

HOMELAND SECURITY

HEARING

BEFORE THE

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS
UNITED STATES SENATE

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

ON

EXAMINING THE PRESIDENT'S PROPOSAL TO ESTABLISH A DEPARTMENT OF HOMELAND SECURITY, FOCUSING ON ITS IMPACT ON PUBLIC HEALTH PREPAREDNESS PROGRAMS, AND ON THE COLLECTIVE BARGAINING RIGHTS OF CERTAIN UNION WORKERS

JULY 16, 2002

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HOMELAND SECURITY

TUESDAY, JULY 16, 2002

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, D.C.

The committee met, pursuant to notice, at 10:05 a.m., in room SD-430, Dirksen Senate Office Building, Hon. Edward M. Kennedy (chairman of the committee) presiding.

Present: Senators Kennedy, Murray, Reed, Gregg, Frist, Hutchinson, and Sessions.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. It is a privilege to convene this morning hearing on the Administration's proposal to create a Department of Homeland Security. We welcome Governor Tom Ridge to our committee, and we are grateful for his leadership and all that he has done to protect our Nation's security.

We live in a Nation forever changed by the tragic events of September 11. The searing images of the terrorist attacks on that fateful day were grim proof to every American that we are vulnerable to grave new threats, and that we must take whatever steps are necessary to protect America from these dangers.

As the anthrax attacks that followed soon after made clear, the remarkable new techniques of modern biological science can be used to harm rather than to heal, to kill and not to cure.

The magnitude of this aspect of the new threat was highlighted again by recent chilling reports that a polio virus has been created from inert and widely available chemicals.

Our defenses against the threat of bioterrorism have been neglected and underfunded for too long. Congress took action to correct many aspects of this deficiency by enacting the bioterrorism bill signed by President Bush last month. This legislation prepares the Nation to deal with biological attacks by strengthening hospitals, public health agencies, and medical research laboratories across the country.

A deadly biological attack is likely to be detected first by a local physician, who will turn to the agency that responds to disease outbreaks every day of the year—the CDC. To deal with an attack, doctors will rely on the vaccines and antibiotics developed by the Nation's medical research agency—the NIH.

Thanks to the new resources provided recently by Congress for bioterrorism preparedness, these and other agencies in the Department of Health and Human Services are now making significant

progress in improving the Nation's readiness for bioterrorist attacks.

Research at NIH has demonstrated that the Nation's stocks of smallpox vaccine can be diluted yet still retain their potency to defend against that deadly virus. Grants by CDC to every State and territory have already begun to strengthen the Nation's ability to detect, contain, and treat a biological attack.

Many of us feel that we should build on the strengths of these existing programs rather than create potential confusion by transferring them to the new Department of Homeland Security or by giving that new Department the responsibility for their direction.

Our concerns about the President's proposals are not based on an aversion to change but rather on a careful analysis of the impact of these moves on our common goal—enhancing the Nation's security. Many major health organizations and expert panels have also carefully scrutinized the President's proposal. Their overwhelming conclusion is that transferring public health preparedness programs from CDC or stripping NIH of its ability to make key decisions about the Nation's bioterrorism research program would do a disservice to the goal of enhancing our security.

For example, the Brookings Institution just completed a thorough analysis of the President's plan and determined that "researching natural disease and researching biological weapons have a great deal of overlap. Trying to place the latter under DHS auspices while keeping the former under current HHS control risks creating artificial divides."

The report concluded that "the administration has not made a strong case for why a substantial amount of biological research should be taken away from the Department of Health and Human Services."

Reservations about transferring public health preparedness activities away from CDC are equally strong. The President recently received a letter signed by a coalition of major health groups, including the American Nurses' Association, the American Public Health Association, and the Association of Academic Health Centers. In their letter, these organizations conclude that "separating bioterrorism preparedness from the rest of the Nation's public health infrastructure is likely to reverse the most important steps the Nation has taken in decades to achieve broad-based public health preparedness."

I believe that it is our responsibility on this committee to pay close attention to these concerns and to ensure that the legislation establishing the new Department does not undermine the important ongoing programs at HHS to enhance our national preparedness for bioterrorism.

The terrorist attacks last fall also made clear that union workers are true heroes in protecting homeland security. Union members risked and lost their lives and saved countless others by their actions on September 11. We will never forget the example set by firefighters, construction workers, and Government workers on that day. The brave flight attendant recognized by the President in the State of the Union Address was a member of a union. The postal workers and the hospital worker killed as a result of the bioterrorist attacks were all union members.

The dedication and resolve of these men and women represent the best of America. Nearly 50,000 of the Federal workers affected by the proposed homeland security reorganization are union members. We must protect their right to remain union members and enable other employees in the new Department to exercise their fundamental right to form a union. Unions are essential in order to protect the ability of workers to speak out in the face of security lapses and to enhance our national security in many other ways.

Unfortunately, the administration's proposal does not adequately protect the collective bargaining rights of these vital Federal workers. The administration should not be able to use an executive order to deprive Federal workers of their collective bargaining rights in the new Department. Earlier this year, however, the administration stripped clerical and other workers in the Department of Justice of their long-held union membership after years of dedicated service.

Many of us feel that Federal workers in the new homeland security agency should be able to retain those rights unless their primary responsibility consists of intelligence, counterintelligence, or other investigative duties directly related to the investigation of terrorism. It is essential that any reorganization respect and protect the rights of these dedicated Federal employees whose work is so vital to its success.

I recognize Senator Gregg.

OPENING STATEMENT OF SENATOR GREGG

Senator GREGG. Mr. Chairman, I am going to have to leave to go to the floor, but I do want to welcome Governor Ridge here who is working so hard to try to pull together the matrix of this extremely complex issue and make sense of it as we move down the road toward getting better prepared to defend our Nation in this time of extreme peril when there are people who want to do us harm, very evil people.

I think that our sole criterion for evaluating the proposals from the administration on creating the homeland security agency should be does it improve our capacity to fight terrorism. That should be the only test. The other issues which are important, obviously, such as were outlined by the chairman in his opening statement are significant public policy questions at a time when we are not at war. But the issue of war supersedes those issues in my opinion.

The administration has come forward with an aggressive proposal, and I think it deserves to be given a presumption that it makes sense and is moving in the right direction, and unless I am dissuaded by some clear argument that it does not make sense, I intend to support it.

The NIH has a huge role here, obviously, in developing technology to fight bioterrorism. How it integrates—because it is obviously still going to do the research—with the homeland security agency is an issue which I think the chairman has appropriately highlighted.

Increasing public health capability is something that we were doing before 9/11 and something that we have expanded radically since 9/11. I do think that the efforts which we are making in pub-

lic health to try to address terrorism issues, the issues which evolve around as biological attack especially, but any type of attack that involves a significant amount of injury which immediately calls in the public health agencies, those do work in tandem with benefiting the entire society because in upgrading public health to address those issues, you upgrade public health to address other issues, that might occur within the community, other accidents, for that matter.

So I do not see them as mutually exclusive, and I do not see that they are going to be pulling each other apart. I see them working together to move forward and significantly improve our public health capability as a result of that.

On the labor issues, I think this Department has a right and a need to have special labor treatment. We simply cannot afford incompetence in this Department. The people who are running the different elements within this agency are going to have to have the capacity to replace people who are not doing the job.

We saw specifically in an agency which I have direct appropriating authority over, the Immigration and Naturalization Agency, incompetence, and as a result, things happened that should not have happened. Would 9/11 have been avoided? Probably not. But certainly we could make large strides toward muting it and having it not occur again if we have an agency that is efficient.

So I do think that the people who run these various agencies which are charged with protecting our population from terrorist attack have to have the authority to run them efficiently and effectively and have to have the authority to replace people who simply are not cutting it. And that is just a fact of life if we are going to survive and win this war. So I suspect we will have issues there.

In general, I want to thank the Governor for his superb effort and his incredible focus on this, reflecting the President's obvious commitment to this. The President appears to have a one-item agenda some days, and I think it is the item that we should have, which is fighting terrorism and making sure that our Nation survives this war and that our culture is not undermined by these extraordinarily evil people.

So I thank the Governor for coming and I apologize for having to leave in order to protect certain rights which I know the chairman would want me to do on the floor involving another bill.

The CHAIRMAN. What are you smiling at, Governor Ridge?
[Laughter.]

Thank you, Senator Gregg.

The CHAIRMAN. As you have already caught in the wind, Governor Ridge, we are considering legislation on the floor at half-past-ten, so we will ask you to proceed, and I know that our colleagues will be here for as long as they can, but we wanted to have a chance to get your views on these matters. We want to thank you very much for being here.

Governor Ridge is a decorated veteran, a former Member of the House, a leading Governor, who now carries great responsibilities for coordinating our national effort in homeland security. We welcome him today.

I have said that Governor Ridge has reached out to us on this committee to gain our ideas as well as in the Judiciary Committee

on issues of immigration, and he has been accessible and available to us here. We are very appreciative of those efforts, and we look forward to hearing from you, Governor.

**STATEMENT OF TOM RIDGE, DIRECTOR, OFFICE OF
HOMELAND SECURITY, WASHINGTON, DC**

Mr. RIDGE. Thank you very much, Mr. Chairman.

On a personal note, I want to publicly acknowledge and express my appreciation for your availability and openness to begin discussion on many of these issues long before this legislation was ever established. From time to time, we have entertained in a very respectful way a different view on how we accomplish certain goals, but we are united I think as Republicans and Democrats to get the job done, and terrorists can do what they might, but they are not going to infringe on our ability to conduct business as we have been conducting it for 200 years, and we will keep conducting it that way.

I am grateful to have this opportunity to appear before you and Senator Gregg and understand his hectic schedule as well as that of other members of the committee, including the chairman.

So to all of the distinguished members of this committee, please know that President Bush has asked me to convey his appreciation for the comprehensive, timely, and bipartisan manner in which the Senate has considered his proposal to make America safer by creating a Department of Homeland Security.

The President has signed an executive order creating a transition planning office for the new Department housed within the Office of Management and Budget. I testify today in my capacity as director of this office, and I look forward to working with you this today and in the future.

When President Bush established the Office of Homeland Security last October, the first mission he assigned was, and I quote, "to develop and coordinate the implementation of a comprehensive national strategy to secure the United States from terrorist threats or attacks."

This morning, the President released the Nation's first ever National Strategy for Homeland Security, and at some point in time, I do commend it to my colleagues in public service on the Hill. It does lay out a road map of how we not only reorient the Federal Government, and it certainly provides the foundation and the justification for the new Department, but how through this reorganization, we develop the strategic partnerships we need to build a national capacity to deal with the terrorist threat.

It is a focused and forward-looking strategy to secure the Nation from terrorism. It builds on the significant improvements that the Federal Government, Congress, States, and localities have made to our security since September 11, and it provides a framework to guide our actions in the future. A vital component, obviously, of this strategy is the new Department of Homeland Security.

The fundamental mission of the Department of Homeland Security is threefold, Mr. Chairman and members of the committee—to prevent terrorist attacks within the United States, to measure and reduce our vulnerability to terrorism, and to minimize the loss of life and damage and speedy recovery from any future attack.

The Department of Homeland Security is needed not just to strengthen the Federal Government's response to terrorism, but to strengthen our partnerships with States and localities and the private sector. When the home town is secure, the homeland will be secure, and these partnerships are critical to securing the homeland.

As you know, States and localities have the primary role in responding to a crisis, including outbreaks of disease. Terrorists are actively trying to get their hands on biological agents and weapons to use against our citizens and against our communities. When a doctor or local public health official determines that a disease may have been caused by a terrorist, they need to know they can count on one department to inform the public and coordinate and manage the Nation's response.

Just as important, the new Department will help ensure our preparedness well before an attack occurs. It will help train health care professionals to recognize rare diseases and treat toxic exposures. It will help hospitalizes expand their surge capabilities and build isolation facilities. It will assist in upgrading public health laboratories. It will develop regional disease surveillance systems so we can quickly determine if an outbreak is caused by man or by mother nature. And it will encourage States and localities to take sensible measures such as mutual aid compacts and emergency credentialing for out-of-area first responders, particularly from within the medical community.

The Department will coordinate with its Federal partners as well. Working with the Secretary of Health and Human Services, it will develop, maintain, and deploy the national pharmaceutical stockpile. Working with Health and Human Services and the Department of Agriculture, it will administer the Select Agents Program. Working with the Department of Agriculture, it will help protect our food supply from agro-terrorism.

Working with the Department of Energy, it will oversee research that may one day unlock the micro-bio components of our deadliest pathogens and help make the 21st century, in Senator Kennedy's words, "the century of the life sciences."

Indeed, the success of our response to bioterrorism incident depends in large part on the quality of our vaccines, therapeutics, and diagnostic tests.

The President's proposal envisions a national network of laboratories modeled on the national laboratories that helped us win the cold war. The new Department will harness the greatest minds of our Nation to counter the greatest threat of our generation.

I would add that the President's budget proposes \$2.4 billion to update our medical toolkit. Nearly three-fourths of that is dedicated to a public-private academic partnership led by the National Institutes of Health. It is all part of a proposed 300 percent increase in the Federal budget for biodefense.

Currently, the bulk of our bioterrorism research and development is located in the Department of Health and Human Services. It is isolated from other Federal research and development on weapons of mass destruction. The President's plan will consolidate funding and oversight for these programs to ensure a synergy of effort.

The current homeland security apparatus grew up in an ad hoc fashion, without any real strategic direction, over the course of many decades. The President's reorganization plan, on the other hand, is well-planned and well thought out. It proposes that 22 agencies with significant homeland security responsibilities be moved into the new Department. The President faced many difficult, tough, real world choices. I believe he made the right ones.

In developing the plan, we heard from first responders—businessmen and businesswomen, doctors and health care workers, scientists, academics, other experts, and of course, we took the counsel of Members of Congress. Their best efforts and their best ideas are reflected in both the new Department and the National Strategy as well.

This is not about moving managerial boxes around on an organizational chart. It is about ensuring that we have the resources and the people in place to address the ever-changing threat of terrorism. Terrorists are strategic actors. They choose their targets deliberately based on observed weaknesses in our defense and preparations. They use speed and surprise to terrorize.

Protecting ourselves requires that we be just as flexible and just as nimble, with the ability to quickly spot the gaps in our defense and just as quickly fill them.

The new Secretary of Homeland Security must be able to set goals and priorities. Under the President's plan, he or she will have freedom to manage—in the President's words, get the right people in the right place at the right time with the right pay.

Under the President's proposal, the new Secretary will also have latitude to shift resources to counter the threat. I know this is problematic, having been a Member of Congress and understanding very much the congressional mandate to oversee every dollar expended, but I would say very respectfully to my former colleagues that you have a budget process, an authorization process, and an appropriations process, and giving the new Secretary the latitude to transfer and reprogram dollars will not be without oversight. It will continue with the most vigorous oversight Congress can provide and will for that reason hopefully be included as part of the congressional response to the President's initiative.

Change is never easy, but we do face a different kind of enemy. Their strategy and their tactics are different. They do not distinguish between combatants and noncombatants. They do not distinguish between soldiers and citizens. They do not respect borders, and they do not fight on traditional battlefields. Instead, these are shadow soldiers who seek to turn our cities into battlefields and use our openness and our freedom and our diversity against us. It is a new threat from a very new and deadly enemy, and the President believes it is time for us to think anew as well.

I thank the members of the Committee on Health, Education, Labor, and Pensions and the Senate as a whole for their serious and expeditious action on behalf of the President's proposal.

Thank you.

[The prepared statement of Mr. Ridge follows:]

PREPARED STATEMENT OF TOM RIDGE

I. INTRODUCTION

Mr. Chairman, Mr. Gregg, distinguished members of the Committee on Health, Education, Labor, and Pensions. President Bush asked me to convey his appreciation for the comprehensive, expeditious, and most importantly, bipartisan manner in which the Senate is considering his proposal to make America safer by creating a Cabinet-level Department of Homeland Security to unite essential agencies that must work more closely together.

In the weeks since the President submitted a detailed legislative proposal to Congress, both the Senate and the House of Representatives have conducted hearings to consider different aspects of the draft Homeland Security Act of 2002. In the Administration's view, many of the amendments to the Administration's legislative proposal under consideration in both chambers would strengthen the ability of the new Department to provide a unified homeland security structure that will improve protection against today's threats and be flexible enough to help meet the unknown threats of the future. Some of the amendments under consideration, however, would impair the Department's ability to secure our homeland. In this statement, I will review aspects of the President's proposal related to preventing bioterrorism.

Through all of this legislative activity, it is important to stay focused on our goal. The United States is a nation at risk of terrorist attacks and it will remain so for the foreseeable future. We need to strengthen our efforts to protect America, and the current governmental structure limits our ability to do so. Change is needed now. It is our job—Executive Branch and Legislative Branch working together—to implement this change.

II. THE NEED FOR HOMELAND SECURITY: THREAT AND VULNERABILITY

We are today a Nation at risk to terrorist attacks and will remain so for the foreseeable future. The terrorist threat to America takes many forms, has many places to hide, and is often invisible. Yet the need for improved homeland security is not tied solely to today's terrorist threat. It is tied to our enduring vulnerability.

All assessments of the terrorist threat must start with a clear understanding that terrorists are strategic actors. They choose their targets deliberately based on the weaknesses they observe in our defenses and our preparations. They can balance the difficulty in successfully executing a particular attack against the magnitude of loss it might cause. They can monitor our media and listen to our policymakers as our Nation discusses how to protect itself—and adjust their plans accordingly. Where we insulate ourselves from one form of attack, they can shift and focus on an other exposed vulnerability.

The United States faces a profound danger of terrorism. We were dealt a grave blow on September 11 and we face today the real possibility of additional attacks of similar or even greater magnitude. Our enemies are working to obtain chemical, biological, radiological, and nuclear weapons for the stated purpose of killing vast numbers of Americans. Terrorists continue to employ conventional means of attack, such as bombs and guns. At the same time, they are gaining expertise in less traditional means, such as cyber attacks. And, as we saw on September 11, our terrorist enemies will use new tactics and exploit surprise to carry out their attacks and magnify their deadly effects.

Our population and way of life are the source of our Nation's great strength, but also a source of inherent vulnerability. Our population is large, diverse, and highly mobile, allowing terrorists to hide within our midst. Americans assemble at schools, sporting arenas, malls, concert halls, office buildings, high-rise residences, and places of worship, presenting targets with the potential for many casualties. Much of America lives in densely populated urban areas, making our major cities conspicuous potential targets. Our factories, power plants, and parts of our transportation system could be attacked to cause systemic disruption. Americans subsist on the produce of farms in rural areas nationwide, making our heartland a potential target for agroterrorism.

The U.S. government has no higher purpose than to ensure the security of our people and preserve our democratic way of life. Terrorism directly threatens the foundations of our Nation—our people, our way of life, and our economic prosperity. In the war on terrorism, as in all wars, the more we know about our enemy, the easier it is to defeat him. Similarly, the more we know about our vulnerabilities, the better we can protect them.

III. THE NATIONAL STRATEGY FOR HOMELAND SECURITY

When President Bush established the Office of Homeland Security in October 2001, the first mission he assigned the Office was “to develop and coordinate the implementation of a comprehensive national strategy to secure the United States from terrorist threats or attacks.” The President recognized that the United States has never had a shared national vision of what must be done to secure the homeland against the full range of terrorist threats we face today and might face in the future.

The National Strategy for Homeland Security released this morning by President Bush is the product of over eight months of intense consultation across the breadth of the United States. In preparing this document, we consulted with thousands of people across the country—from the public and private sector and from numerous disciplines. Their ideas are reflected in the Strategy. Above all, we sought to create a national strategy that can mobilize and organize our Nation to secure the U.S. homeland from the threat of terrorism.

The National Strategy for Homeland Security will help to prepare our Nation for the work ahead in several ways. It is a single, comprehensive statement of virtually everything that needs to be done to secure the homeland to which all Americans can refer. It provides direction to the federal government departments and agencies that have a role in homeland security. It suggests steps that state and local governments, private companies and organizations, and individual Americans can take to improve our security and offers incentives for them to do so. It recommends certain actions to the Congress. In this way, the Strategy provides a framework for the contributions that we all can make to secure our homeland.

The Strategy aligns and focuses homeland security functions into six critical mission areas: Intelligence and warning; Border and transportation security; Domestic counterterrorism; Protecting critical infrastructure; Defending against catastrophic terrorism; and Emergency preparedness and response.

The first three of these mission areas focus primarily on preventing terrorist attacks; the next two on reducing our vulnerability; and the final one on minimizing the damage and recovering from attacks. Starting with the President’s FY04 Budget, every homeland security dollar in future budgets will correspond with one, and only one, critical mission area. In this way, the Strategy provides a framework to align the resources of the federal budget directly to the task of securing the homeland.

In addition, the Strategy also describes four foundations of our homeland security effort—unique American strengths that cut across all of the mission areas, across all levels of government, and across all sectors of our society. There are: (1) law; (2) science and technology; (3) information sharing and systems; and (4) international cooperation.

The Strategy is a national, not just federal, strategy. It recognizes that homeland security is a shared responsibility and that the federal government does not have the solution to all problems. The Strategy pays close attention to the roles of the state and local government, the private-sector, and citizens. The President’s intent in publishing the National Strategy for Homeland Security is to help Americans achieve a shared cooperation in the area of homeland security for years to come.

IV. OVERVIEW OF THE PROPOSED DEPARTMENT OF HOMELAND SECURITY

When President Bush directed his Administration to develop the National Strategy for Homeland Security, it was immediately clear that doing so would require careful study of how the federal government is organized for the mission of homeland security. Like many who have examined this question, we quickly concluded that the federal government can be much better organized than it presently is. Homeland security is, in many respects, a new mission, so it should come as no surprise that our strategic review concluded that the structure of the federal government must be adapted to meet the challenges before us.

The President proposed the establishment of the Department of Homeland Security on June 6, roughly five weeks prior to the publication of the Strategy. The proposal to create the Department preceded the Strategy because we finished our work on the organizational issue first and because of our wish to deliver the proposal to create the new Department to the Congress in time for action during the current legislative session. As the President said in his June 6 address to the Nation, “we face an urgent need, and we must move quickly, this year, before the end of the congressional session.”

Creating the Department of Homeland Security proposed by President Bush would result in the most significant transformation of the U.S. government in over a half-century. It would transform and largely realign the government’s confusing

patchwork of homeland security activities into a single department whose primary mission is to protect our homeland.

Currently, no federal government department has homeland security as its primary mission. In fact, responsibilities for homeland security are dispersed among more than 100 different government organizations. Creating a unified homeland security structure will align the efforts of many of these organizations and ensure that this crucial mission—protecting our homeland—is the top priority and responsibility of one department and one Cabinet secretary. The fundamental mission of the Department would be to: Prevent terrorist attacks within the United States; Reduce America's vulnerability to terrorism; and Minimize the damage and recover from attacks that do occur.

The Department of Homeland Security would mobilize and focus the resources of the federal government, state and local governments, the private sector, and the American people to accomplish its mission. It would have a clear, efficient organizational structure with four primary divisions.

Establishing a new department to meet current and future homeland security challenges is both a vital enterprise and an extraordinarily difficult and complex one. The success of a new department in protecting our country will depend upon two principal factors: (1) ensuring that the new Department has the right building blocks moved into it, and (2) ensuring that the leadership of the new Department is given the right set of tools to work with and manage those blocks to ensure that the benefits of consolidation, in terms of both security and efficiency, can be achieved. There are a variety of issues in both categories, and we have strong views about many of them. I look forward to answering any specific questions members of the Committee may have about the President's proposal. I'll use the balance of this statement to focus on aspects of the proposal that relate to protecting the American people from the threat of bioterrorism.

RESPONDING TO THE THREAT OF BIOTERRORISM

There are few threats that could endanger our national survival. The threat posed by the Soviet Union's vast nuclear arsenal was one such threat. The threat of bioterrorism is another. If properly employed, certain biological agents could cause tens or hundreds of thousands of casualties and wreak huge economic damage. Given the vast quantities of biological weapons that already exist around the world, the risk of terrorists and their supporters obtaining and using these weapons is sufficient to warrant a massive effort to prevent such attacks.

Under the President's proposal, the Department of Homeland Security would unify much of the federal government's efforts to develop and implement scientific and technological countermeasures against human, animal, and plant diseases that could be used as terrorist weapons. The Department would sponsor and establish national priorities for research, development, and testing to invent new vaccines, antidotes, diagnostics, therapies, and other technologies against bioterrorism; to recognize, identify, and confirm the occurrence of an attack; and to minimize the morbidity and mortality caused by such an attack. In addition, the federal government will set standards and guidelines for state and local biological preparedness and response efforts.

The President recognizes that all these efforts against bioterrorism must be part of a broader research and development program. Therefore, the President's proposal would charge the new Department with leading the federal government's whole range of homeland security science and technology efforts. Currently, the bulk of our scientific efforts against biological terrorism are conducted by the Department of Health and Human Services and are separate from research against other weapons of mass destruction. The President's proposal would consolidate the funding and oversight for these programs with other scientific initiatives in order to ensure that priority threats receive an appropriate percentage of our national research and development investment. This effort would avoid stove-piped approaches to research and development by pursuing priority programs in multipurpose research institutions such as the National Institute of Health. Working within the context of the national priorities established by the Department of Homeland Security, the NIH and others would continue to make decisions on the disbursement of research funding dollars consistent with sound science and expertise.

The President's proposed legislation would transfer the select agent registration enforcement programs and activities of HHS, the National Pharmaceutical Stockpile, the new National Bio-Weapons Defense Analysis Center of the Department of Defense, the Plum Island Animal Disease Center of the Department of Agriculture, and various programs and activities of the Department of Energy related to the non-proliferation of CBRN technologies and material.

SELECT AGENT PROGRAM

The recently enacted Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorized the Department of Human Services (HHS) and the Department of Agriculture (USDA) to promulgate and enforce regulations concerning the possession and use of Select Agents—certain hazardous biological organisms and toxins widely used in over 300 research laboratories across America. Examples include the bacterium that causes anthrax, the bacterium that causes Plague, and the virus that causes Ebola, a lethal hemorrhagic fever. Select Agents are prime candidates for use by would-be bioterrorists and thus, when used in research, must be kept constantly under safe and secure conditions.

The Administration believes that the new Department, with its strong multi-purpose security infrastructure, will be best suited to prevent nefarious or other irresponsible uses of Select Agents. The Administration proposes that the Secretary of Homeland Security would administer the select agents program in consultation with the Secretaries of HHS and USDA with these agencies continuing to make key medical and scientific decisions, such as which biological agents should be included in the select agents list.

THE NATIONAL PHARMACEUTICAL STOCKPILE

CDC currently manages 12 “push packages” of pharmaceutical and medical supplies and equipment strategically located around the United States; additional lots of pharmaceuticals and caches of medical materiel are maintained by manufacturers under special contractual arrangements with CDC. One of the push packages was dispatched to New York City on September 11 and elements of the stockpile were used to respond to the anthrax attacks.

The President’s proposal integrates the stockpile with other national emergency preparedness and response assets at the new Department. The Secretary of Homeland Security will assume responsibility for continued development, maintenance, and deployment of the stockpile—making it an integral part of the larger suite of federal response assets managed by FEMA and other future DHS components—while the Secretary of Health and Human Services will continue to determine its contents. The arrangement will ensure effective blending of the public health expertise of HHS with the logistical and emergency management expertise of DHS.

RESEARCH IN LIFE AND ENVIRONMENTAL SCIENCES

The Department of Homeland Security would also oversee portions of the Department of Energy program in the life and environmental sciences. This activity will provide a core around which to grow DHS programs in, for example, identifying and understanding the microbial components that define a pathogen’s life cycle, transmission, virulence, and invasiveness; sequencing the genomes of select organisms and strains as well as developing central bioinformatic resources or tools for rapid use of genomic information; and dealing with the threat of engineered pathogens.

V. CONCLUSION

Over the past nine months, the Administration has conducted a thorough review of existing government institutions and systems for providing homeland security, such as law enforcement, public safety, public health, and emergency management. We concluded that the current arrangement was not the best way to organize for homeland security because responsibility is scattered across the government, information is not fully shared, authority is shared by multiple agencies, and numerous redundancies cause inefficiency.

The fragmentation of border security responsibilities is a case in point. In his testimony before a House Committee last week, Treasury Secretary Paul O’Neill cited a recent example of overlapping responsibilities. The Customs Service—part of the Department of Treasury—stopped a suspicious boat and searched it for illegal drugs and other contraband. However, the Customs agents found illegal aliens. Customs transferred the aliens to the Coast Guard—currently part of the Department of Transportation. The Coast Guard, upon reaching land, then turned over the aliens to the Immigration and Naturalization Service—currently part of the Department of Justice. In such a fragmented system, a terrorist can easily slip through the bureaucratic maze undetected. Under the President’s reorganization proposal, a single department would be responsible for border security.

The Homeland Security Act of 2002 includes twenty-two of the more than one hundred Executive Branch organizations or entities that have significant homeland security responsibilities. The President’s proposal includes those agencies whose primary focus is in the areas of preventing terrorist attacks, reducing our Nation’s vul-

nerability to terrorism, and building our recovery capabilities. It includes those agencies whose ability to contribute to homeland security would be improved by being in a Department whose core competency and single mission was homeland security.

In the weeks since President Bush submitted a concise draft bill to the Congress, the Administration has worked closely with Senate committees as they have considered our proposal. Our intent is to ensure that the final bill establishes clear and workable lines of authority and accountability, leverages the strengths of the agencies that will compose the Department of Homeland Security, and provides the new Secretary the authorities and management flexibility he or she will need to effect enormous change so that the new Department can adapt to the changing threat of terrorism. The Administration's proposal does not seek to usurp the prerogatives of the Congress or any Committee. We are simply trying to ensure that, on a practical basis, the Department of Homeland Security can get organized and operational—and do the best possible job of protecting Americans.

Again, I thank the members of the Committee on Health, Education, Labor, and Pensions and the Senate for the serious and expeditious action you are taking on this proposal to strengthen the Nation's collective effort to secure America.

Senator REED. [presiding]. Thank you very much, Governor Ridge, for your statement and also for your great leadership and service in this demanding role as Director of Homeland Security. I had the privilege of serving with you in the House, and I am not surprised that you have responded so significantly well to this challenge.

Let me begin with a question that was introduced by both Senator Kennedy and Senator Gregg, and that is the status of employees and workers who might be in this Homeland Security Department.

Everyone recognizes the need for flexibility, particularly in an international emergency, but as I understand Federal labor laws, they do give a great degree of flexibility in emergencies. There is a danger, though, that this might be used simply to create a work force that is not fairly represented in a collective way, which has been consistent with our policy for years.

I note that the President last January through executive order used a very rarely used authority to forbid secretaries for Federal attorneys to organize. Previously, this power was used only for army intelligence, naval intelligence, those people who were dealing with very sensitive materials.

So can you give us the assurance that legitimate rights of workers in your proposed Department will be protected through their right to organize and bargain?

Mr. RIDGE. Senator, I would like to reiterate not just my assurance but, more important, the President's assurance. These men and women, if Congress goes along with the President's plan, transfer into this new agency with their collective bargaining rights that would be preserved as well as the benefits associated with that. They would transfer in with the same whistleblower protection, civil rights protections, veterans' preference protections.

However, the President is hopeful that, working with Congress, we can carve out some new prerogatives for the management team so that we can create the kind of flexibility to attract and retain not only the men and women who may be thinking about retirement—and there are many Senators who are worried about work force retirement; it is going to reach a very critical stage in the next 2 or 3 years—but also to give this new management team the capacity outside the existing civil service limitations to go out and attract the very best people at certain levels of the administration.

So we want to preserve those protections, and we are certainly hopeful that while we preserve the Title V protections, we can give the new management team some options, some discretion, to go out and attract and retain the best people possible.

But I reiterate the President's commitment. These men and women are encouraged to be upright and to operate in an environment that encourages their recognition of not only their mission, but if there is a problem that they see, I think the President would view any analysis that said we have a problem structurally as a constructive piece of information, and we would want that to be shared, and the President wants a workplace that is free of discrimination and any kind of potential retaliation.

This work force needs to be empowered. They need to be empowered with a sense of mission. They need to be comfortable with their job security. But the management team also needs to be empowered—empowered to give these employees more technology, empowered to go out from time to time and attract the best people throughout this country, be it from the public sector or the private sector.

Senator REED. Thank you, Governor. I am sure this is not the last time that you will be asked about this.

Mr. RIDGE. It is a legitimate concern, President, and the President appreciates it as well. And it is not about the Title V protections. What we are hoping to do—because the President has said they will apply—whistleblowers, civil rights, veterans' preference—but there needs to be a way that the new management team can go out and attract some of the best people.

I know the concern on the Hill, legitimately, is will it be used to undermine collective bargaining rights. Well, it will not. But the question is should this new management team have the flexibility to be able to deal with an employee who does not do the job. The agency is going to be held accountable, and I think we are just looking for ways to create some discretion for the new Secretary.

Senator REED. Let me follow up with another question, Governor. In fact, your experience as Governor is vitally important to your new role, because a lot of what is going to be done is not at the Federal Government, but it is a partnership between Federal, State, and local governments.

As we speak here today in Washington, the Governors are assembled in Idaho, bemoaning the fact that their budgets are in tatters, that they are looking at exhausting all of their extra capital and resources. And yet collectively, we have to marshal significant resources to this fight.

This Homeland Security Department that you are proposing would be involved in using State health departments to monitor disease, and helping local hospitals to construct capacity and increase their response capabilities.

I guess the basic question is even if we assume we can put the pieces together here in Washington, where are the States going to get the money to match the effort that is needed. If they cannot come up with resources, will the Federal Government have to step in and provide those resources?

Mr. RIDGE. Senator, that is a very appropriate question because I talked to 30-plus Governors yesterday when we set up a con-

ference call to talk about the President's National Strategy, and not surprisingly, that very issue came up. Having been a Governor during 5 or 6 years when the economy was booming, I appreciate the challenges that my colleagues have had for the past year.

Senator REED. You got out in time.

Mr. RIDGE. Of course, if they had been like Pennsylvania and set aside or created a huge rainy day fund, it might not have been quite a predicament, but it is a huge predicament for my former colleagues; it is massive no matter how much money they set aside.

I think it is pretty clear, number one, that later today or tomorrow, we are going to set out a companion piece that shows what the States and locals have begun to do on their own—and obviously, they are already expending money, and a lot of it, and we applaud that.

Second, there will be some investments that the Federal Government makes that they will make unilaterally—there will be no match.

Third, in anticipation of the legitimate concerns that the Governors presently have with the economic status of their States and ability of those States, there are a couple of places here where we do have matching funds required, but in many instances, one could say it is a very soft match, that by and large, the primary source of revenue to get us through the first year, the 2003 budget year, will be the Federal Government. But it is not to be denied—States and local governments have stepped up, and when you get a chance to take a look at the initiatives undertaken by the States and local communities, the country can be proud that there are a lot of people working very hard on securing their home towns and the States. The Governors and the mayors on both sides of the aisle have done an outstanding job in doing just that.

Senator REED. Thank you very much, Governor.

Senator Frist, Senator Hutchinson?

Senator FRIST. I will defer to my colleague.

Senator REED. The early bird rule.

Senator Hutchinson?

Senator HUTCHINSON. Thank you, Mr. Chairman.

Governor Ridge, thank you for your appearance today and for your leadership and willingness to serve in a time of crisis for our Nation and to serve with great distinction. We are grateful for your service.

In your testimony, you indicate that one of the fundamental missions of the Department as the President has envisioned it, is to reduce America's vulnerability to terrorism. You very rightly testified that if properly employed, certainly biological agents could cause tens of hundreds of thousands of casualties and wreak huge economic damage.

You say that "Given the vast quality of biological weapons that already exist around the world, the risk of terrorists and their supporters obtaining and using these weapons is sufficient to warrant a massive effort to prevent such attacks."

I could not agree more, and I think this is probably the great nightmare for most public policy officials. Senior administration officials have told me that what keeps them awake at night is their concern about the possibility of a biological terrorist attack.

And we face a very real and very serious crisis in the supply of vaccines against biological weapons. According to the Defense Science Board, we currently have effective countermeasures against only 13 of the 50 pathogens most likely to be used as bio-weapons. We only have four major vaccine manufacturers in the Nation, and even in basic childhood vaccines we have a serious shortage in our country.

As the Department of Defense and the Department of Health and Human Services work to finalize a proposal to create a new Vaccine Council to coordinate the requirement for vaccines against biological weapons, is it your understanding that that council will be located in the Office of Homeland Security or the new Department of Homeland Security? What is your vision for how we can address this crisis in the area of biological vaccines?

Mr. RIDGE. Senator, that interagency effort would play, I think, an invaluable role in providing some guidance and leadership in tandem with the new Secretary of the Department of Homeland Security. It is pretty clear, as you have very appropriately identified, that Health and Human Services, the Department of Homeland Security, the Department of Defense, and even other agencies have an interest in identifying not only the potential pathogens and the potential biological threats but also, in anticipation of their use, coming up with diagnostic tools, vaccines, and the like to deal with those threats.

So I suspect, one, that it would just add value to the deliberations that the new Secretary and his team would make as they try to give a strategic focus to the bioterrorism research and development dollars that the President would like to task this agency to do. I know it is a matter of concern here, particularly with Congress, who have worked so hard and so successfully on your own bioterrorism measure. Having identified the problem and committed resources to it and having Health and Human Services as the lead agency in dealing with this issue, there is a transfer of some of that responsibility—not a transfer of personnel, not a transfer of assets—but there is a transfer of some of that responsibility in identifying where some of those dollars are going to be spent, and I know that that is a point of consideration and concern that Members have that that money would end up being directed by the Department of Homeland Security. But it would be directed in consultation with Health and Human Services and the Department of Defense as we take in the strategic need of the country based on threat information.

Senator HUTCHINSON. And, Governor, if I might just follow that up, there have been numerous studies that have recommended that in the area of vaccine production, we not rely upon a sole provider or the private sector and that our Nation establish a Government-owned, contractor-operated, GO-CO, production facility for our vaccine needs.

DOD has recommended this approach at least twice from their own internal studies, and the Institute of Medicine has likewise recommended, as well as the previous Surgeon General.

Right now, we are totally dependent upon Bioport for anthrax vaccine production. What is your personal attitude toward where we should rely and where we should look for vaccine production?

Mr. RIDGE. Well, I think again you have highlighted a need that has been identified by other departments within the Federal Government. You mentioned the Department of Defense suggested that building up this capacity is something that we ought to consider doing. I suspect that the Secretary of Health and Human Services, as he takes a look at the vaccine production capacity in this country, depending on if we had a surge need—I understand that they have talked positively about this kind of arrangement. And I would suspect that the new Secretary would want to entertain a collaborative effort with DOD and HHS in that direction. I do not think I could prejudge where the new Secretary would take that discussion, but since the need has been identified in part by some of his or her colleagues on the Cabinet, it might be a very appropriate subject for interagency collaboration and interagency financing since the benefit will go across both defense and civilian use.

So I think it is certainly worth the new Secretary examining in collaboration with a couple of Cabinet partners.

Senator HUTCHINSON. Thank you, Governor.

Senator REED. Thank you, Senator.

Senator Murray?

Senator MURRAY. Thank you, Mr. Chairman.

Governor, thank you for being here today. I appreciate the good job that you have been doing. You have been asked to take on a very challenging position at a very important time in our Nation's history, and I appreciate all of your efforts. You have been accessible and have worked with us on a number of issues, and I really appreciate it.

One of the issues that I have talked with you a lot about is our Northern border. There is no doubt that we need to have an effective, strong plan between ourselves and the Canadian Government and the Mexican Government about people who come in, but it also really impacts our economy as well, as we slow it down. In Washington State, we have the second highest unemployment in the Nation, and part of that is because the flow of goods between Canada and Washington State has been tremendously impacted since September 11.

So we need to have a good plan. We need to work well with those governments. We need to make sure that we do not impact the free flow of goods, but we also want to make sure that we have good contacts with those governments to ensure they are doing everything they can so we can move those goods effectively without worrying about who is coming across our border.

I wonder if you could share with us today your assessment of the Northern border situation, where we are working with the Government of Canada to ensure that we have the security that we require as we work through this.

Mr. RIDGE. Senator, I appreciate you raising the issue, because you and I have had this conversation many times, that while we look to securing our borders, we also understand that we must do so in a way that does not jeopardize communities, families, and jobs and the economic vitality particularly of the border States where there is so much economic interaction.

We are moving ahead I think very positively and quite aggressively on a 30-point proposal that we began with our Canadian

counterparts in December of last year. It involves creating a “smart” border between the two countries. And if you will take a look at the National Strategy for Homeland Security, you will be able to see some of the priorities for the 2004 budget, and one of those priorities as identified in the strategy is the “smart” border with Canada and Mexico, which means that while we are going to work with the private sector to set up protocols, to secure goods and the transfer of goods across the borders, and while we are going to work with the Canadian Government, we may have to make some strategic infrastructure investments as well, and certainly to make some technological investments.

I know that the Canadian Government and my counterpart, John Manley, who is the Vice Prime Minister, actually has a fund that they can use for some infrastructure improvements at the border. So once we get this border accord completed—we are hoping to get it done within the next, I would say, 2 or 3 months—and people are working very hard on it; it is very complicated; it talks about infrastructure, it talks about people, it talks about cargo, and it involves the private sector—we would then want to take a look at the other issues, and one of those would be infrastructure needs.

So again, I think a lot of progress has been made, and it is specifically directed by the President, who said we need 21st century smart borders; we have to secure them, but let us be mindful of the fact that people’s livelihoods depend on it.

So I appreciate your support of that initiative, and I think there is more to be said as we get closer and closer to the final agreement. But it also takes in sharing passenger information lists. We are working on protocols for railroad transportation. We may have something coming into this country from Nova Scotia or Vancouver, and we want to establish a means by which, if they are cleared in Canada, they can move unimpeded into this country; they feel the same way.

So a lot of good progress has been made, and hopefully, we can bring it to conclusion before the end of the year.

Senator MURRAY. Another challenge to that is if there is some kind of bioterrorist or agro-terrorist act right along the border, do you believe that we have good, quick exchange of information, channels available, between Canada and the United States?

Mr. RIDGE. Your question is timely and appropriate inasmuch as one of the things that the Deputy Prime Minister and I have identified is that we really focused in on people, cargo and infrastructure. That is the first series of things that we want to do. But we also see the possibility, because we are such good neighbors and we have such a unique relationship among countries, that we take the next step, the next accord, between the two countries into issues like this—perhaps collaborative research, sharing the kind of information that would help both countries deal with a bioterrorism event.

So I think there is still more work to be done, but I must tell you that I have been very encouraged by the extraordinary commitment of our Department of State, INS, Customs—everybody is working very hard to accomplish this—but the total commitment of the Canadian Government to get it done and then, once this phase

is completed, move on to the next phase to discuss some of the issue that you have addressed in your question to me.

Senator MURRAY. Very good. I look forward to working with you on that.

I do have one more question that I specifically wanted to raise with you this morning. In the administration proposal, you are proposing to transfer much of the chemical, biological, and nuclear response and the research activities to the Department of Homeland Security. I have to say that that does cause me some concern, because we are transferring some very important efforts into an organization that is really struggling to find its niche. What is really of special concern to me is specific populations—children, elderly, pregnant women. I do not believe they receive as much attention when we develop our medical research and our emergency evacuation plans and responses to that.

A specific and very good example of that is the hoods that we have been hearing a lot of publicity about here, that we have placed in the Capitol for people who are here. They are designed to protect Members, staff, and the public who are here in case of some kind of exposure.

Those hoods do not fit kids. As one of our first questions when we saw that—you have a parent with a child, and everybody has a hood on, and that parent is panicked because their child does not have a hood that fits, and that is the case here today.

How do you and other organizations that are putting together these plans take into account the research, whether it is on immunization or whether it is the hoods or all the other things that we are looking at? How do we make sure that people are not just all categorized as one set of people, but that we do take into account children and women and pregnant women in many of these areas?

Mr. RIDGE. I think that the primary focal point for this kind of research and the sensitive to unique populations within that research is very much part of the protocol of the CDC and the NIH. I think that is where it has been, and that is where it should continue to reside.

I want to focus on the research and development concerns that you have expressed. As part of the overall NIH budget, which I think is about \$27 billion—I am not sure—is really limited to about \$1.5 billion, and that sum—and there is very, very appropriate language in the President's measure that says that we share this responsibility with the Secretary of Health and Human Services, that the research infrastructure remains there. This is really a very significant collaboration between the new Department in this one area of terrorism-related research.

I say that because the President would like to give this Secretary and this Department the benefit of not only the relationship with Health and Human Services but also with the intelligence community so that on an annual basis, a piece of the research that we do in this country—and \$1.5 billion out of \$27 billion is a significant piece, but only about 6 or 7 percent—can be directed, depending on the circumstances, to a potential biological threat. It would be in that context that the new Secretary would work to bring a strategic focus to this limited number of research dollars, and hopefully in tandem with HHS, with NIH and the CDC, who obviously do not

aggregate America's population. They understand that, depending on your immune system, depending on your age, depending on a variety of things, it will affect how you respond to any of the anti-dotes or vaccines. But this basic research is to deal with potential threats and use of that information in collaboration with NIH and the Centers for Disease Control and Health and Human Services I think will certainly recognize the unique nature of some of these populations.

Senator MURRAY. As we move quickly to consolidate, I think it is very important that we do not lose sight of those very important roles of some of those agencies and their focus, especially on these populations. Sometimes that can get lost when you crunch a bunch of people together. So I just want to point that out, and I will be reminding us over and over again as we move through this.

Thank you.

Mr. RIDGE. Thank you, Senator.

Senator REED. Before I recognize Senator Frist, I have to go to the floor and be the presiding officer at 11, so I would ask the Senator to, at the conclusion of his questioning, adjourn the hearing or recognize other colleagues who may have arrived.

Senator Frist.

Senator FRIST. [presiding]. Thank you, Mr. Chairman.

Governor Ridge, welcome. I apologize for not being here earlier. I did read your written comments.

Mr. RIDGE. You have probably heard most of it before, Senator.

Senator FRIST. No, no. I want to restate what everybody has said. Your tremendous leadership and insight during difficult times has been something that we should both thank you and congratulate you.

Let me make some general comments, and then I want to come back and ask some clarifying questions. Some of which you may have already answered, but I have a few questions just to predict where we would be in 3 years under this new structure.

But before doing that, I want to comment on two things—coordination and communication. In August of last year, the GAO released its report stating that the coordination of Federal terrorism research and preparedness and response programs was fragmented creating inefficiencies. These inefficiencies were reflected in what we saw in the response to anthrax last October. We did the best we could, but the inevitable outcome of having fragmentation are barriers in both coordination and communication.

There are 21 different agencies that have the task of responding to bioterrorism, and there are several other agencies in charge of coordination. Inevitably, you will see the confusion and lack of accountability inherent in a fragmented system.

I mention because I think the Homeland Security proposal directly focuses on problems we saw in October and November as well as what is structurally inherent in the current system.

We started dealing through this committee in a bipartisan way with the issue of bioterrorism about 4 years ago due to a disconnect between our intelligence community, our public health community, and our research community. Coming from the medical profession, if the intelligence community had identified risks, why wasn't there sufficient research? How the research is outlined and prioritized in

this country is based on the input, the lobbying, the identified objectives, but there was no communication with the intelligence community. So I am delighted to see that that is being addressed in the proposal.

The components that you mention that I fully support as part of the Department of Homeland Security are the stockpile, the National Disaster Medical System, and some of the public health components.

However, I do have certain concerns. We must ensure that we have a strong public health infrastructure.

In this country, we have not sufficiently invested in that infrastructure over the last 30 years. It has not been supported as much as I would like, or as I think is necessary.

Our public health infrastructure has not been a priority. And I want to make absolutely sure that in terms of preparedness, we have a system in place that will inherently be supporting public health.

I mention that because as we developed our bioterrorism bill in this committee in 2000 and 2002, I found myself spending more time with my colleagues to make sure that, of the initial \$3 billion, about \$1 billion continued to support public health. I fear we are going to lose the support for public health.

Second, dual use is absolutely critical. When we spend \$3 billion on bioterrorism, or \$6 billion this coming year, one of the beautiful things is that it involves dual use. There are about 1,000 people hospitalized every day for foodborne infections, and about 5,000 people die every year. Additionally, 20,000 people die of the flu every year. If it is not a bioterrorist attack of Ebola virus or the plague or anthrax or smallpox or hemorrhagic viral fever, the same system that responds in terms of surveillance is the system that picks up the foodborne or the flu. I want to make absolutely sure that structurally, we are addressing issues of dual use.

Finally—and I think you answered the question with Senator Murray—when we talk about vaccines and the great expertise that is currently in place, the big fear is that as we strip away certain, more targeted research, there is a stripping away instead of being able to capitalize on the shared benefits of peer-to-peer professional researchers working together. Research related to a vaccine for HIV/AIDS, which may be outside of direct concern to developing an anthrax or smallpox vaccine, may provide insight into developing the other vaccines. A vaccine is a vaccine.

Let me just throw those concerns out there and let you respond, and then I would like to ask a couple of other questions.

Mr. RIDGE. Well, Senator, I think you have highlighted one of the most critical initiatives contained within the President's proposal and obviously one of the highest priorities of this country.

We know that these terrorists will use, if they can get their hands on them by theft, by their own research, or by acquisition, bioterrorism weapons against us. We know that. Someone used anthrax as a weapon, and we know what we did right in response to that, and we know where there are gaps and weaknesses in our public health infrastructure in response to that.

We know that we need one central agency to be able to coordinate response to a bioterrorism event. So as difficult and as painful

to the families who were affected by the anthrax crisis—the loss was tragic, and irreplaceable—the country learned a great deal about itself. Unfortunately, there probably were not enough advocates for public health support prior to October 2001, such as yourself and a few others. Now there is enormous support. As you know, the President in his 2003 budget has a significant request in which, with your leadership and continued support, I am confident that the Congress will make available to the public health community.

So as we identify the task before us—and I think you have very appropriately sequenced the responsibilities—prevention, preparation and response—I think those call for a rather unique relationship between the new Secretary of the Department of Homeland Security and the Secretary of Health and Human Services. It is the only relationship between the new Secretary and an existing member of the Cabinet that I think is reiterated in very clear terms in the President's legislation. And if I might, where it says "the conduct of certain public health-related activities," it says "except as the President may otherwise direct, the Secretary"—that is the Secretary of the Department of Homeland Security—"shall carry out the civilian, human, fundamental health-related, biological, biomedical, infectious disease, defense, research and development, including vaccine research and development, responsibilities through"—not independently—"the Department of Health and Human Services, including the Public Health Service, under agreements with the Secretary of Health and Human Services and may transfer moneys to those entities."

There are many other references to that kind of relationship that the new Secretary will have. So I think pretty clearly in recognition of what we need to accomplish, the President has said that this cannot be done without, frankly, the collaboration and the inter-agency agreement between the two Secretaries.

Second, if I might, I do want to focus on the research and development component, because I understand the concern that—I want to underscore that the \$1.5 billion gives the Secretary the flexibility to engage the NIH and other pieces of the national research infrastructure that we have for very specifically related scientific research based upon a threat assessment. To your point, you saw before—there was never a connection between the intelligence community, the medical community, the scientific community.

So I think it is reasonable and very responsible, again in collaboration with the Secretary of Health and Human Services, to say that out of this funding that NIH receives, about \$27 billion, a piece of that be directed—it may be that perhaps all of it ends up with NIH—but not necessarily where the science of ongoing research is taking them, which are very legitimate needs and causes, but depending upon the threat, direct that research to a specific outcome.

And as you pointed out, more often than not, in this kind of research, there is dual use—not only will we be able to combat potential bioterrorist attack, but there will applications across medicine generally.

Senator FRIST. On the relationship between the Cabinet members and the language stating the "Secretary acting through the

Secretary of Health and Human Services” a different construct, you began to explain it by emphasizing the close coordination. Is there another example in Federal statute where a Cabinet member has statutory authority over activities of personnel who report to a different Cabinet member?

Mr. RIDGE. Well, I do not believe so, although I am not—I do not want to give you a conclusion based on research, because I have done none. I do not know if it exists elsewhere. I do know that in response to the new threat and in recognition of the enormous capacity and the technical infrastructure, the scientific infrastructure, and the personnel, the President believes that the decisions made as to where to send these dollars should be made in conjunction with the Secretary of Health and Human Services, and there is great likelihood—more possibility than not—that we will end up going back down to CDC or NIH.

Senator FRIST. In the prevention and even the preparedness component, the coordination, communication, and is the prioritization is critical. In the response component, when you have the Secretary of Homeland Security acting through the Secretary of Health and Human Services, if there is a disagreement between the two Secretaries in terms of responding to an emergency, how are disputes resolved between these two Secretaries?

Mr. RIDGE. Senator, I believe that included in the President’s proposal to the Congress is the retention of the nonstatutory office within the white House with regard to the existence of the position that I present hold as an Assistant to the President for Homeland Security, and that is a coordination role, and from time to time, a monitoring role and a decisionmaking role that is a specific process. Again, you do not want to get bogged down in process if you have to make quick decisions, but I think there is a decisionmaking capacity within the White House if there is a dispute that cannot be resolved between the principals to move this along as quickly as possible, and more often than not, it may end up with that assistant to the President being involved in getting it done.

I guess I cannot think of too many occasions when they would be at ends, because again, it is not matter of transferring personnel or any of the assets from Health and Human Services over to the Department of Homeland Security. It is really coordinating the direction of the research.

In regard to an incident that would occur, you mentioned—and I recall you and I having a lengthy conversation when we were dealing with the anthrax challenges confronting the Congress of the United States—we know there were good, thoughtful, well-intentioned voices, but there were a lot of them. We know that there was not a great deal of coordination at the outset generally around this country.

I think the President’s vision is that if you work with HHS to direct some of this research, if an incident like that occurred, the Department of Homeland Security would be the coordinator, but the medical and scientific response would still be through Health and Human Services. The investigative work would continue to be through the FBI and traditional law enforcement. So you would finally have one agency, one person accountable for coordinating the public response, public information, and overseeing the medical

work, the investigative work, the law enforcement work that might necessarily be associated with that.

It is not designed to replace the scientific or medical expertise that HHS and NIH bring to public health generally or to a bioterrorism incident. It is designed to coordinate that aspect of a Federal response. It is a national incident management system. The Department would be in charge of coordinating the activities, but we would be leaning on Dr. Fauci, and we would be leaning on Secretary Thompson and others to provide the medical and scientific response.

Senator FRIST. Because this is an important issue, both from a legislative standpoint as well as an administration standpoint, we need to be prepared, in terms of response by having one voice in that response. I do not want to see a debate regarding a response playing out in a Cabinet room, with language like "Secretary of Homeland Security acting through the Secretary of Health and Human Services." We need to recognize who is in charge at the end of the day.

And that just reminds me—

Mr. RIDGE. If I might, Senator, I think you set up the possibility of a conflict like that. We know that NIH and HHS historically have focused on naturally-occurring disease. They have, they will, they should—they are good. They are very good at what they do. But I have to say that if it came down to a point where you were going to carve out five or six percentage points of a research budget to direct, redirect—or it may even be new money depending on how Congress acted—in anticipation of a very specific, credible bioterrorism threat based on information we get from the intelligence community, hopefully, there will not be too much dispute.

Obviously, you have ongoing research into naturally-occurring diseases, and we should continue to do that, but if there is a need to shift just a modest sum of these resources in anticipation of a terrorist-injected pathogen into America, I would hope that there would not be too much disagreement that for the time being, that is where the priority should be.

Senator FRIST. That reminds me—because I will probably submit some other questions—that we are going to hold the record open for 14 days for members who might have additional questions but who were unable to be with us today.

Let me close with one other series of questions that focus on personnel. We hear a lot from our colleagues and constituents about this.

There has been some confusion with regard to transfer of personnel to the Department of Homeland Security from the Department of Health and Human Services.

Could you clarify or expand upon—which of the personnel who are currently in HHS would actually be transferred to the new Department?

Mr. RIDGE. It would be very few. I think those who maintain the national pharmaceutical stockpile—it is a very limited number. I think there is a sense that we are going to have a massive transfer of HHS personnel, and that is not the case.

And I will—thank you—it is good to be assisted by very capable and responsive people as I am and always have been, fortunately—

out of the 62,000 full-time-equivalent employees, we take a look at a proposed transfer out of the 62,000 of about 600.

Senator FRIST. Okay. Just for the record, could you give us some sort of feel for who that 600 would be? That information would be helpful.

Mr. RIDGE. Yes. The Civilian Biodefense Research Programs and the Biological Preparedness and Response Programs; and there are 300 in the general category, for which I would have to give you more explicit—a better explanation.

Senator FRIST. Governor, thank you.

The issue of prevention, preparedness, and response; the fragmentation that has been so inherent in our existing structure; the lack of coordination and communication that has been institutionally inherited by the current administration must be addressed. Although I have not gone through the proposal in detail, the heart of the proposal is coordination and communication and better use of resources. You, the President, and the administration should be congratulated for leadership.

In my mind, this risk is real. This risk is increasing and not decreasing over time—and people do not realize that; they do not realize that we are at greater risk now than we were 6 months ago, a year ago, or 2 years ago. The only thing that is going to reduce that risk is an effort to reduce our vulnerabilities as a Nation. The purpose of bioterrorism is to personalize terror, and you do personalize that terror by going where people are not fully prepared. We must move from an underprepared to a more and more prepared state.

I want to thank you, and I would like to give you the opportunity to say anything in closing. If not, we will keep the record open for 14 days for other questions as we go forward.

Mr. RIDGE. Thank you, Senator, for the courtesies extended to me not only at this hearing but in the private conversations that we have had in the past as we continue to work on the bioterrorist threat. You and your colleagues have been more than open and accessible, and I look forward to a continued relationship with you, and I really appreciate your leadership on the bioterrorism threat to this country.

Just to underscore what you have stated, I think we do need to understand in this country that the globalization of science and information means that every, single day, we are at potentially greater risk. Heretofore, in the fifties and sixties, when by and large, the body of scientific knowledge and technology and equipment that was available to create these weapons of terror was unique, and it was held by a few sovereigns and a few countries, and by a few scientists. But over the past 40 or 50 years, as education has been global, as the markets become global, as access to this information and science has become global, the notion that we are immune to attack simply because we have the best scientists and the best research facilities is no longer accurate. We are no longer immune. The others may not have the best, but they have enough to create havoc and terror through a bioterrorism event.

So I appreciate your underscoring the fact that we will have to accept an enduring vulnerability, a permanent condition, and the best way for us to reduce the threat is to focus on prevention, prep-

aration, and response, and I look forward to working with you in that regard.

Senator FRIST. Governor, thank you. Thanks for your leadership, and thanks for being with us today.

With that, we stand adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF JANET HEINRICH

Mr. Chairman and Members of the Committee: I appreciate the opportunity to submit this statement for the record on the proposed creation of the Department of Homeland Security. Since the terrorist attacks of September 11, 2001, and the subsequent anthrax incidents, there has been concern about the ability of the federal government to prepare for and coordinate an effective public health response to such events, given the broad distribution of responsibility for that task at the federal level. Our earlier work found, for example, that more than 20 federal departments and agencies carry some responsibility for bioterrorism preparedness and response and that these efforts are fragmented. Emergency response is further complicated by the need to coordinate actions with agencies at the state and local level, where much of the response activity would occur.

The President's proposed Homeland Security Act of 2002 would bring many of these federal entities with homeland security responsibilities—including public health preparedness and response—into one department, in an effort to mobilize and focus assets and resources at all levels of government. The aspects of the proposal concerned with public health preparedness and response would involve two primary changes to the current system, which are found in Title V of the proposed legislation. First, the proposal would transfer certain emergency preparedness and response programs from multiple agencies to the new department. Second, it would transfer the control over, but not the operation of, other public health preparedness assistance programs, such as providing emergency preparedness planning assistance to state and local governments, from the Department of Health and Human Services (HHS) to the new department. Title III of the proposed legislation would also transfer responsibility for certain chemical, biological, radiological, and nuclear research and development programs and activities to the new department.

In order to assist the Committee in its consideration of this extensive reorganization of our government, this statement focuses on Titles III and V of the President's proposal and the implications of (1) the proposed transfer of specific public health preparedness and response programs currently housed in HHS into the new department, (2) the proposed transfer of control over certain other public health preparedness assistance programs from HHS to the new department, and (3) the proposed transfer of responsibility for research and development on chemical, biological, radiological, and nuclear threats to the new department. The statement is based largely on our previous and ongoing work on homeland security, as well as a review of the proposed legislation.

In summary, we believe that the proposed reorganization has the potential to repair the fragmentation we have noted in the coordination of public health preparedness and response programs at the federal, state, and local levels. As we have recommended, the proposal would institutionalize the responsibility for homeland security in federal statute. We expect that, in addition to improving overall coordination, the transfer of programs from multiple agencies to the new department could reduce overlap among programs and facilitate response in times of disaster. However, we have concerns about the proposed transfer of control of public health assistance programs that have both basic public health and homeland security functions from HHS to the new department. These dual-purpose programs have important synergies that we believe should be maintained. We are concerned that transferring control over these programs, including priority setting, to the new department has the potential to disrupt some programs that are critical to basic public health responsibilities. We do not believe that the President's proposal is sufficiently clear on how both the homeland security and the public health objectives would be accomplished. The proposed Department of Homeland Security would also be tasked with developing national policy for and coordination of the federal government's civilian research and development efforts to counter chemical, biological, radiological, and nuclear threats. However, we are concerned that the proposed transfer of control and priority setting for research from the organizations where the research would be conducted could also be disruptive to dual-purpose programs.

BACKGROUND

In response to global challenges the government faces in the coming years, we have a unique opportunity to create an extremely effective and performance-based organization that can strengthen the nation's ability to protect its borders and citizens against terrorism. There is likely to be considerable benefit over time from restructuring some of the homeland security functions, including reducing risk and improving the economy, efficiency, and effectiveness of these consolidated agencies

and programs. Realistically, however, in the short term, the magnitude of the challenges that the new department faces will clearly require substantial time and effort, and will take additional resources to make it fully effective.

The Comptroller General has testified that the Congress should consider several very specific criteria in its evaluation of whether individual agencies or programs should be included or excluded from the proposed department. Those criteria include the following:

Mission Relevancy: Is homeland security a major part of the agency or program mission? Is it the primary mission of the agency or program?

Similar Goals and Objectives: Does the agency or program being considered for the new department share primary goals and objectives with the other agencies or programs being consolidated?

Leverage Effectiveness: Does the agency or program being considered for the new department promote synergy and help to leverage the effectiveness of other agencies and programs or the new department as a whole? In other words, is the whole greater than the sum of the parts?

Gains Through Consolidation: Does the agency or program being considered for the new department improve the efficiency and effectiveness of homeland security missions through eliminating duplications and overlaps, closing gaps, and aligning or merging common roles and responsibilities?

Integrated Information Sharing/Coordination: Does the agency or program being considered for the new department contribute to or leverage the ability of the new department to enhance the sharing of critical information or otherwise improve the coordination of missions and activities related to homeland security?

Compatible Cultures: Can the organizational culture of the agency or program being considered for the new department effectively meld with the other entities that will be consolidated? Field structures and approaches to achieving missions vary considerably between agencies.

Impact on Excluded Agencies: What is the impact on departments losing components to the new department? What is the impact on agencies with homeland security missions left out of the new department?

Federal, state, and local government agencies have differing roles with regard to public health emergency preparedness and response. The federal government conducts a variety of activities, including developing interagency response plans, increasing state and local response capabilities, developing and deploying federal response teams, increasing the availability of medical treatments, participating in and sponsoring exercises, planning for victim aid, and providing support in times of disaster and during special events such as the Olympic games. One of its main functions is to provide support for the primary responders at the state and local level, including emergency medical service personnel, public health officials, doctors, and nurses. This support is critical because the burden of response falls initially on state and local emergency response agencies.

The President's proposal would transfer the Laboratory Registration/ Select Agent Transfer Program—which controls biological agents with the potential for use in bioterrorism—from HHS to the new department. Currently administered by the Centers for Disease Control and Prevention (CDC), the program's mission is the security of those biologic agents that have the potential for use by terrorists. The proposal provides for the new department to consult with appropriate agencies, which would include HHS, in maintaining the select agent list.

In addition, the President's proposal transfers control over many of the programs that provide preparedness and response support for the state and local governments to a new Department of Homeland Security. Among other changes, the proposed legislation transfers HHS's Office of the Assistant Secretary for Public Health Emergency Preparedness to the new department. Included in this transfer is the Office of Emergency Preparedness (OEP), which currently leads the National Disaster Medical System (NDMS) in conjunction with several other agencies and the Metropolitan Medical Response System (MMRS).⁸ The Strategic National Stockpile, currently administered by CDC, would also be transferred, although the Secretary of HHS would still manage the stockpile and continue to determine its contents.

Under the President's proposal, the new department would also be responsible for all current HHS public health emergency preparedness activities carried out to assist state and local governments or private organizations to plan, prepare for, prevent, identify, and respond to biological, chemical, radiological, and nuclear events and public health emergencies. Although not specifically named in the proposal, this would include CDC's Bioterrorism Preparedness and Response program and the Health Resources and Services Administration's (HRSA) Bioterrorism Hospital Preparedness Program. These programs provide grants to states and cities to develop plans and build capacity for communication, disease surveillance, epidemiology, hos-

pital planning, laboratory analysis, and other basic public health functions. Except as otherwise directed by the President, the Secretary of Homeland Security would carry out these activities through HHS under agreements to be negotiated with the Secretary of HHS. Further, the Secretary of Homeland Security would be authorized to set the priorities for these preparedness and response activities.

The new Department of Homeland Security would also be responsible for conducting a national scientific research and development program, including developing national policy and coordinating the federal government's civilian efforts to counter chemical, biological, radiological, and nuclear weapons or other emerging terrorist threats. Its responsibilities would also include establishing priorities and directing and supporting national research and development and procurement of technology and systems for detecting, preventing, protecting against, and responding to terrorist acts using chemical, biological, radiological, or nuclear weapons. Portions of the Departments of Agriculture, Defense, and Energy that conduct research would be transferred to the new Department of Homeland Security. The Department of Homeland Security would carry out its civilian health-related biological, biomedical, and infectious disease defense research and development through agreements with HHS, unless otherwise directed by the President. As part of this responsibility, the new department would establish priorities and direction for programs of basic and applied research on the detection, treatment, and prevention of infectious diseases such as those conducted by the National Institutes of Health (NIH).

TRANSFER OF CERTAIN PUBLIC HEALTH PROGRAMS HAS POTENTIAL TO IMPROVE COORDINATION

The transfer of federal assets and resources in the President's proposed legislation has the potential to improve coordination of public health preparedness and response activities at the federal, state, and local levels. Our past work has detailed a lack of coordination in the programs that house these activities, which are currently dispersed across numerous federal agencies. In addition, we have discussed the need for an institutionalized responsibility for homeland security in federal statute.

The proposal would transfer the Laboratory Registration/Select Agent Transfer Program from HHS to the new department. The select agent program, recently revised and expanded by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, generally requires the registration of persons and laboratory facilities possessing specific biologic agents and toxins-called select agents-that have the potential to pose a serious threat to public health and safety. Select agents include approximately 40 viruses, bacteria, rickettsia, fungi, and toxins. Examples include Ebola, anthrax, botulinum, and ricin. The 2002 act expanded the program to cover facilities that possess the agents as well as the facilities that transfer the agents.

The mission of the select agent program appears to be closely aligned with homeland security. As stated earlier, one key consideration in evaluating whether individual agencies or programs should be included or excluded from the proposed department is the extent to which homeland security is a major part of the agency or program mission. By these criteria, the transfer of the select agent program would enhance efficiency and accountability.

The President's proposal also provides the potential to consolidate programs, thereby reducing the number of points of contact with which state and local officials have to contend. However, coordination would still be required with multiple agencies across departments. Many of the agencies involved in these programs have differing perspectives and priorities, and the proposal does not sufficiently clarify the lines of authority of different parties in the event of an emergency, such as between the Federal Bureau of Investigation (FBI) and public health officials investigating a suspected bioterrorist incident.

We have reported that many state and local officials have expressed concerns about the coordination of federal public health preparedness and response efforts. Officials from state public health agencies and state emergency management agencies have told us that federal programs for improving state and local preparedness are not carefully coordinated or well organized. For example, federal programs managed by the Federal Emergency Management Agency (FEMA), Department of Justice (DOJ), OEP, and CDC all currently provide funds to assist state and local governments. Each program conditions the receipt of funds on the completion of a plan, but officials have told us that the preparation of multiple, generally overlapping plans can be an inefficient process. In addition, state and local officials told us that having so many federal entities involved in preparedness and response has led to

confusion, making it difficult for them to identify available federal preparedness resources and effectively partner with the federal government.

The proposed transfer of numerous federal response teams and assets to the new department would enhance efficiency and accountability for these activities. This would involve a number of separate federal programs for emergency preparedness and response, whose missions are closely aligned with homeland security, including FEMA; certain units of DOJ; and HHS's Office of the Assistant Secretary for Public Health Emergency Preparedness, including OEP and its NDMS and MMRS programs, along with the Strategic National Stockpile. In our previous work, we found that in spite of numerous efforts to improve coordination of the separate federal programs, problems remained, and we recommended consolidating the FEMA and DOJ programs to improve the coordination. The proposal places these programs under the control of the Under Secretary for Emergency Preparedness and Response, who could potentially reduce overlap and improve coordination. This change would make one individual accountable for these programs and would provide a central source for federal assistance.

The proposed transfer of MMRS, a collection of local response systems funded by HHS in metropolitan areas, has the potential to enhance its communication and coordination. Officials from one state told us that their state has MMRSs in multiple cities but there is no mechanism in place to allow communication and coordination among them. Although the proposed department has the potential to facilitate the coordination of this program, this example highlights the need for greater regional coordination, an issue on which the proposal is silent.

Because the new department would not include all agencies with public health responsibilities related to homeland security, coordination across departments would still be required for some programs. For example, NDMS functions as a partnership among HHS, the Department of Defense (DOD), the Department of Veterans Affairs (VA), FEMA, state and local governments, and the private sector. However, as the DOD and VA programs are not included in the proposal, only some of these federal organizations would be brought under the umbrella of the Department of Homeland Security. Similarly, the Strategic National Stockpile currently involves multiple agencies. It is administered by CDC, which contracts with VA to purchase and store pharmaceutical and medical supplies that could be used in the event of a terrorist incident. Recently expanded and reorganized, the program will now include management of the nation's inventory of smallpox vaccine. Under the President's proposal, CDC's responsibilities for the stockpile would be transferred to the new department, but VA and HHS involvement would be retained, as well as continuing review by experts of the contents of the stockpile to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered.

Although the proposed department has the potential to improve emergency response functions, its success depends on several factors. In addition to facilitating coordination and maintaining key relationships with other departments, these factors include merging the perspectives of the various programs that would be integrated under the proposal and clarifying the lines of authority of different parties in the event of an emergency. As an example, in the recent anthrax events, local officials complained about differing priorities between the FBI and the public health officials in handling suspicious specimens. According to the public health officials, FBI officials insisted on first informing FBI managers of any test results, which delayed getting test results to treating physicians. The public health officials viewed contacting physicians as the first priority in order to ensure that effective treatment could begin as quickly as possible.

NEW DEPARTMENT'S CONTROL OF ESSENTIAL PUBLIC HEALTH CAPACITIES RAISES CONCERN

The President's proposal to shift the responsibility for all programs assisting state and local agencies in public health emergency preparedness and response from HHS to the new department raises concern because of the dual-purpose nature of these activities. These programs include essential public health functions that, while important for homeland security, are critical to basic public health core capacities. Therefore, we are concerned about the transfer of control over the programs, including priority setting, that the proposal would give to the new department. We recognize the need for coordination of these activities with other homeland security functions, but the President's proposal is not clear on how the public health and homeland security objectives would be balanced.

Under the President's proposal, responsibility for programs with dual homeland security and public health purposes would be transferred to the new department. These include such current HHS assistance programs as CDC's Bioterrorism Pre-

paredness and Response program and HRSA's Bioterrorism Hospital Preparedness Program. Functions funded through these programs are central to investigations of naturally occurring infectious disease outbreaks and to regular public health communications, as well as to identifying and responding to a bioterrorist event. For example, CDC has used funds from these programs to help state and local health agencies build an electronic infrastructure for public health communications to improve the collection and transmission of information related to both bioterrorist incidents and other public health events. Just as with the West Nile virus outbreak in New York City, which initially was feared to be the result of bioterrorism, when an unusual case of disease occurs public health officials must investigate to determine whether it is naturally occurring or intentionally caused. Although the origin of the disease may not be clear at the outset, the same public health resources are needed to investigate, regardless of the source.

States are planning to use funds from these assistance programs to build the dual-purpose public health infrastructure and core capacities that the recently enacted Public Health Security and Bioterrorism Preparedness and Response Act of 2002 stated are needed. States plan to expand laboratory capacity, enhance their ability to conduct infectious disease surveillance and epidemiological investigations, improve communication among public health agencies, and develop plans for communicating with the public. States also plan to use these funds to hire and train additional staff in many of these areas, including epidemiology.

Our concern regarding these dual-purpose programs relates to the structure provided for in the President's proposal. The Secretary of Homeland Security would be given control over programs to be carried out by HHS. The proposal also authorizes the President to direct that these programs no longer be carried out through agreements with HHS, without addressing the circumstances under which such authority would be exercised. We are concerned that this approach may disrupt the synergy that exists in these dual-purpose programs. We are also concerned that the separation of control over the programs from their operations could lead to difficulty in balancing priorities. Although the HHS programs are important for homeland security, they are just as important to the day-to-day needs of public health agencies and hospitals, such as reporting on disease outbreaks and providing alerts to the medical community. The current proposal does not clearly provide a structure that ensures that the goals of both homeland security and public health will be met.

TRANSFER OF CONTROL AND PRIORITY SETTING OVER DUAL-PURPOSE RESEARCH AND DEVELOPMENT RAISES CONCERN

The proposed Department of Homeland Security would be tasked with developing national policy for and coordinating the federal government's civilian research and development efforts to counter chemical, biological, radiological, and nuclear threats. In addition to coordination, we believe the role of the new department should include forging collaborative relationships with programs at all levels of government and developing a strategic plan for research and development. However, we have many of the same concerns regarding the transfer of responsibility for the research and development programs that we have regarding the transfer of the public health preparedness programs. We are concerned about the implications of the proposed transfer of control and priority setting for dual-purpose research. For example, some research programs have broad missions that are not easily separated into homeland security research and research for other purposes. We are concerned that such dual-purpose research activities may lose the synergy of their current placement in programs. In addition, we see a potential for duplication of capacity that already exists in the federal laboratories.

We have previously reported that while federal research and development programs are coordinated in a variety of ways, coordination is limited, raising the potential for duplication of efforts among federal agencies. Coordination is limited by the extent of compartmentalization of efforts because of the sensitivity of the research and development programs, security classification of research, and the absence of a single coordinating entity to ensure against duplication. For example, DOD's Defense Advanced Research Projects Agency was unaware of U.S. Coast Guard plans to develop methods to detect biological agents on infected cruise ships and, therefore, was unable to share information on its research to develop biological detection devices for buildings that could have applicability in this area.

The new department will need to develop mechanisms to coordinate and integrate information on research and development being performed across the government related to chemical, biological, radiological, and nuclear terrorism, as well as user needs. We reported in 1999 and again in 2001 that the current formal and informal research and development coordination mechanisms may not ensure that potential

overlaps, gaps, and opportunities for collaboration are addressed. It should be noted, however, that the President's proposal tasks the new department with coordinating the federal government's "civilian efforts" only. We believe the new department will also need to coordinate with DOD and the intelligence agencies that conduct research and development efforts designed to detect and respond to weapons of mass destruction. In addition, the first responders and local governments possess practical knowledge about their technological needs and relevant design limitations that should be taken into account in federal efforts to provide new equipment, such as protective gear and sensor systems, and help set standards for performance and interoperability. Therefore, the new department will have to develop collaborative relationships with these organizations to facilitate technological improvements and encourage cooperative behavior.

The President's proposal could help improve coordination of federal research and development by giving one person the responsibility for creating a single national research and development strategy that could address coordination, reduce potential duplication, and ensure that important issues are addressed. In 2001, we recommended the creation of a unified strategy to reduce duplication and leverage resources, and suggested that the plan be coordinated with federal agencies performing research as well as state and local authorities. The development of such a plan would help to ensure that research gaps are filled, unproductive duplication is minimized, and that individual agency plans are consistent with the overall goals.

The President's proposal would also transfer the responsibility for civilian health-related biological defense research and development programs to the new department, but the programs would continue to be carried out through HHS. These programs, now primarily sponsored by NIH, include a variety of efforts to understand basic biological mechanisms of infection and to develop and test rapid diagnostic tools, vaccines, and antibacterial and antiviral drugs. These efforts have dual-purpose applicability. The scientific research on biologic agents that could be used by terrorists cannot be readily separated from research on emerging infectious diseases. For example, NIH-funded research on a drug to treat cytomegalovirus complications in patients with HIV is now being investigated as a prototype for developing antiviral drugs against smallpox. Conversely, research being carried out on antiviral drugs in the NIH biodefense research program is expected to be useful in the development of treatments for hepatitis C.

The proposal to transfer responsibility to the new department for research and development programs that would continue to be carried out by HHS raises many of the same concerns we have with the structure the proposal creates for public health preparedness programs. Although there is a clear need for the new department to have responsibility for setting policy, developing a strategy, providing leadership, and overall coordinating of research and development efforts in these areas, we are concerned that control and priority-setting responsibility will not be vested in those best positioned to understand the potential of basic research efforts or the relevance of research being carried out in other, non-biodefense programs.

In addition, the proposal would allow the new department to direct, fund, and conduct research related to chemical, biological, radiological, nuclear, and other emerging terrorist threats on its own. This raises the potential for duplication of efforts, lack of efficiency, and an increased need for coordination with other departments that would continue to carry out relevant research. We are concerned that the proposal could result in a duplication of capacity that already exists in the current federal laboratories.

CONCLUDING OBSERVATIONS

Many aspects of the proposed consolidation of response activities are in line with our previous recommendations to consolidate programs, coordinate functions, and provide a statutory basis for leadership of homeland security. The transfer of the HHS medical response programs has the potential to reduce overlap among programs and facilitate response in times of disaster. However, we are concerned that the proposal does not provide the clear delineation of roles and responsibilities that is needed. We are also concerned about the broad control the proposal grants to the new department for research and development and public health preparedness programs. Although there is a need to coordinate these activities with the other homeland security preparedness and response programs that would be brought into the new department, there is also a need to maintain the priorities for basic public health capacities that are currently funded through these dual-purpose programs. We do not believe that the President's proposal adequately addresses how to accomplish both objectives. We are also concerned that the proposal would transfer the

control and priority setting over dual-purpose research and has the potential to create an unnecessary duplication of federal research capacity.

CONTACT AND ACKNOWLEDGMENTS

For further information about this statement, please contact me at (202) 512-7118. Robert Copeland, Marcia Crosse, Greg Ferrante, and Deborah Miller also made key contributions to this statement.

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STATEMENT OF THE AMERICAN SOCIETY FOR MICROBIOLOGY

INTRODUCTION

The American Society for Microbiology (ASM) wishes to submit the following statement for the record to the Senate Health, Education, Labor and Pensions Committee for the hearing on Homeland Security and bioterrorism issues. The ASM is the largest life science society with over 40,000 members and its principal goal is the study and advancement of scientific knowledge of microbiology for the benefit of human welfare.

The ASM has worked with the Administration, the Congress and federal agencies on measures to protect against biological weapons and bioterrorism. Most recently, ASM provided expert advice on provisions to expand the Biological Weapons Statute in the USA Patriot Act and on Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which expands controls on certain dangerous biological agents and toxins. ASM members are involved in research and public health initiatives aimed at eradicating the scourge of infectious diseases, which daily end the lives of thousands of Americans and tens of thousands around the world. Infectious diseases remain the major cause of death in the world for those

under the age of 45 and particularly for children. They are the third leading cause of death in the United States.

The ASM considers it critical that the proposed DHS build upon existing science and technology programs that hold promise in the defense against bioterrorism and in the effort against deadly infectious diseases. We would like to focus our comments on issues that Congress should consider on how best to achieve this goal.

THE ROLE OF THE DEPARTMENT OF HOMELAND SECURITY

1. Role of science and technology in Homeland Security is Critical

The terrorist events of September 11 and the anthrax biocrimes reveal the need and complexity of homeland defense. The ASM, therefore, supports oversight, coordination and leadership for biodefense activities in a Department of Homeland Security (DHS). Given that science and technology will play a vital role in the biodefense of the nation, the ASM believes it is essential to establish a strong science and technology function in the DHS. This science component will provide the necessary linkage between the Secretary of Homeland Security and the numerous mission agencies charged with science and technology development.

2. The Department of Homeland Security has an important role to play in defending the nation against biological threats.

The DHS will have an important role in developing the nation's defenses against, and responses to, biological threats. The role of DHS should be to integrate threat analysis and vulnerability assessments and to identify priorities for preventive and protective steps to be taken by other federal agencies to protect the American public. The DHS can coordinate, review, and evaluate scientific and technical programs related to human, animal, and plant life. The DHS will be a proper governmental vehicle to coordinate and to integrate the expanded roles of mission agencies in bioterrorism related research. The important role of the United States Army Medical Research Institute for Infectious Diseases (USAMRIID) should be recognized and strengthened and it should interface with the proposed DHS.

It will be important to define the boundaries between DHS and the mission agency with major responsibility for protecting the nation's health, HHS. An appropriate coordination office or position should be established within DHS. One approach, for example, would be for DHS to establish a position or appoint a person with the appropriate scientific background who would report to both the DHS Secretary and the HHS Secretary. That person would also work with the National Institutes of Health (NIH) and National Institute of Allergies and Infectious Diseases to ensure integration of threat and vulnerability analysis about bioterrorism. The goal, of course, would be mutually agreed upon research priorities that address threatening biological agents.

Other mechanisms and/or functions may be needed for HHS and DHS to serve the vital role of coordinating the pursuit of an integrated research and development agenda for counter-terrorism, including highly directed, high risk, fast-paced, classified projects, and to manage between research results and applications to develop and evaluate specific technologies and for procurement. For example, NIH/NIAID has already accelerated basic and clinical research related to bioterrorism to focus on "Category A" agents considered by CDC to pose the highest threat. Last fall, the NIAID conducted a study to show that existing stocks of smallpox vaccine could be diluted at least 5-fold to provide immediate protection in case of a smallpox attack. NIAID also accelerated screening of antiviral compounds for activity against smallpox and related viruses and accelerated development of a "new generation" bioengineered anthrax vaccine and a promising Ebola virus vaccine. It has launched seven new fiscal year 2002 initiatives to expedite biodefense research.

3. ASM recommends that HHS continue to be responsible for the prioritization, direction, and conduct of federal research efforts related to civilian, human, health-related biological, biomedical, and infectious diseases.

Pathogenic microbes pose a threat to national security whether they occur naturally or are released in a bioterrorism attack. Biodefense research is part of the continuum of biomedical research aimed at protecting the nation and the world against infectious diseases. The capability to develop countermeasures and interventions is directly related to information generated by biomedical research on pathogenic microbes and the host response to these microbes. Therefore, it is critical that federal research efforts related to civilian human health-related biological, biomedical, and infectious diseases should be prioritized and conducted by, and at the direction of, the Department of Health and Human Services (HHS).

It is important to distinguish between oversight functions such as policy and planning guidance and coordination, which would be served by the DHS and the responsibility and authority for the direction, control and conduct of scientific research.

ASM recommends that HHS, a public health and biomedical research agency of unparalleled success, should continue to be responsible for the conduct and direction of scientific research.

The Administration's Bill recognizes the necessity that HHS conduct the research and development programs related to infectious diseases. Section 303(a)(1) of the Bill provides that the Secretary of DHS shall carry out responsibilities related to civilian human health-related biological, biomedical, and infectious diseases through HHS and the Public Health Service "under agreements with the Secretary of Health and Human Services, and may transfer funds to him in connection with such agreements." Section 301(2) of the Administration's Bill, however, gives DHS primary authority and responsibility for the conduct of national scientific research including "directing, funding, and conducting research and development" related to biological threats. Additionally, at Section 303(a)(2), the Bill provides that DHS, in consultation with HHS, "shall have authority to establish the research and development program, including the setting of priorities." The ASM believes that the proposed restructuring of program authorities in the Administration's bill will create unpredictability for research programs, will divert monies from research and will not be the best approach to achieving the goal of civilian biodefense, which requires the involvement of the best scientific minds and the support of excellent science based on merit review.

The HHS, the federal agency with the major mission for protecting the public health, is best qualified to establish biomedical research and development programs, identify scientific opportunities and the research approaches for ensuring that biodefense needs are met in the best way possible. The National Institute of Allergy and Infectious Diseases (NIAID) is best able to bring together all aspects of biomedical research and the full capability of science to ensure breakthroughs and advances of high quality for biodefense. The ability to build on the body of scientific knowledge underpins the capability of the United States to combat bioterrorism. For example, the national response mounted by NIH/NIAID to AIDS demonstrates the capability of science to respond to a threat. The response was based on years of accumulated scientific knowledge and biomedical research that had been well supported by Congress. The response to bioterrorism will require the same long-term dedication of financial resources and scientific talent.

The NIAID, working with the DHS, has the knowledge about scientific capabilities to respond to threats and vulnerabilities related to the biological sciences. It can identify the science and infrastructure relevant to the most pressing issues and take advantage of the most highly leveraged opportunities for research that can contribute to counter-terrorism solutions. Because it is difficult to distinguish an introduced infectious disease from a naturally occurring one, the strategies to protect against either event in terms of new scientific and technical approaches, including surveillance, prevention and response, are the same. There will be dual benefits for public health in that investment in research to develop new therapeutics, vaccines, antivirals, genomics, diagnostics, sensitive detection devices and innovative surveillance approaches for biological agents will carry over to public health breakthroughs for all infectious diseases.

The nation has already seen the ability of HHS to respond to bioterrorism. In the months since September 11, 2001, the NIAID has rapidly accelerated work to protect the nation against the threat of bioterrorism. This acceleration has occurred across the spectrum of scientific activities from basic research in microbial biology to the development of vaccines and therapeutics to research related to diagnostic systems. It is critical that this work continue to develop rapidly and efficiently without delay, disruption or loss of momentum.

A scientific health agency, HHS, rather than the nonscientific, nonpublic health DHS should have the principal authority for developing and prioritizing scientific and health related programs. Essentially, therefore, the ASM suggests reversing the responsibilities identified in Section 303(a)(2) of the Administration's Bill. HHS, in consultation and coordination with DHS, should retain responsibility for accelerated research and development programs, including prioritizing such projects

THE PUBLIC HEALTH SYSTEM FOR BIODEFENSE

The ASM is also concerned that the nation not create a separate public health system for biodefense. Therefore, the ASM would leave primary responsibility for planning for public health emergencies arising from biological causes with the HHS and Center for Disease Control. At the earliest possible moment after the outbreak of a contagion, it is critical to determine the nature of the organism and to distinguish between a bioterrorism attack and a natural event. Then, public authorities

must respond rapidly and appropriately to the health threat that either one would present. The ASM believes CDC should be charged with these tasks.

Section 505(a)(2) of the Administration's Bill requires DHS to carry out these functions under agreement with HHS. Again, the ASM believes the important and appropriate role for DHS is to coordinate planning and development of programs and to lend technical assistance to the responsible agency. It is entirely appropriate for HHS to coordinate and consult with DHS. As with the direction and control of research, however, the primary duty and authority should remain with the scientific agency with the existing knowledge, experience, and expertise to fulfill the critical mission. A scientific person within the DHS with the appropriate public health background and reporting to both the DHS Secretary and HHS Secretary could work closely with the CDC Director to achieve mutually agreed upon public health priorities for bioterrorism preparedness and response.

ADMINISTRATION AND ENFORCEMENT OF THE PROGRAM FOR REGISTRATION FOR
POSSESSION AND USE OF SELECT AGENTS

Agriculture, the food supply, and the environment are potential targets of bioterrorism along with humans. It is important, therefore, to integrate and coordinate programs related to human, animal, and plant agents. Section 302(a) of the Administration Bill transfers to DHS the select agent registration and enforcement programs of HHS. However, it does not transfer the select agent registration and enforcement programs of the Department of Agriculture to the DHS. Subtitle C of the Public Health Security and Bioterrorism Preparedness Act of 2002 mandated coordination of activities of HHS and the Secretary of Agriculture regarding "overlap agents"—that is, agents that appear on the separate lists prepared by HHS and Agriculture. Without doubt, such coordination must occur. Bioterrorism research and surveillance extends and applies to infectious disease and select agent research. The ASM believes that integration of the select agent registration program inevitably will assist in the creation of an efficient registration process thereby expediting registration.

The proper administration of the select agent program is key to the development of the nation's biodefense capability and response and must balance the concerns for public safety with the need to not unduly encumber legitimate scientific research and laboratory diagnostic testing. The ASM continues to believe that HHS has the scientific and institutional knowledge and expertise related to dangerous biological agents, biosafety, and biosecurity in microbiological and biomedical laboratories and that it is best qualified to achieve the goal of protecting the public health and safety without interfering with research, and clinical and diagnostic laboratory medicine. Transferring this program to DHS raises many questions with regard to the administration of this program which must be carefully considered by Congress, which recently enacted new legislation and additional requirements for select agents. The ASM, therefore, requests that a review be done by an interagency group with the involvement of scientific societies to assess the advisability of removing the select agent program from HHS authority.

EACH TRANSFER OF A SCIENTIFIC FUNCTION SHOULD BE SPECIFICALLY REVIEWED

Some additional specific measures in the Administration Bill require further consideration and comment by the ASM. The ASM continues to study the Administration Bill to evaluate the best approach to achieving expedited research that advances the defense against bioterrorism but does not dilute the continuing, critical battle against naturally occurring infectious diseases. The ASM suggests expeditious review of the appropriateness of each transfer of a facility or responsibility related to biological organisms from an existing agency. Similarly, the proposed transfers within the USDA should be carefully reviewed, in particular the justification should be considered for transferring Plum Island which addresses animal diseases but not incorporating the equivalent functional unit that addresses plant diseases.

For example, as noted above, the defense against bioterrorism must be fully integrated into the nation's public health system that is led by the Centers for Disease Control and Prevention. Currently, CDC would use the national pharmaceutical stockpile in response to infectious disease outbreaks—both natural and intentional. Sections 501(3)(B) and 502(6) would transfer the Strategic National Stockpile to DHS. Such transfer should be reviewed carefully during further consideration of the Bill. HHS should be responsible for developing the materials in the stockpile. Therefore, it seems appropriate for HHS to continue management of the stockpile. The ASM, however, understands the coordination and oversight function envisioned for DHS, and the final resolution of the management of the stockpile ultimately must depend upon the resolution of the scope and role of DHS responsibilities and activi-

ties. At this time, we also recommend that there be an external review of the CDC to ensure optimal preparedness for public health emergencies and bioterrorism and to ensure appropriate integration with existing programs.

CONCLUSION

We appreciate the opportunity to submit this statement. The ASM is committed to working with Congress and the Administration to achieve the most efficient and effective system in the world for research, control, and response to the threat posed by biological agents.

[Whereupon, at 11:12 a.m., the committee was adjourned.]

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