focused on support for domestic preparedness and homeland security.

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In order to meet the challenge of biological warfare across the spectrum, our program must address the need for both materiel improvement and operational concepts to use the new and improved equipment. In order to address the issue of bioterrorism, we have documented gaps and deficiencies in exercises, such as TOPOFF, and these will be the focus of reprioritized efforts within the Department of Defense. One of the lessons of the TOPOFF exercise was that to work effectively during an actual crisis, various governmental agencies must actually exercise beforehand or their "cultural differences" will overcome any plan. We will continue to work with other agencies, including the new office of homeland security, to ensure good working relationships. One specific area we will focus on is to help define what support the Department of Defense can provide and work with other agencies to define what support they request and need.

While the DOD can provide unique expertise and materiel support, it is not charged with lead federal agent responsibilities as described in the Federal Response Plan. In the area of domestic terrorism medical response, the Department of Health and Human Services takes charge and requests support as needed. However, the Department of Defense provides materiel support to other organizations.

Congress has provided a number of statutory methods for the Department of Defense to support other federal, state, and local agencies in preparing for and responding to weapons of mass destruction (WMD) terrorism. Requests may come to the department for operational support or for the purchase of equipment. These requests are approved on a case-by-case basis. My office has dealt with a number of requests from other-federal agencies for individual and collective protective equipment and access to vaccines, while the operational support provided by the Department is coordinated through the Secretary of the Army. The Department will continue to provide this support within statutory and regulatory limits and balance requests against the readiness of military forces to accomplish their warfighting mission.

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DOD can offer many of its systems, either those in the field or in development, and expertise that may prove useful to civilians. DOD's chemical and biological detection equipment could be applied in civilian situations, as can many of our medical countermeasures. However, the provision of materiel alone does not enhance capability, it needs to be accompanied by valid operational concepts, training, and maintenance.

Our armed forces are trained primarily to fight foreign adversaries. However, our forces also maintain significant capabilities to support homeland security, through such operational units as the Chemical and Biological Rapid Response Team, the Technical Escort Unit, the WMD–Civil Support Teams, and the Marines' Chemical and Biological Incident Response Force (CBIRF).

In order to enhance our nation's overall capabilities the Department of Defense participates in programs to support the transition of military equipment and concepts to other-than-DOD agencies. Specifically,

The Technical Support Working Group (TSWG), rapidly prototypes emerging technologies for high priority federal interagency requirements (www.tswg.gov);

The InterAgency Board for Equipment Standardization and Interoperability (known as the IAB), is a partnership with federal, state, and local agencies focused on the capabilities necessary for fire, medical, and law enforcement responses to WMD terrorism (www.iab.gov);

The Domestic Preparedness Program, mandated under the 1997 Nunn-Lugar-Domenici legislation, trained and equipped municipalities to address WMD terrorism (the program transferred to the Department of justice in 2000, reports remain available at www2.sbccom.army.mil/hld/); and

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Interagency Agreements with departments of Justice's Office Domestic Preparedness to purchase equipment in support of Justice's grant program;

Medical training programs from the U.S. Army Medical Research Institutes for Infectious Disease and Chemical Defense; and

The White House Office of Science and Technology Policy chaired Weapons of Mass Destruction Program, Research and Development Subgroup.

These efforts represent a snap shot of the Department's procurement and research support to address bioterrorism. As the Lead Federal Agencies assess their needs, DOD anticipates additional requests of or participation in these groups.

Some of the Department's requirements to protect the military force correlate with civilian requirements to protect the population against biological terrorism. For instance, one of the concepts being investigated for the development and production of biological defense vaccines is a vaccine production facility. In order to coordinate the needs of the interested agencies, the DOD, relatively early in the process of considering alternatives for vaccine acquisition, established a Federal Interagency Advisory Group. Participants, in addition to those from DOD agencies, have included representatives from:

The White House [Office of Homeland Security, Office of Science and Technology Policy, National Security Council, Office of Management and Budget],

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Federal Emergency Management Agency,

Department of Health and Human Services (DHHS) [National Institutes of Health, Public Health Service,

Food and Drug Administration, Centers for Disease Control and Prevention, and the Office of the Assistant Secretary for Health and The Surgeon General]

Department of Agriculture

U.S. Agency for International Development.

This group, which I chair, has served as a highly effective and productive forum for discussions concerning U.S. vaccine acquisition—particularly vaccines for defense against biological warfare agents—for force health protection and public health needs for the civilian sector.

CONCLUSION

For operational responses to biological terrorism, the Department of Defense is working closely with the lead federal agencies as defined in the Federal Response Plan to ensure a well coordinated response. As I discussed, the Department of Defense is exploring an extensive array of leading edge scientific approaches to counter biological warfare and biological terrorism threats. We are working closely with several other federal agencies to provide unique science and technology resources to support national security and homeland security needs. We will continue to work closely with other agencies to ensure that the warfighter is protected with the best available technologies and that U.S. citizens are provided as great a degree of protection as possible. Thank you for the opportunity to speak here today, I would be happy to respond to any questions.

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BIOGRAPHY FOR ANNA JOHNSON-WINEGAR

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Dr. Anna Johnson-Winegar is the Deputy Assistant to the Secretary of Defense, Chemical and Biological Matters (DATSD (CBM)). She serves as the single focal-point within OSD responsible for oversight, coordination, and integration of the chemical/biological defense, counter proliferation support, chemical demilitarization and Assembled Chemical Weapons Assessment (ACWA) programs. She is a member of the OSD Steering Committee for Chemical-Biological Defense, and represents the DOD on numerous interagency and international groups addressing CB issues.

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Before joining the Pentagon staff, Dr. Johnson-Winegar was head of Human Systems Department at the Office of Naval Research (ONR), where she was responsible for the direction, program planning, management, and oversight of their programs in biomedical, cognitive and neural sciences, human factors, and training technologies.

Before joining the ONR, Dr. Johnson-Winegar served as Director of Environmental and Life Sciences in the Office of Director of Defense Research and Engineering (DDR&E). Her primary responsibilities included monitoring and coordinating all DOD research and development in the areas of medical and life sciences, training and personnel technologies, environmental sciences, environmental quality and civil engineering, chemical and biological warfare defense, and human systems interface.

Before joining DDR&E, Dr. Johnson-Winegar served as the Director of Medical Chemical and Biological Defense Research Programs at the United States Army Medical Research and Materiel Command at Fort Detrick, Maryland. In that capacity, her duties included planning, programming, and managing the entire scope of research programs in medical chemical and biological defense. Her previous positions included product manager at the U.S. Army Medical Materiel Development Activity, and research investigator at the U.S. Army Medical Research Institute of Infectious Diseases. She also participated as a biological weapons inspector in Iraq for UNSCOM.

Dr. Johnson-Winegar received a Bachelor of Arts degree in Biology from Hood College, as well as Master of Science and Ph.D. degrees in Microbiology from Catholic University of America. She has published numerous technical manuscripts, and authored/co-authored several book chapters. She is a long-standing member of many professional societies, including the American Society for Microbiology, American Academy of Microbiology (Fellow), American Association for the Advancement of Science, International Society of Toxicology, Society for Industrial Microbiology, Association for Women in Science, and Sigma Xi. She is an alumna of the Federal Executive Institute, and a graduate of various short courses in the general fields of science and technology, policy development, and management. She is Level III certified for acquisition management in systems planning, research, development, and engineering. She serves as a member of the National Board of Directors of the American Cancer Society (ACS), and is President of the ACS Mid-Atlantic Division. In 1998, she received the lifetime achievement award from Women in Science and Engineering.

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Chairman **BOEHLERT.** Thank you so very much. Dr. Henderson.

STATEMENT OF DONALD A. HENDERSON, M.D., DIRECTOR, OFFICE OF PUBLIC HEALTH PREPAREDNESS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. **HENDERSON.** Thank you very much. Mr. Chairman, and, Members of the Committee, I am pleased to have the opportunity to appear before you today and to discuss various issues pertaining to bioterrorism, particularly as they relate to the scientific issues and challenges confronting us. I have only recently assumed the Directorship of the new Office of Public Health Preparedness created by Secretary Thompson, and, thus, I am still on the ascending limb of a rapid learning curve regarding the diverse array of activities that have been mounted throughout government to address the challenge of biological terrorism.

In preface I would note that I have been engaged for a decade in endeavoring to anticipate the problems posed by bioterrorism, in devising policies to deal with them, and in advocating for a more vigorous and concerned response than had been taken over recent years. My active involvement dates back to 1990 when I was asked to serve at OSTP, as Science Advisor to President Bush, and later as Director of the Johns Hopkins Center for Civilian Biodefense.

Despite such experience, I can only say that the nature of events of the past several weeks, the public and media responses to the occurrences, and the number of questions that have risen have proved to be far more complex and very different than I or my professional colleagues anticipated. We have all learned a very great deal. However, there is much yet to learn and major tasks ahead if we are going to fully comprehend the challenges we face and to address them fully and competently as we must.

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The newly created HHS office of Public Health Preparedness has been charged with the responsibility for providing direction to the many different HHS programs dealing with bioterrorism and of serving to direct and coordinate these activities with other parts of government. The primary focus is on the biological threats, for these are the ones for which we are least prepared, and, at the same time, are the ones that most seriously threaten the integrity of civil government. Successfully coming to grips with these will go a long way in helping us deal with both chemical and nuclear threats.

Research and development pertinent to biological weapons is desperately needed. But until very recently, and few appreciate this, most academic institutions excluded from their educational and research programs activities that had anything to do with biological or chemical weapons, however important and well-intentioned they might be.

These attitudes have changed. But the legacy is that there is today little expertise in the field in academia. Moreover, there has been little support for research in the exotic diseases and organisms such as might be involved in a biological event. And, moreover, both research biologists in academia and the biotechnology industry have had relatively little contact with biological defense programs that hither to were the principal source of such funds.

Thus, the development of new and creative research programs, involving particularly HHS and DOD, in collaboration with academia and the biotech firms, are particularly needed. There are now several especially urgent research and development needs which we have identified, which I will mention briefly, at HHS. These are all being addressed very aggressively: first, the tissue cell culture of smallpox vaccine; second, a second-generation recombinant anthrax vaccine; thirdly, antiviral drugs for treatment of smallpox vaccination complications; fourth, diagnostic instruments capable of being used under field circumstances and economic enough to be used widely, drugs to counter the effects of toxins among anthrax victims, mechanisms for disease surveillance, sensor and diagnostic detection devices for organisms.

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Meanwhile, contracts have been placed to provide the Nation with sufficient smallpox vaccine to satisfy all citizens, and it is anticipated that a second-generation anthrax vaccine could come online within 18 months, and all efforts are being made to speed that effort.

In the longer term, there is much that could and must be done to cope not only with bioterrorism, but, in fact, the broader problem of new infections and epidemic agents arising either naturally or as a result of a deliberate release. There are any number of collaborative efforts underway across agencies and departments. Although we do not as yet have an overall research strategy and program, activities with OSTP, the National Academy of Sciences, and others are playing an important role in beginning to move toward that important and needed blueprint.

Are we today better equipped to deal with biological weapons attack than we were on the 11th of September or a year ago? The answer, I would say, is definitely yes. Is there more to be done? The answer is no less than the affirmative.

However, after so many years of permitting our public health infrastructure to deteriorate, after so many years in which the research so badly needed to deal with bioweapons has been allowed to stagnate, after so many years of complacency that we have permanently conquered the infectious diseases, we cannot in only a year or two or three regain the level of competency and control of what we must have. But certainly a good beginning has been made. Thank you.

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[The prepared statement of Dr. Henderson follows:]

PREPARED STATEMENT OF DONALD A. HENDERSON

Mr. Chairman and Members of the Committee, thank you for inviting me here today. The Department of Health and Human Services (HHS) welcomes your interest in our efforts to respond to terrorist events, including uses of biological weapons against the civilian population. I am Dr. D. A. Henderson, Director of the newly created HHS Office of Public Health Preparedness, which will coordinate the Department-wide response to public health emergencies. To that end, I look forward to working with the Office of Homeland

Security and our other partners at the Federal, state and local level to protect the American people from acts of terrorism.

HHS READINESS TO RESPOND TO MASS CASUALTY EVENTS

Although the Department of Defense (DOD) has developed defenses for biological warfare, there are additional concerns that need to be addressed to provide an adequate civilian defense from a bioterrorist attack. The potential list of microbial pathogens that threaten civilian populations is larger than that of classical biological warfare threats. HHS's identification of the major bioterrorism threat agents—a list developed in collaboration with experts in medicine and public health, law enforcement, and national security—is included as an Appendix to this testimony. Moreover, the populations to be protected are different from those generally involved in combat situations because the civilian community includes people of all ages and health status.

As you know, local and state governments bear much of the initial burden and responsibility for providing an effective response by medical and public health professionals to a terrorist attack on the civilian population. If the disease outbreak reaches any significant magnitude, however, local resources will be overwhelmed, and the Federal Government will be required to provide protective and responsive measures for the affected populations. HHS is working on a number of fronts to assist our partners at the state and local level, including local hospitals and medical practitioners, to deal with the effects of biological, chemical, and other terrorist acts.

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Metropolitan Medical Response System

Since Fiscal Year 1995, for example, HHS through its Office of Emergency Preparedness (OEP) has been developing local Metropolitan Medical Response Systems (MMRS). Through contractual relationships, the MMRS uses existing emergency response systems—emergency management, medical and mental health providers, public health departments, law enforcement, fire departments, EMS and the National Guard—to provide an integrated, unified response to a mass casualty event. As of September 30, 2001, OEP has contracted with 97 municipalities to develop MMRSs. During FY 2002, we intend to invest $20 million in 25 additional cities (for a total of 122) for bioterrorism-related planning through the MMRS and to help them improve their medical response capabilities.

National Disaster Medical System (NDMS)

As HHS's action agent for responding to requests for assistance and resources, OEP also manages the National Disaster Medical System (NDMS), which was established in partnership with DOD, the Department of Veterans Affairs (VA), the Federal Emergency Management Agency (FEMA), and the Public Health Service Commissioned Corps Readiness Force. The NDMS can be called into action, depending upon the severity of the event, to assist in providing needed services to ensure the continued health and well being of disaster victims.

The National Disaster Medical System is a group of more than 7,000 volunteer health and support

professionals who can be deployed anywhere in the country to assist communities in which local response systems are overwhelmed or incapacitated. Organized into 44 Disaster Medical Assistance Teams, these volunteers would provide on-site medical triage, patient care and transportation to medical facilities. Four National Medical Response Teams (NMRTs), which travel with their own caches of pharmaceuticals, have capabilities to detect illness-causing agents, decontaminate victims, provide medical care and remove victims from the scene. Three of the four NMRTs can be mobilized and deployed anywhere in the Nation; the fourth is permanently stationed in the Washington, D.C. area. The NDMS also includes Disaster Mortuary Operations Response Teams that handle the disposition of the remains of victims of major disasters, as well as provide for victim identification and assistance to their families.

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The Department of Veterans Affairs is one of the largest purchasers of pharmaceuticals and medical supplies in the world. Capitalizing on this buying power, HHS and VA have entered into an agreement under which the VA manages and stores specialized pharmaceutical caches for OEP's National Medical Response Teams. The VA has purchased many of the items in the pharmaceutical stockpile. The VA is also responsible for maintaining the inventory, ensuring its security, and rotating the stock to ensure that the caches are ready for deployment with the specialized National Medical Response Teams.

National Pharmaceutical Stockpile

HHS has also developed the National Pharmaceutical Stockpile Program (NPS) into a major national security asset. The purpose of the NPS is to be able to rapidly respond to a domestic biological or chemical terrorist event with antibiotics, antidotes, vaccines and medical material to help save lives and prevent further spread of disease resulting from the terrorist threat agent. Operated by HHS's Centers for Disease Control and Prevention (CDC), the NPS Program would provide an initial, broad-based response within 12 hours of the federal authorization to deploy, followed by a prompt and more targeted response as dictated by the specific nature of the biological or chemical agent that is used.

One of the NPS "12-hour Push Packages" was brought to operational status on September 11th. CDC delivered a 12-hour Push Package of pharmaceuticals and medical supplies by ground, vendor managed inventory by air, and a technical advisory team in New York City, all within 7 hours of the order to deploy. Three out of the four non-military aircraft in United States airspace on the night of September 11th were carrying National Pharmaceutical Stockpile assets and personnel to New York City.

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The Stockpile Program was developed as a supplementary response asset mainly to address biological and chemical terrorism. But following the events of September 11th, the program is now being expanded for response to an all-hazards event. The Stockpile presently is able to provide a full course of anthrax post-exposure prophylaxis to more than 2 million persons. Secretary Thompson has directed that the Stockpile development be accelerated to provide increased anthrax prophylaxis capacity for 12 million persons, and CDC will reach that level of response within the next 12 months. We will also add four more push packs to

the eight already located across the country, making more emergency supplies available and augmenting our existing supplies of 400 tons by another 200 tons.

But we must accelerate the production of vaccines and antibiotics and invest in essential programs to ensure the speedy and orderly distribution of antibiotics and other supplies in the event of a biological event. That is why the President has called for an additional $1.5 billion in federal funding for those areas most critical to our ability to respond to bioterrorist threats. His proposal includes include $643 million to expand the National Pharmaceutical Stockpile and $509 million to speed the development and purchase of smallpox vaccine.

Just last week, Secretary Thompson announced that Acambis Inc., with support from its subcontractor, Baxter International Inc., has been awarded a $428 million contract to produce 155 million doses of smallpox vaccine by the end of 2002. Production of the vaccine under the new contract could begin as soon as this month and, once completed, will bring the total number of vaccine doses in the Nation's stockpile to 286 million by the end of next year, enough to protect every United States citizen, if needed. In light of increasing concerns regarding the possible use of biological agents such as smallpox in acts of terrorism or war, HHS is undertaking efforts to stockpile as much vaccine as needed to protect the Nation in the event of an outbreak of smallpox.

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CDC Surveillance and Prevention Efforts

As our nation's premier prevention agency, CDC's top priority is to protect the Nation's health. To do this, CDC focuses on building a solid public health infrastructure—at CDC, as well as at the state and local level to protect the health of all citizens. CDC has used funds provided by Congress to begin the process of improving the expertise, facilities and procedures of state and local health departments and within CDC itself related to bioterrorism. CDC has a dedicated anti-bioterrorism staff of more than 100 full-time professionals comprising expertise in epidemiology, surveillance, secure communications, and laboratory diagnostics.

Over the last three years, CDC has awarded more than $130 million in cooperative agreements to 50 states, one territory and four major metropolitan health departments to support,

(1) Preparedness planning and readiness assessment;

(2) Epidemiology and surveillance

(3) Laboratory capacity for biological or chemical agents; and

(4) The Health Alert Network (a nationwide electronic communications system).

Since September 11, almost 500 CDC staff have been sent to the field. For example, at the height of the anthrax response in the Nation's Capital, there were 85 staff in Washington, DC alone. These experts included epidemiologists, industrial hygienists involved in environmental sampling and clean up,

laboratorians, communications specialists to assist with media relations, and logistics and management staff. CDC not only investigated cases that proved to be anthrax in four states and the District of Columbia, but also investigated suspicious cases in six other states. These cases proved not to be anthrax, but required CDC assistance to go through the process of ruling them out. CDC experts were needed to augment the staff of state and local health departments, who would have been severely overtaxed without our help. The Administration has requested $20 million to support additional expert epidemiology teams that can be sent to states and cities to help them respond quickly to infectious disease outbreaks and other public health risks. And let me reiterate Secretary Thompson's conviction that every state should have at least one federally funded epidemiologist who has been trained in the CDC's Epidemic Intelligence Service (EIS) training program. The President's budget will accomplish this goal.

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CDC and ATSDR Remediation Support Activities

Since the intentional release of anthrax spores, one of the areas on which CDC and HHS's Agency for Toxic Substances and Disease Registry (ATSDR) have focused is the identification and cleanup of contaminated facilities. We have refined methods for environmental sampling to assess whether anthrax contamination had occurred. In buildings, that has meant sampling of air and surfaces. CDC and ATSDR have issued recommendations on how to conduct environmental sampling and how laboratories should analyze those samples. We also recommended environmental sampling strategies to characterize the extent of exposure and to guide cleanup. We issued recommendations to protect first responders, investigators, and cleanup personnel. As buildings were identified as contaminated, we provided technical input to EPA and others tasked with cleanup to determine where remediation was necessary. These recommendations have been widely disseminated to federal, state and local health and environmental agencies, and are available at CDC's bioterrorism website (*http://www.bt.cdc.gov*).

EPA has devised strategies for remediation and has gained much experience through its activities to date. Disease experts at CDC are developing strategies to prevent the spread of disease during and after bioterrorist attacks. Although there are some data on chemical disinfectants in the scientific literature, there are no historical data that indicate the best way to eliminate spores from an office building, or to disinfect a sorting machine. The ability of a disinfectant to kill an anthrax spore is dependent upon time of contact and concentration and is mitigated by the amount and composition of material through which it must penetrate to get to the spore. For many of the clean-up methods being used to kill anthrax spores, we will not know their effectiveness until we go through the process. EPA understands this and has sought help from a variety of sources, including CDC and ATSDR, to ensure that the appropriate indicators are used and that post-sampling strategies are adequate.

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With regard to the effectiveness of cleaning, even our most exhaustive sampling strategies will not identify every spore. It is unlikely that any cleaning strategy will kill every spore. However, the EPA should be able to clean and re-test to the point where we all are comfortable that spores have been killed or

removed from surfaces where human contact is likely to occur. A range of sampling methods and strategies should be used to ensure the safety of building occupants.

In heavily contaminated areas, such as Senator Daschle's suite and the Brentwood postal facility, fumigation is being proposed as the method of clean-up. The use of fumigants is a potential hazard for clean-up workers, those in areas adjacent to the buildings, and those that must re-occupy the building. A fumigant that is effective at killing spores is, of necessity, a highly toxic agent. The protection of workers during the fumigation process is a matter of good industrial hygiene. EPA, CDC and ATSDR are working together to ensure remediation workers are protected during the fumigation processes. EPA works with local public health agencies to ensure that people in the area but outside of the building being fumigated are notified and kept at a safe distance.

With regard to the safety of those who will re-occupy the building, it is important to determine both that the area is clear of the fumigant and that there is no health risk. Again, CDC, ATSDR, and the Occupational Safety and Health Administration (OSHA) have developed exposure limits for fumigants, and detection methods are available to determine when any residual fumigant is well below established limits. After buildings are cleaned and post-cleaning environmental sampling has been conducted, CDC and ATSDR are committed to providing technical input to the incident command and other experts to determine whether the building is ready for re-occupancy.

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HHS ROLE IN VACCINE AND DRUG RESEARCH AND DEVELOPMENT

With the support of Congress, the President has implemented a government-wide emergency response package to help deal with the tragic events of September 11th and subsequent anthrax attacks. This complements efforts already underway to prepare our nation against such heinous attacks, including threats of bioterrorism. For example, CDC, the Food and Drug Administration (FDA), and the National Institutes of Health (NIH), all within HHS, are collaborating with the DOD and other agencies to support and encourage research to address scientific issues related to bioterrorism. The capability to detect and counter bioterrorism depends to a substantial degree on the state of relevant medical science. In some cases, new vaccines, antitoxins, or innovative drug treatments need to be developed, manufactured (or produced), and/or stocked. Moreover, we need to learn more about the pathogenesis and epidemiology of the infectious diseases that do not affect the U.S. population currently. We have only limited knowledge about how artificial methods of dispersion may affect the infection rate, virulence, or impact of these biological agents. HHS's continuing, collaborative, research agenda at CDC, FDA, NIH, and with DOD, is critical to overall preparedness.

Let me briefly outline the vital role that HHS agencies, particularly the FDA and NIH, play in our nation's research and development agenda for vaccines and other drugs.

Food and Drug Administration

Even before the events of September 11, HHS's Food and Drug Administration actively cooperated with DOD in the operation of DOD's vaccine development program and the maintenance of their stockpile program. Any vaccine or drug development, whether by a government agency or private industry, must be

in accordance with FDA requirements that ensure the safety, effectiveness and manufacturing quality of the finished product. FDA provides regulatory guidance to DOD, CDC, and others regarding the studies required to develop new vaccines and drugs, as well as assistance during all phases of development. FDA also works with DOD's office that screens new and unusual ideas for development of products to treat diseases and develop diagnostic tools.

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The scope of FDA's regulatory responsibility extends to both approved (licensed) products and investigational products (unlicensed products). FDA's Center for Biologics Evaluation Research (CBER) is responsible for evaluating the safety, purity, and potency of biological products such as vaccines, antitoxins and blood products. FDA's Center for Drug Evaluation and Research (CDER) is responsible for a similar regulatory process for drugs. Bio-warfare defense vaccines and drugs undergo the same FDA review process as any other vaccines or drugs.

FDA will work with potential sponsors of experimental therapies, at all stages of the product development process in order to stimulate scientific interchange and clarify FDA regulatory requirements. A sponsor of a vaccine or drug under review must also provide adequate product labeling to allow health care providers to understand the product's proper use, including its potential benefits and risks, to communicate with patients, and to safely deliver the product to the public.

When all of the clinical, chemistry, pre-approval inspection, manufacturing, labeling and other issues have been adequately resolved, FDA will approve the application. Licensing or approving a new vaccine or drug is only one stage of FDA's oversight of medical product safety. Following issuance of the license, there is continued post-marketing surveillance of the product by monitoring adverse events through the Adverse Event Reporting System. Subsequent to the issuance to the license, FDA also monitors the manufacturer's production activities through FDA inspections to determine the manufacturer's compliance with good manufacturing practices (GMP) regulations. Because of the complex manufacturing processes for most biological products, manufacturers may be required to submit samples of each licensed vaccine lot, along with manufacturing testing results, to FDA for review and permission to release the lot for distribution.

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National Institutes of Health

The NIH bioterrorism research program, spearheaded by the National Institute of Allergy and Infectious Diseases (NIAID), includes both short- and long-term research targeted at the design, development, evaluation and approval of diagnostics, therapies and vaccines needed to control infections caused by microbes with potential for use as biological weapons. NIAID efforts have primarily focused on the bioterrorist threats posed by anthrax and smallpox, and many of these efforts are carried out in collaboration with other Federal agencies.

NIAID formed a Working Group on Anthrax Vaccines (WGAV) in 1998 to develop and test a new

vaccine that could be used in response to a bioterrorist event. Such a vaccine must be capable of generating protective immunity against inhalation spores within a relatively short period of time after 1–2 immunizing doses. Through an Inter-Agency Agreement, NIAID is collaborating with the Department of Defense's U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) on a research plan to develop a new vaccine based on the use of recombinant protective antigen vaccine (rPA) to protect all ages of the American public, including military personnel. In preparation for Phase 1 clinical trials of rPA vaccines, NIH is working with CDC, FDA and DOD to refine standard serological tests to assess the effectiveness of anthrax vaccines. These tests would enable comparison of new rPA vaccines to the currently licensed anthrax (or AVA) vaccine. If the new vaccine is capable of generating a rapid immune response, it may provide a quick transition to protective immunity to those individuals undergoing treatment with antibiotics due to an anthrax exposure.

NIAID also has expanded the national research capacity substantially over the past few years on those bioterrorist threat agents of greatest concern. First, NIAID has solicited from the scientific community research proposals on anthrax and other bacterial pathogens, in an effort to further encourage research that may lead to better means of diagnosis, prevention, and treatment.

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Second, NIAID recently awarded administrative supplements to several active research grants to further studies on how anthrax causes disease, which could expedite the development and implementation of novel, more effective therapeutic intervention strategies. NIAID also anticipates funding several new research proposals on the molecular mechanisms involved in the germination of anthrax spores in vivo; such work may provide the basis for a novel and very promising post-attack strategy, one that would be more acceptable than the widespread use of antimicrobial drugs which are not specific for anthrax and, when given to large groups of exposed individuals, may promote the development of antibiotic resistant strains of other bacteria.

Through an Inter-Agency Agreement with the Office of Naval Research, NIAID has provided funding to help complete work on sequencing the DNA of the chromosome of anthrax; additional funds were also provided by the Department of Energy for this purpose. The information derived from this genome-sequencing project should be of great value in developing rapid diagnostic tests, as well as new vaccines and antibiotics therapies against mutant strains of anthrax.

NIAID research on smallpox focuses on extending existing vaccine stocks to increase the number of available doses, developing new vaccines and treatments, as well as diagnostic tools to detect the disease quickly. Although a worldwide immunization program eradicated smallpox disease decades ago, small quantities of smallpox virus still exists under guarded conditions at CDC and in Russia, but several rogue nations may have samples. NIAID, in collaboration with DOD, CDC, and the Department of Energy, funds increased research to:

Develop and evaluate at least three anti-viral drugs with pre-clinical activity against smallpox and vaccinia viruses and acceptable clinical safety;

Extend the usefulness of the currently available, older vaccine by doing human studies to see if we can "stretch" available stocks by diluting it;

Help develop a safe, sterile smallpox vaccine grown in cell cultures using modern technology;

Explore development of a vaccine that can be used in all segments of the civilian population (i.e., the immune-suppressed, pregnant mothers, etc.); and

Increase our knowledge of the genome of smallpox and related viruses.

NIAID recently launched a Phase 2 clinical trial to further evaluate the effectiveness of different strengths of vaccine in order to possibly expand the use of the limited smallpox vaccine supply; CDC and FDA have cooperated to ensure that the NIH study is carried out as expeditiously as possible.

In addition, NIAID and DOD's Defense Advanced Research Projects Agency (DARPA) have funded a collaborative effort involving those two agencies along with four academic centers, the CDC, USAMRIID, and the American Type Culture Collection that will focus on designing and implementing an "Orthopoxvirus Genomics and Bioinformatics Resource Center." This Center will conduct sequence and functional comparisons of genes to provide insights for the selection of targets for the design of anti-virals and vaccines. The Center will design and maintain relational databases to store, display, annotate and query genome sequences, structural information, phenotypic data and bibliographic information. Part of the effort will include development and maintenance of a "Poxvirus Bioinformatics Resource Center" website to facilitate the availability of this data for other researchers.

CONCLUSION

Mr. Chairman, let me again emphasize that the Administration is taking aggressive steps to make sure that our country is well protected from bioterrorism. Moreover, the government at all levels is responding to bioterrorist threats, and responding well.

Contemplating bioterrorism is unpleasant, but it is imperative. Under the leadership of President Bush, Secretary Thompson, and Homeland Security Director Ridge, we are taking all the steps necessary to keep America safe in an era when biological and chemical attacks are as possible as they are unthinkable.

Thank you, Mr. Chairman, for letting me speak about this matter of critical importance. I will be happy to answer any questions which you or members of the Committee may have.

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BIOGRAPHY FOR DONALD A. HENDERSON

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(Footnote 1 return)
For example, in 1984, the Rajneeshee religious cult contaminated restaurant salad bars in The Dalles, Oregon. The cult infected residents with *Salmonella* on Election Day to influence the results of county elections. Although no one died, 751 people were diagnosed with foodborne illness.

(Footnote 2 return)
GAO Report (GAO–01–915), Bioterrorism: Federal Research and Preparedness Activities, September 2001.